

# Joint open letter to Commissioner Vassiliou on the pharmaceutical package

Ms. Androulla Vassiliou  
European Commissioner for Health  
European Commission  
200 rue de la Loi  
B-1049 Brussels - Belgium

Brussels, 9 November 2008

Dear Ms. Vassiliou,

As representatives of a wide range of organisations of patients, consumers, health professionals and social health insurances, we would like to convey you with all our trust and support. We have every confidence that you will protect public health interests when discussing the forthcoming "pharmaceutical package".

The delay in the adoption of the package offers a valuable opportunity to reconsider the industry oriented approach taken so far on this sensitive dossier and to ensure that the new legislation on medicines does genuinely respond to patients' and consumers' needs and expectations.

Consumers and patients have a fundamental right to relevant, independent and comparative information not only about medicines, but also about health, and treatments. We will therefore support Commission initiatives that truly enable citizens to make informed choices and promote the rational use of medicines.

When examining the proposal on information to patients, we would like you to acknowledge that it is not possible to make a clear distinction between non-promotional information and advertising. We would urge you to oppose any unsolicited form of direct communication between the marketing authorization holders and the general public on prescription only medicines.

The wider public health community has unanimously stated, in the last public consultation on this topic, that the pharmaceutical industry cannot be considered as a reliable source of unbiased information, due to an obvious and unavoidable conflict of interest.

The existing legislation already allows pharmaceutical companies to provide information to the public on health and diseases (Article 86 of Directive 2001/83/EC). They make the most of the opportunities provided by this provision, often going beyond with disease awareness campaigns and even disease-mongering. On the other hand, several experiences have shown that pharmaceutical companies fail to disclose important information regarding their products and changes in the legislation are indeed needed to oblige marketing authorization holders to disclose all information on clinical trials and pharmacovigilance. Moreover it is essential to require medicines agencies to disseminate the periodic safety assessment reports and the data used when evaluating medicines for market authorisation and monitoring their use.

The proposed changes to the pharmacovigilance legislation are welcomed as they are necessary to ensure patient safety. We would ask the Commission to go further by conferring the risk assessment advisory committee the authority to withdraw medicines from the market without delay - thus ensuring immediate user protection - and by allowing the enforcement of strong dissuasive sanctions in cases of non-compliance. In addition, we believe that the pharmacovigilance activities within medicines agencies should be fully financed by public money.

Regarding the section on counterfeit medicines, we strongly support the Commission commitment to foster the safety and the transparency of the medicines' supply chain. We ask you to ensure that any new measure is proportionate, based on evidence and on a sound impact assessment. The proposal should also include specific measures to tackle the illegal sales of medicines on the internet which is the major source of counterfeit medicines.



AIM



The signatories of this letter ask you to continue to lead in defending patients and consumer in the pharmaceutical package and to ensure that public health considerations supersede industrial interests.

Yours sincerely,

AGE - European Older People's Platform  
AIM - Association Internationale de la Mutualité  
BEUC – European Consumer's Organisation  
EATG - European AIDS Treatment Group  
EPHA - European Public Health Alliance  
HAI Europe – Health Action International  
ISDB - International Society of Drug Bulletins  
MiEF – Medicines in Europe Forum



**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.org](http://www.age-platform.org)  
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: [rita.kessler@aim-mutual.org](mailto:rita.kessler@aim-mutual.org)



**BEUC** - BEUC's membership includes 41 reputed, 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.eu](http://www.beuc.eu) Contact: [ilaria.Passarani@beuc.eu](mailto: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](http://www.eatg.org)  
Contact: [wim-vandevelde@usa.net](mailto:wim-vandevelde@usa.net)



**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](http://www.eph.org) Contact: [epha@epha.org](mailto:epha@epha.org)



**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 Alves: [teresa@haiweb.org](mailto:teresa@haiweb.org)



**ISDB** – The 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](http://www.isdbweb.org) Contact: Maria Font [maria.font@ulss20.verona.it](mailto:maria.font@ulss20.verona.it)



**MiEF** – The 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](mailto:pierrechirac@aol.com) or Antoine Vial [europedumedicament@free.fr](mailto:europedumedicament@free.fr)