

Open letter

Brussels, December 19, 2011

Subject: Application of the Staff Regulations concerning employees who take part in an outside activity, intend to leave or leave the service at the EMA

Dear Mr Rasi,

We are writing to you on behalf of the Alliance for Lobbying Transparency and Ethics Regulation (ALTER-EU), Formindép and Health Action International (HAI) Europe in your capacity as Executive Director of the European Medicines Agency (EMA) to present our concerns about the application of the Staff Regulations at the EMA, to kindly request clarification on internal staff rules at EMA and to request a meeting with you to discuss our recommendations.

Our concerns stem from events leading up to, and following the departure of EMA's former Executive Director, Thomas Lönngren, and how these relate to both EMA and the former Executive Director's duties under the Staff Regulations, specifically Articles 11, 12 and 16. As a former member of the Management Board, you will be aware of the facts in this case, although we understand that you did not participate in the Management Board's decision.

The attachment to this letter outlines our concerns regarding:

- The arrangement of Mr Lönngren's post-EMA employment with private sector pharmaceutical industry whilst he was still working for EMA;
- Mr Lönngren's participation in pharmaceutical industry-based networks during and after his Executive Directorship;
- The rigour of the EMA's evaluation and the authorisation process;
- The decision to approve Mr Lönngren's future activities and its coherence with other EMA conflict of interest policies;
- The fact that, having left the service, some of Mr Lönngren's public activities imply that he continues to formally represent EMA.

In the attached summary, we ask specific questions regarding the steps that EMA will take to prevent similar occurrences in the future. In addition to the questions raised below, we would like to request a meeting with you to discuss our recommendations in order to find tangible solutions to the shortcomings identified here.

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 Regulations can be found in the recent ALTER-EU report which we also enclose with this letter.

We have been encouraged by your commitment to tackle this serious issue which you made during your hearing at the ENVI Committee. Moreover, in your recent address to EMA's Patients and Consumers Working Party, of which HAI Europe is a member, you spoke of the need to base regulatory decisions on scientific fact and to limit the possibility for undue influence from the pharmaceutical industry.

As recently appointed Executive Director of EMA, we hope that you will address these issues during your tenure. The dutiful application of rigorous Staff Regulations will help to ensure public trust in the objectivity of EMA decisions and safeguard the public interest.

We look forward to hearing from you.

Yours sincerely,

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

Anne Chailleu, Formindép

Katrina Perehudoff, Health Action International (HAI) Europe

Enclosure Summary of concerns and questions raised by ALTER-EU, Formindép and HAI Europe
ALTER-EU report on Blocking the Revolving Door

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.

Summary of concerns and questions raised by ALTER-EU, Formindep and HAI Europe

RE: the application of the Staff Regulations to EMA's former Executive Director during and after his service

Our concerns arise from analysis of events leading up to and following the departure of EMA's former Executive Director, Thomas Lönngren, and how these events relate to Mr Lönngren's duties under the Staff Regulations, specifically Articles 11,12 and 16.

1. The arrangement of Mr Lönngren's post-EMA employment with private sector pharmaceutical industry whilst he was still working for EMA

Evidence suggests Thomas Lönngren's post-EMA employment activities with private sector pharmaceutical industry were arranged whilst he was still in public service at EMA. Mr Lönngren's own consultancy firm, Pharma Executive Consulting Ltd, was incorporated on 2 November 2010¹ (two months before he left EMA) within the headquarters of NDA Regulatory Science Ltd (hereafter NDA). NDA is a consultancy which helps pharmaceutical companies obtain marketing approval in Europe. They have hired the former Executive Director to be a strategic advisor on their Management Board². However, correspondence between Mr Lönngren and EMA has led us to believe that this relationship was only disclosed in February 2011, some two months after he left EMA, under Article 16 of the Staff Regulations³. A relationship between the head of a regulatory body and a private firm advising clients on how to ease regulatory hurdles raises serious concerns about the potential for an abuse of office and could cast doubt on the independence of EMA.

