Mr. John Dalli European Commissioner European Commission B-1049 Brussels

Open Letter

Brussels, 24 February 2011

Re: Conflict of interest for former EMA Executive Director Thomas Lönngren

Dear Commissioner Dalli,

We are writing to you on behalf of the Alliance for Lobby Transparency and Ethics Regulation (ALTER-EU), the European Consumers' Organisation (BEUC), the European Public Health Alliance (EPHA), Health Action International Europe (HAI), and the International Society of Drug Bulletins (ISDB) in your capacity as responsible Commissioner for the European Medicines Agency (EMA) regarding the recent appointments of its former Executive Director, Thomas Lönngren.

As you will be aware, since leaving the EMA, Mr. Lönngren has taken up several positions with private sector companies, including NDA Advisory Services, a consultancy specialised in helping pharmaceutical companies get their products approved for sale on the European market. These appointments occurred just weeks after Mr. Lönngren left his post at the EMA.

It appears that there was no 'cooling off' period between his former and current employment, nor any restrictions on the services he provides to NDA and its clients. This has led us to believe that the rules regarding conflicts of interest may not have been respected, notably Title II article 16(96) of the Staff Regulations of the Officials of the European Communities:

An official shall, after leaving the service, continue to be bound by the duty to behave with integrity and discretion as regards the acceptance of certain appointments or benefits.

Officials intending to engage in an occupational activity, whether gainful or not, within two years of leaving the service shall inform their institution thereof. If that activity is related to the work carried out by the official during the last three years of service and could lead to a conflict with the legitimate interests of the institution, the Appointing Authority may, having regard to the interests of the service, either forbid him from undertaking it or give its approval subject to any conditions it thinks fit. The institution shall, after consulting the Joint Committee, notify its decision within 30 working days of being so informed. If no such notification has been made by the end of that period, this shall be deemed to constitute implicit acceptance.

We question if due consideration was given to conflicts of interests between the responsibilities and portfolios of a former Executive Director and a strategic advisor to pharmaceutical companies whose products his previous role would have evaluated and authorised.

We have concerns about the rigor of the authorisation process followed by the EMA, which allowed Mr. Lönngren to take positions in the private pharmaceutical sector immediately upon his departure from public service at a drug regulatory agency.

We feel confident that you will agree that transparency and accountability represent a fundamental basis of policy making, as well as ensuring citizens' trust in their policy makers. There are currently several high profile dossiers on pharmaceutical policies under discussion, including the revision of the Clinical Trials Directive, where we have concerns that a conflict of interest may arise involving Mr. Lönngren's past and current employment. In goes without saying, that a former head of the EU drug regulatory agency has an extensive network and knowledge in the field, and this opens up

the potential to influence the outcome of these dossier discussions. We question whether this is appropriate, and suggest that this damages public trust in the regulatory agency.

As the Commissioner responsible for the EMA, we would like to bring this matter to your attention and ask whether the rules regarding conflict of interest have been sufficiently and duly respected. In case of the contrary, we request that the EMA's approval of Mr. Lönngren's new appointments be reconsidered in the public interest.

Sincerely,

Erik Wesselius ALTER-EU Monique Goyens BEUC

Monika Kosińska EPHA Teresa Leonardo Alves HAI

Jörg Schaaber ISDB

Notes:



ALTER-EU is a coalition of over 160 civil society groups, trade unions, academics and public affairs firms concerned with the increasing influence exerted by corporate lobbyists on the political agenda in Europe.

BEUC, the European Consumers' Organisation has a membership of 44 well respected, independent national consumer organisations from 31 European countries (EU, EEA and applicant countries). BEUC acts as the umbrella group in Brussels for these organisations and our main task is to represent our members and defend the interests of all Europe's consumers.



EPHA is the European Platform bringing together public health organisations representing professional groups, patients, health promotion and disease specific NGOs and other health associations



Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.



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 the pharmaceutical industry. Currently it has 79 members in 40 countries around the world. ISDB journals play an important role, helping health professionals to compare newly released drugs with existing treatments.