Joint Committee Opinion n.1/2011 of 8 March 2011

Present	Role
Vincenzo Salvatore	Chair
Frances Nuttall Noël Wathion Monika Benstetter Jaki Oliver	Member Member Member (appointed by the Staff Committee) Member (appointed by the Staff Committee)

The Joint Committee

in the consultation procedure governed by Article 16 of the Staff Regulations of Officials of the European Communities, as applicable by analogy to members of temporary staff of the Agency pursuant to Article 11 of the Conditions of Employment of Other Servants of the European Communities

HAVING REGARD to the Acting Executive Director's decision of 15 February 2011 (Doc. Ref.: EMA/127436/2011) setting up the Joint Committee;

WHEREAS, with regard to Mr Thomas Lönngren's engagement in occupational activities after leaving the service, on 9 February 2011 Mr Andreas Pott, Acting Executive Director of the Agency, requested the Chair of the Joint Committee "*to convene the committee well within the statutory deadlines and submit to me* [i.e. him] *an opinion of the committee with regard to compliance with the Code of Conduct of the agency and Art 16 of the SR*";

WHEREAS, the Joint Committee was convened and held a first meeting to discuss the issue at stake on 28 February 2011, with follow up meetings held on 4, 7 and 8 March 2011 when this opinion was adopted;

HAVING REGARD to the documents and information provided to the Joint Committee further to the request to be convened, consisting of the following three documents: a letter dated 28 January 2010 (to be read "28 December 2010") addressed by Mr Thomas Lönngren to the Chairman of the EMA Management Board on his future employment intentions, the reply from the Chairman of the EMA Management Board sent to him on 11 January 2011 (Doc. Ref.: EMA/7743/2011) and a letter with an attached memo marked confidential addressed by Thomas Lönngren to the Acting Executive Director (CCed to the Chairman of the EMA Management Board) on 10 February 2011;

HAVING REGARD to the communication received from Winckworth Sherwood LLP on behalf of Thomas Lönngren on 7 March 2011, providing additional information and clarifications;

CONSIDERING the documents submitted and having regard to the factual circumstances, as represented by the former member of staff;

HAVING REGARD to Article 16 of the Staff Regulations of Officials of the European Communities (SR), as applicable by analogy to members of temporary staff of the Agency pursuant to Article 11 of the Conditions of Employment of Other Servants of the European Communities (CEOS);

HAVING REGARD to the Agency Code of Conduct (Doc. Ref.: EMEA/6470/03/2368) and namely to the provision set paragraph 2 of its Annex 2, "EMEA Guidance on Confidentiality and Discretion", with regard to "*Continuing duty of confidentiality*";

AFTER THOROUGH CONSIDERATION AND DISCUSSION, UNANIMOUSLY ADOPTED THE FOLLOWING

Opinion

I. LEGAL FRAMEWORK

Pursuant to Article 16 of the Staff Regulations 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 and 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 institutions, 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.

It has to be noted that, as the Agency does not employ officials, Article 16 of the SR is applicable to Agency's members of staff by analogy pursuant to Article 11 of the Conditions of Employment of Other Servants of the European Communities.

That implies that the temporary nature of engagement of Agency's members of staff may be taken into consideration by the authority authorised to conclude contracts when taking a decision under Article 16 of SR by analogy.

In addition to the relevant provisions set by the SR and CEOS with regard to activities carried out by EU staff after leaving the service, additional obligations upon the European Medicines Agency's members of staff stem from the Agency's Code of Conduct (Doc. Ref.: EMEA/6470/03/2368) and namely from the provision set out in paragraph 2 of its Annex 2 "EMEA Guidance on Confidentiality and Discretion", with regard to "*Continuing duty of confidentiality*", according to which: "*Staff members are required to behave with integrity and discretion after leaving the Agency. In addition, in line with the Staff Regulations and current commercial practices, the EMEA is entitled to impose restrictions on employment after members of staff leave the EMEA (Article 16 of the Staff Regulations). Staff leaving the EMEA are free to use the skills acquired in the course of their employment at the EMEA so long as such use does not interfere with their obligation of confidentiality. This is, in particular intended to prevent breaches of confidentiality that would be detrimental to the public interest, interests of the Agency and EU Institutions, Member States, applicants or holders of marketing authorisations*".

II. FACTUAL BACKGROUND

Mr Thomas Lönngren took up his duties as Executive Director of the European Medicines Agency on 1st January 2001 and left the service on 31st December 2010.