You may be aware that in a similar case concerning the application of the Staff Regulations at the European Food Safety Authority, the European Ombudsman ruled on 7 December 2011 that post-employment activities negotiated while EU officials are in public office can constitute a conflict of interest which EU agencies should be aware of and should evaluate under the Staff Regulations.⁴

Questions to EMA:

When did EMA first become aware of Mr Lönngren's negotiations with NDA? Did EMA know that he was discussing his post-EMA professional activities with NDA whilst he was still Executive Director of EMA?

How will EMA ensure that all EMA staff are aware of their responsibility to declare negotiations regarding future employment?

How will the EMA ensure consistent application of Article 12(b) of the Staff Regulation that requires staff to notify the EMA of any paid or unpaid outside activities that may be incompatible with the institution's interests?

2. Mr. Lönngren's participation in pharmaceutical industry-based networks during and after his Executive Directorship

During his term as Executive Director, Mr Lönngren participated in a number of organisations and activities which brought together medicines' regulators and pharmaceutical companies, as well as a pharmaceutical industry think tank⁵. In 2011, it was reported that he had become a member of the Scientific Advisory Board of the pharmaceutical company H Lundbeck A/S and an advisor to Novo Nordisk⁶. While these two appointments have yet to be publicly confirmed, the possibility that a former regulator may use his extensive network and knowledge in the field of pharmaceutical registration to advise pharmaceutical companies raises serious concerns. We question the appropriateness of EMA staff participating in networks with strong links to the pharmaceutical industry in the scope of their public roles or as an outside activity during or after their service.

Questions to EMA:

How does EMA evaluate membership of, or participation in, industry initiatives, activities or organisations vis-a-vis the potential for undue influence on staff and specifically EMA's regulatory duty?

¹ Certificate of Incorporation. <http://www.alter-eu.org/documents/2011/12/13/1/C3%B6nngrens-lobby-firm>

² <http://www.inpharm.com/news/110119/ema-thomas-lonnngren-nda-group>

³ In a letter from Thomas Lönngren to Andreas Pott. 10 February 2011. URL:

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.

⁵ Refers to the Athenaeum Network. As mentioned in correspondence:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500103924.pdf

⁶ <http://www.cbio.com.au/releases/11.01.27%20Appointment%20of%20Dr%20Thomas%20Lonnngren%20To%20The%20CBio%20Board.pdf>

What steps will EMA take to ensure that Article 12(b) of the Staff Regulations is applied to staff wishing to pursue similar outside activities during their employment?

How will EMA ensure sufficient distance between EMA staff and membership-based industry bodies?

3. The rigour of EMA's evaluation and authorisation process

We have identified several shortcomings in the process by which Mr Lönngren's post-employment activities were authorised.

Learning of Mr Lönngren's future employment activities⁷, the Chair of the Management Board gave consent based on a very general and incomplete description of these future roles⁸. Only later was more information sought. In our view, the tone of an email from Mr Pott⁹ (then acting Executive Director), in which he requested further information from Mr Lönngren, seems highly inappropriate and suggests a disregard of the dutiful observance of Article 16. Only after media coverage was a Joint Committee convened to assess if Mr. Lönngren's future employment could undermine the best interests and objectives of EMA¹⁰. This sequence of events suggests a far more coherent and robust approach to the evaluation of potential conflicts of interest is needed.

In our view, a Joint Committee should be convened on a rolling basis to evaluate the post-employment activities of EMA staff wishing to leave the service; it is in EMA's best interests to make a decision on the most complete and accurate information. To that end, EMA should be taking steps to emphasise to staff how important the process of authorisation under Article 16 is, and how they are obliged to provide a full and complete picture of proposed professional activities. To verify and to further explore the information provided, EMA could make contact with the planned employer and take other pro-active steps to ensure that all aspects of the new role are obtained before a decision about authorisation takes place.

We recognise that EMA has a wide margin of discretion in implementing the Staff Regulations. Without clear inter-agency guidance, it is even more appropriate that EMA adopts its own consistent and rigorous approach.

Question to EMA:

How will EMA ensure a systematic approach to the application of the Staff Regulations and how will future cases be evaluated?

