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

Brussels, 13 October 2009

Joint open letter to President Barroso

Future Commission: need for change in health goods governance:

EU pharmaceutical and medical device policies and regulations should be under the competence of Health and Consumer protection's Commissioners

Dear President Barroso,

First, we would like to congratulate you on your re-appointment as President of the European Commission. We fully support your willingness to put citizens firmly at the centre of European politics, as you expressed in your political guidelines for the next Commission.

We understand you will have to decide on the new College of Commissioners in the coming weeks and we wish to draw your attention to an opportunity to **review the way medicine and medical device policies are managed** in order to put citizens' interests first.

One of the Commission's core responsibilities is to "*ensure a high level of human health protection"* for European citizens (European Treaty). Experience shows, however, that this cannot be properly achieved when pharmaceuticals and medical devices are considered like other consumer products. **Experience shows that the current management of pharmaceuticals and medical devices by the Directorate General Enterprises and Industry (DGE) puts patient safety at risk.**

The European Commission's proposals made in December 2008 ("pharmaceutical package") illustrate the unbalanced approach taken by the DGE: pharmaceutical companies' short-term profitability is favoured at the expense of public health (**a**). This can be partly explained by the pharmaceutical industry and its allies being overwhelmingly represented in comparison with the other stakeholders in the "high level groups" such as the "G10 Medicines process" (2001-2005) and the "Pharmaceutical Forum" (2005-2009), which were organised by the DGE in order to prepare the ground for legislation changes.

Moreover, the European Medicines Agency's (EMEA) dependence on the DGE leads to excessive secrecy, with an exaggerated fear of upsetting commercial susceptibilities, and to undue delays in decisions when it comes to recommending the withdrawal of a medicine in order to protect the European population from adverse drug reactions.

In order to put EU citizens' needs and concerns first, we request you **make public health the main driver for pharmaceutical and medical device policies at EU level by giving the lead role on these policies to Commissioners in charge of health and consumer protection.**

Putting our request into practice would **better reflect the well thought allocation of competencies in the Member States** (Ministers of Health manage pharmaceutical policy in all Member States).

It would also allow for **more coherent policy making**, recognising that pharmaceutical and medical devices are an integral part of public health and consumer protection policy-making (**b**).

Health and consumer protection are closely linked with each other and should in no case be separated into two Directorates general, one for Health and the other one for Consumer protection. The risk would be to compromise consistency of policy making and to prevent consumers, patients, users, health professionals and social insurance organisations from joining forces in order to work towards public interests.

Transferring responsibility for medicines and medical devices to a Directorate general dealing with responsibility for EU Health policy as well as Consumer protection would help to put EU citizens' needs and concerns first and redress the current imbalance.

It would also contribute to safeguarding sustainability of social protection, and social cohesion, which should be among the European Commission's top priorities for the coming years.

We sincerely hope that you will be able to promote this initiative, and that it will result in significant improvements for European citizens in terms of access to useful and safe medicines at affordable prices, and the development of new medicines that represent a real therapeutic advance.

Yours sincerely,

International Society of Drug Bulletins **Medicines in Europe Forum**

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, their members include 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. users and 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 and medical devices policy. Admittedly, medicines and medical devices 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: europedumedicament@free.fr.

Notes:

a- The pharmaceutical package proposed to:
- deregulate direct-to-consumer advertising (DTCA) for prescription medicines in Europe (under the guise of improving "patient-information") (patient-"information" proposals);
- extend premature marketing authorisation and lay the ground for hiding pharmacovigilance data (pharmacovigilance proposals);
- reinforce intellectual property rights under the guise of fighting against counterfeits to delay competition (fake medicine proposals).

b- Adverse drug reactions are implicated in at least 5% of hospital admissions and are the 5th ranking cause of hospital deaths according to the European Commission itself.