To: Mr. John Dalli
European Commissioner for Health & Consumers Policy
European Commission

CC: Mr. Maroš Šefčovič
European Commissioner for Inter-Institutional Relations and Administration
European Commission

CC: Mr. Eoin O'Shea
Member of the European Court of Auditors

Open letter

Brussels, December 19, 2011

Subject: New information in the activities of the EMA's former Executive Director in the private sector & review of the Staff Regulation

Dear Commissioner Dalli,

We are writing to you on behalf of the Alliance for Lobbying Transparency and Ethics Regulation (ALTER-EU), Formindep and Health Action International (HAI) Europe in your capacity as Commissioner responsible for the European Medicines Agency (EMA), regarding new information on the conduct of its former Executive Director, Mr. Lönngren, while still in his public position as head of medicines regulation and after he left EMA.

Firstly, evidence suggests Mr. Lönngren's post employment activities with private pharmaceutical industry were arranged while he was still employed by EMA. Mr Lönngren's own consultancy firm, Pharma Executive Consulting Ltd, was incorporated on 2 November 2010[1] (two months before he left EMA) within the headquarters of NDA Regulatory Science Ltd (hereafter NDA). NDA is a consulting firm that claims to be advising 90 per cent of the top 20 pharmaceutical companies and that one third of products authorised by the EMA are clients that have benefited from NDA's advice[2].

Correspondence between Mr. Lönngren and EMA has led us to believe that this relationship was only disclosed in February 2011 under Article 16 of the Staff Regulations[3].

In a similar case concerning the application of the Staff Regulations at the European Food Safety Authority (EFSA), the European Ombudsman recently ruled that negotiations by current staff members regarding "*a future job that could amount to 'revolving doors' would themselves constitute a conflict of interest that would fall under the Staff Regulations, in particular Articles 11a and 12."* The Ombudsman clearly indicated that "*within the context of a regulatory agency and in order to discharge its obligations, EFSA would want to ensure that it is informed whenever serving members of its staff are negotiating an employment offer from a prospective employer. EFSA would also want to know when a staff member has accepted such an offer before the end of her/ his contract with EFSA".*[4] This strong signal from the European Ombudsman demonstrates that post-employment activities negotiated while EU officials are in public office can constitute a conflict of interest that EU agencies should be aware of and should evaluate under the Staff Regulations.

A relationship between the head of a regulatory body and a private firm advising clients on how to ease regulatory hurdles raises concerns about the potential for an abuse of office. This practice ultimately casts doubt on the independence of the EMA. It would, therefore, be in the EMA's best interests to review and improve its rules governing the post-employment circumstances of its former staff to ensure that everyone is aware of their responsibility to declare negotiations regarding future jobs.

1 Certificate of Incorporation. http://www.alter-eu.org/documents/2011/12/13/l%C3%B6nngrens-lobby-firm
2 http://www.ndareg.com/index.php
3 http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500103924.pdf
4 European Ombudsman ruling no. 775/2010/ANA, 7 December 2011.

Secondly, since leaving the EMA to work for private industry, Mr Lönngren has spoken publicly as a representative of his former employer. In March 2011, he was listed as a Strategic Advisor to EMA when speaking at BioScience: the World Life Sciences Forum in the section “Decision-makers' perspectives”[5].

Moreover, in October 2011, Mr Lönngren spoke at the European Health Forum Gastein on “The regulatory perspective” and he was billed as the former head of the EMA[6]. This ongoing confusion between his former public role and current private engagements casts doubt on the real division of his capacities. Mr Lönngren’s continued public profile in the context of his former EMA role is of concern as he now has a series of corporate jobs which require him to act in his clients’ private interests.

Thirdly, Mr Lönngren has participated in a number of organisations that bring together medicines' regulators and pharmaceutical companies, as well as pharmaceutical industry think tanks[7]. His membership of these organisations, which began when he was the Executive Director, continues since leaving the EMA. In 2011, it was reported that Mr. Lönngren had become a member of the Scientific Advisory Board of the pharmaceutical company H Lundbeck A/S and an adviser to Novo Nordisk[8]. While these two appointments have yet to be publicly confirmed, the possibility that a former regulator may use his insider knowledge to advise pharmaceutical companies is worrying. We question the appropriateness of the head of Europe’s regulatory body acting as an adviser to pharmaceutical industry networks and think tanks both during and after his executive post at the EMA. Such practices could lead to regulatory capture, in which EU officials are overly sympathetic with the industries they are charged with regulating.

The application of Article 11 and 12 of the Staff Regulation at Agencies under your competence does not systematically prevent close relationships between regulatory officials and industry bodies, nor does it address the negotiation of post-employment activities while officials are still in office. Following the ruling of the European Ombudsman on EFSA, additional measures could be taken to ensure a common approach to monitor and regulate future activities arranged while EU officials are in public service at the Agencies.

Overall, we consider that the Staff Regulations should be reviewed and tightened in a number of areas. A complete list of recommendations to improve the Staff Regulation can be found in the recent ALTER-EU report which we enclose with this letter.

In our previous correspondence, you indicated that a Task Force on Independence and Conflicts of Interests would be created within DG SANCO to improve coherence across Agencies in cases such as this. We would welcome any opportunity to provide constructive feedback on the Task Force’s conclusions and initiatives.

As Commissioner responsible for the EMA, we hope that you will consider our concern for the independence of Europe’s medicines regulator in light of the aforementioned facts. We hope that you will join our call for the revolving door rules within the Staff Regulations to be reviewed and strengthened in order to build public trust.

Yours sincerely,

Vicky Cann, Alliance for Lobbying Transparency & Ethics Regulation (ALTER-EU)

Anne Chailleu, Formindep

Katrina Perehudoff, Health Action International (HAI) Europe

Enclosure: ALTER-EU report on Blocking the Revolving Door

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[5] http://www.biovision.org/bv2011/program-session.html/123-plenary-session-would-pasteur-and-fleming-have-survived-the-precautionnary-principle
[6] http://www.ehfg.org/index.php?id=782#c1843
[7] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500103924.pdf
[8] http://www.cbio.com.au/releases/11.01.27%20Appointment%20of%20Dr%20Thomas%20Lonngren%20To%20The%20CBio%20Board.pdf

Notes:

Alliance for Lobbying Transparency & Ethics Regulation (ALTER-EU) is a coalition of over 200 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 network of health, consumer and development organisations working to increase access to essential medicines and improve their rational use.