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

Open letter

Brussels, June 20, 2011

Subject: Safeguards against post-employment conflicts of interest at the European Medicines Agency and the need for a review of Staff Regulations

Dear Commissioner Dalli,

We are writing to you on behalf of the Alliance for Lobby Transparency and Ethics Regulation (ALTER-EU), Formindep, Health Action International Europe (HAI Europe) and the International Society of Drug Bulletins (ISDB), in your capacity as Commissioner responsible for the European Medicines Agency (EMA), regarding the application of Article 16 of the Staff Regulations[1] on the future activities of its former Executive Director.

You will recall that questions have been asked by public health and transparency campaigners regarding the rigor of the authorisation process followed by the EMA, which allowed Mr. Lönngren to take positions in the private pharmaceutical sector within weeks of his departure from public service at the EMA.[2]

These concerns were recently sustained by members of the European Parliament, who moved to postpone the discharge of the EMA's 2009 budget on the grounds that, amongst others, the Agency's handling of conflicts of interest could jeopardise the objective evaluation of medicinal products. In its Report, the Committee of Budget Control "*notes that Article 16 of the Staff Regulations grants wide discretionary power on the Management Board to allow or forbid this type of employment...*" [3]

Upon learning of the former Executive Director's future employment activities, the Chair of the Management Board gave consent based on a very general and incomplete description of these future roles. Only later was a Joint Committee convened to assess if his future employment could undermine the best interests and objectives of the EMA. Subsequently, the Joint Committee imposed a set of limitations on his new and future professional activities and these limitations were later adopted by the Management Board. In a letter to EMA in May 2011, HAI Europe and Corporate Europe Observatory (CEO) expressed strong concern about the shortcomings of the limitations imposed.[4]

This sequence of events regarding the approval of Mr. Lönngren's job move has led us to believe that a far more coherent approach to evaluating (and preventing) potential conflicts of interest is needed. There appear to be major differences in how agencies like EMA, European Food Safety Authority (EFSA) and the European Commission itself interpret and implement Article 16 of the Staff Regulations. In all the institutions, decisions are made on a case-by-case basis but with different approaches, which is far from ideal. Our conclusion is that the current provisions regarding post-employment conflicts of interest in the Staff Regulations are not sufficiently clear.

We ask you to take this opportunity to initiate a review of the Staff Regulations. You are ideally positioned to pursue a review because the agencies under your oversight have been directly affected by its application. In our view, stronger Staff Regulations should set-out a clear, standard approach for evaluating potential conflicts of interest. As a matter of consistency, the rules and procedures for the Staff Regulations should be automatically applied when Commission and Agency staff members leave the public service, and via a clearly-defined process.

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1 http://ec.europa.eu/civil_service/docs/toc100_en.pdf
2 http://haieurope.org/wp-content/uploads/2011/02/25-Feb-2011-Joint-Open-Letter-to-European-Commission.pdf
3 http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2011-0153+0+DOC+PDF+V0//EN&language=EN
4 http://haieurope.org/wp-content/uploads/2011/05/09-May-2011-Joint-Open-letter-to-MEPs-regarding-EMA-Audit-.pdf

Among the changes to the Staff Regulations that we would recommend is to add a definition of what constitutes a 'conflict of interest'. The responsible authorities should actively scrutinise possible conflicts of interest, including making contact with the planned employer and taking other pro-active steps. Introducing a cooling-off period of at least two years with a clear ban on Commission and agency staff moving into jobs that involve lobbying or lobbying advice would also be a logical step forward. As you will know, Commissioners currently have an 18 month cooling-off period, while for those involved in EU electricity regulation, the period is three years.[5]

There should also be a comprehensive online transparency around the Commission's decision to approve or reject post-employment requests. Decisions should be immediately made available online and be searchable, sortable and downloadable.

As Commissioner responsible for the EMA, we hope that you will take up this challenge. Strengthened Staff Regulations can guard against the potential for improper influence in public agencies, such as the EMA, which is responsible for ensuring the safety, quality and efficacy of medicines in Europe. Ultimately, the appropriate application of improved Staff Regulations can secure public trust in the objectivity of decisions that can impact on public health.

Sincerely,

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Anne Chailleu
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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.

Formindep is an independent, self-funded association of health professionals and citizens advocating for medical information and education transparent and freed from any other interest than the patients.

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.

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.

5 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:211:0055:0093:EN:PDF