4. The decision to approve the former Executive Director's future activities and its coherence with other EMA conflict of interest policies

The Management Board concluded that Mr Lönngren's paid and unpaid roles as a strategic advisor to the pharmaceutical industry do not represent a conflict of interest with his former employment¹¹. His post-employment activities were approved, subject to a set of limitations imposed for a period of two years. But we remind EMA that 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 advice¹². In our view, the potential for NDA's clients to benefit, however indirectly, from Mr Lönngren's extensive network and knowledge of the regulatory system is in conflict with the core mandate of EMA and invokes substantial risk of conflicts of interest for a former Executive Director who oversaw the evaluation and approval of medicines.

We consider that the Management Board's conclusion appears to be incompatible with EMA's own internal policy on the handling of conflicts of interest that defines experts who hold strategic advisory roles to pharmaceutical companies as having direct interests with industry. Advisory roles warrant a higher risk level and certain restrictions on the expert's involvement at the Agency. Clearly the EMA recognises the potential for undue influence posed by strategic advisory

7 In a letter from Thomas Lönngren to Pat O'Mahony. 28 December 2010. URL:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/03/news_detail_001227.jsp&mid=WC0b01ac058004d5c1&url=menus/news_and_events/news_and_events.jsp&jsenabled=true#

8 In a letter from Pat O'Mahony to Thomas Lönngren. 11 January 2011. URL:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/03/news_detail_001227.jsp&mid=WC0b01ac058004d5c1&url=menus/news_and_events/news_and_events.jsp&jsenabled=true#

9 A copy of the e-mail from Andreas Potts to Thomas Lönngren, dated 8 February 2011, can be found on page 19 of the ALTER-EU publication *Block the Revolving Door*. URL: http://www.alter-eu.org/sites/default/files/AlterEU_revolving_doors_report.pdf

10 EMA Joint Committee Opinion. URL:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/03/news_detail_001227.jsp&mid=WC0b01ac058004d5c1&url=menus/news_and_events/news_and_events.jsp&jsenabled=true#

11 EMA Joint Committee Decision. URL: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/03/WC500103921.pdf

12 <http://www.ndareg.com/index.php>

roles. Yet, the Management Board does not appear to have applied this logic to its former Executive Director. We consider that the conditions which were placed upon Mr Lönngren by the Management Board to be rather limited. There exists loopholes that enable the risk of conflicts of interest to arise.

We also question the extent to which EMA is vigilant in enforcing these conditions. For example, one of the limitations placed upon Mr Lönngren was that he should not hold “any kind of managerial, executive or consultative role in pharmaceutical companies or industry associations”¹³. Yet, Mr Lönngren’s role at NDA is on the Management Board as described on their website¹⁴.

Question to EMA:

Is Mr Lönngren’s role at NDA compatible with the limitations set by EMA’s Management Board?

If so, what is the practical difference between work for “pharmaceutical companies and industry associations” and work for consultants to the pharmaceutical industry when it comes to preventing conflicts of interest?

In the future, on what basis will EMA evaluate the potential for a conflict of interest between the Agency’s core interests in sound and rigorous medicines evaluation and the post-employment activities of staff leaving the service?

5. Mr Lönngren’s public profile suggests that he continues to represent EMA despite having left the service

Since leaving EMA to work for private sector pharmaceutical 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”¹⁵.

Questions to EMA:

Has EMA engaged Mr Lönngren in a paid or unpaid capacity and/or approved his speaking engagements to represent the Agency since the end of his Executive Directorship?

How has his representation of EMA while working for private industry been evaluated against the potential for undue influence and the reputation of EMA as an impartial medicines regulator?

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 EMA¹⁶. 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 posts which require him to act in his clients’ private interests.

Question to EMA:

What steps will EMA take in order to ensure that former staff members employed in the private sector cease to publicly represent EMA?

¹³ EMA Joint Committee Decision. See above.

¹⁴ <http://www.ndareg.com/index.php?our-management>

¹⁵ <http://www.biovision.org/bv2011/program-session.html/123-plenary-session-would-pasteur-and-fleming-have-survived-the-precautionary-principle>

¹⁶ <http://www.ehfg.org/index.php?id=782#c1843>