

Mr. José Manuel Barroso
President of the
European Commission
Rue de la Loi 200
B-1049 Brussels

19 November 2008

Pharmaceutical Package

Dear President,

As representatives of a wide range of organisations of patients, consumers, health professionals and social health insurers, we would like to express our concerns *vis-à-vis* the « Pharmaceutical Package », which is expected to be adopted by the European Commission on 26 November.

The proposed changes to the existing legislation will have a substantial impact on European patients, consumers and national health care systems. Any attempts to alter the current legislative framework should be guided by and based on an in-depth assessment of patients' and consumers' needs.

The three important matters at hand, namely information to patients, pharmacovigilance and counterfeit medicines are extremely complex and politically sensitive. Not only it is crucial to separate these issues – there is no compelling reason for their linkage in the manner the Commission is proposing - but it is imperative that their overall implications on public health are seriously evaluated.

We invite you to carefully reconsider the approach taken so far on this dossier, and ask you to refocus its objectives towards providing patients and consumers with:

- Relevant, independent, comparative, unbiased and non-promotional information about health, treatments and medicines. Ill-considered deregulation of the current rules on information about prescription medicines is likely to lead to higher expenditures while any additional benefits to health or health care quality are yet to be established.
- Accessible, affordable and safe medicines, with added therapeutic value and adequate risk-benefit balance.

Moreover, we encourage you to make sure that any proposals adopted are based on a sound impact assessment and in line with the principles of better regulation. At a time of economic uncertainty, legislation that will ultimately lead to more bureaucracy and increase the financial burden of governments and their health authorities would be injudicious and counter productive.

Finally, in order to better ensure that public health considerations are put before industrial interests, we call for competence on medicines to be transferred from DG ENTERPRISE to DG SANCO, and to become a responsibility of the EU Health Commissioner.

The signatories of this letter respectfully request you to uphold the defence of public health interests when discussing the "pharmaceutical package".

Yours sincerely,

The signatories (see below)

CC to:

- All European Commissioners
- Permanent Representatives of the Member States
- Members of the European Parliament

This letter is also being disseminated to the press.



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 .Contact: 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 Contact: 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 Contact: Ilaria.Passarani@beuc.eu



EAHP -The European Association of Hospital Pharmacists is a working community of 29 national associations of hospital pharmacists. Its European membership includes more than 21,000 professionals. EAHP's aim is to establish a common pharmaceutical policy in Europe. It represents the interest of the profession at the European level, contributes to the scientific development of hospital pharmacy and to the advancement of the position and role of the pharmacists in hospitals. More info: www.eahp.eu. Contact: ed@eahp.eu



EATG - The European AIDS Treatment Group 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 info: www.eatg.org. Contact: wim-vandevelde@usa.net



ECCH -The European Council for Classical Homeopathy (ECCH) is the central European council for 27 national professional associations of homeopathy practitioners from 23 European countries. More info: <http://www.homeopathyecch.org>. Contact: ecch@gn.apc.org



EFN - The European Federation of Nurses Associations (EFN) was established in 1971 and is the independent voice of the profession. The EFN consists of National Nurses Associations from 30 EU Member States, and its work has an effect on the daily work of 6 million nurses throughout the European Union and Europe. The mission of EFN is to strengthen the status and practice of the profession of nursing for the benefit of the health of the citizens and the interests of nurses in the EU & Europe. More info: www.efnweb.eu. Contact: efn@efn.be



EFPAM - stands for European Federation of Patients' Associations for Anthroposophic Medicine, a federation of 15 national associations in 15 European countries, representing some 60.000 patients. More info: <http://www.efpam.org>. Contact: colette.pradelleapma@wanadoo.fr



europaean forum
for primary care

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. Contact: d.aarendonk@euprimarycare.org.



EHN -EHN is a Brussels based alliance of heart foundations and like minded nongovernmental organisations throughout Europe, with member organisations in 26 countries. EHN plays a leading role in the prevention and reduction of cardiovascular disease through advocacy, networking and education so that it is no longer a major cause of premature death and disability throughout Europe. More info: <http://www.ehnheart.org> Contact: slogstrup@ehnheart.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 info: www.epha.org. Contact: epha@epha.org



ERS - With members in over 100 countries, the European Respiratory Society (ERS) aims to alleviate suffering from respiratory disease and to promote lung health through research, knowledge sharing, medical and public education. More info: <http://www.ersnet.org>. Contact: ersinfo.brussels@ersnet.org



ESIP - 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: <http://www.esip.org/>. Contact: esip@esip.org
Note: ESIP members support this position with the specific exception of the International Pension Centre, the Sociálna Poist'ovňa and Försäkringskassan since the subject matter covered by this paper falls outside their field of competence.



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. Contact: 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. Contact: Maria Font maria.font@ulss20.verona.it



IVAA - The IVAA (International Federation of Anthroposophic Medical Associations) represents and coordinates the National Anthroposophic Doctors' Associations on both, the European and international level in regard to political and legal affairs. As a corporate body the IVAA functions as umbrella organization for at the moment 31 member-associations in 18 EU member-states as well as in Norway and Switzerland and in further 11 countries outside Europe. More info: www.ivaa.info. Contact: peter.zimmermann@ivaa.info



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



PGEU - PGEU represents around 400,000 community pharmacists from 30 European Countries, including EU Members States, EU candidate countries and EFTA members. The members of PGEU are national associations and professional bodies of community pharmacists. PGEU's objective is to promote the role of the pharmacists as key actors in public health. Furthermore, PGEU aims to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process. PGEU provides to its members an ideal platform to exchange information, and collect and disseminate best practices. Additionally, it also encourages its members to further develop new projects aiming at anticipating and responding to society's needs, in the broader context of Public Health. More info: www.pgeu.eu Contact: i.silva@pgeu.eu



Picker Institute -The Picker Institute is a non-profit UK charity, which works with patients, professionals and policy makers to promote understanding of the patient's perspective at all levels of healthcare policy and practice. It undertakes a unique combination of research, development and policy activities which together work to make patients' views count. More info: www.pickereurope.org/. Contact: Joan.Walsh@pickerEurope.ac.uk



UEMS -The European Union of Medical Specialists (UEMS) was established in 1958 and currently represents 1.5 million specialist doctors in 35 countries through its National Medical Associations and its 38 Specialist Sections and Boards. . The UEMS represents the professional interests of European Medical Specialists, notably by setting standards for high quality healthcare practice, harmonizing the highest level of medical training and promoting the free movement of specialist doctors within the EU. More info: www.uems.net . Contact: ceo@uems.net