He qualified as a pharmacist from the University of Uppsala, Sweden, Faculty of Pharmacy in 1976, and he holds a master of science in social and regulatory pharmacy.

Before joining the European Medicines Agency he served for more than 20 years with the Swedish national competent authority for medicinal products holding several managerial positions.

On 28 December 2010, three days before leaving the service, Mr Lönngren, at that time still on duty in his role as the Agency's Executive Director, sent a letter to the Chairman of the EMA Management Board, received by email on the following day, informing him of his intention to start his own new company as a consultant in the field of health care and pharmaceuticals with effect from 1st January 2011 and about his possible role in non-executive board positions in the pharmaceutical sector.

In the context of the concerned communication he particularly stressed the following: "*I am very conscious of my obligations and commitments to the EMA and can assure you that in my new role there will be no conflict of interest, breach of code of conduct, nor any of my other legal contractual obligations, as a departing employee of the EMA. It is my intention to uphold the reputation of the EMA and myself in a highly professional manner. I hope to support the EMA as much as possible in everything I do*".

On 11 January 2011, Mr Pat O'Mahony, Chairman of the EMA Management Board, acknowledged receipt of Mr Lönngren's letter informing the Agency that he would be starting his own consultancy business and taking up non-executive board positions following end of his tenure at EMA and letting him know that "*We have no objections to these* ***activities having regard to your assurances that they do not cause a conflict of interest nor breach the code of conduct or any other aspects of Staff Regulations***" (emphasis added).

Further to information subsequently made available to the Agency either by press or by third party intervention concerning Mr Lönngren's alleged activity in the pharmaceutical sector and potential conflict of interests, on 8 February 2011, Mr Andreas Pott requested Mr Lönngren to "*outline in a memo to me all contractual activities you have entered into or which you are planning to do with a brief description of the range of activities such duties entail*".

On 10 February 2011, Mr Lönngren submitted a communication to the Acting Executive Director of the Agency, confirming that he had started up his consultancy company in line with what he had previously announced and clarified that: "*I will be selective in the way I will operate and accept jobs and assignments and I have decided as a rule not to give advice to companies about their ongoing applications or any other business they may have ongoing with EMA and/or the European Commission*".

Mr Lönngren also enclosed a memo with a detailed listing of his current "*post EMA activities*", identified as follows: "

1. *Contract with NDA to give strategic advice to the management of the company and to build up an advisory board on health technology assessment. Date for signing of contract 17 January 2011 (I have no involvement in the company's product specific advice on the regulatory side)*
2. *Appointment as a non-executive board member of CBio Ltd, Australia, agreement signed on 27 January 2011. The company has no approved medicines, no applications under review and no clinical trials in Europe. My role in the board is to provide advice on the company's*

corporate plans, budget and strategic management following the responsibilities of executive directors.

3. *Essex Woodlands. Venture Capital Company investing in the wider health care sector. Mutual agreements with the company during a 6-month period to learn about investment practice and participate in evaluation of investments opportunity. My role is to give a strategic advice on business plan. Date of start 17 January 2011.*
4. *CMR Institute for medicines research. Non-profit organization. Member since 2002. Participating in the institute's board and workshops as chair or speaker.*
5. *Tapestry network. Network that bring together payers HTA and regulators for dialog. Have been members since 2009 in my role as Executive director at EMA. No contract just a informal agreement.*
6. *The Athenaeum Network. A UK based think tank about drug development. Member since 2008.*
7. *I have also invitations and request that (including the two prematurely mentioned in the CBIO's press information) I will consider in due time fully respecting the staff regulation*".

During the ongoing consultation of the Joint Committee, on 7 March 2011 the Agency received a letter from Winckworth Sherwood LLP, acting in the interest and on behalf of Mr Thomas Lönngren, submitting additional information and clarifications on the activities their client has been engaged in.

In particular, with regard to involvement in NDA they clarified that "*Our client's role will be an advisory role regarding the strategic development of the company in the health care sector in general with a particular focus of its services in the new area of health economic assessments. Our client will help create and develop business tools for the company in the area of management based on regulatory science and he will help the Company establish and operate an advisory board on health economic assessment*". They claimed there is no conflict of interest regarding the above mentioned activities as "*Health economy, pricing and reimbursement are not covered by the Agency's mandate nor were they part of any of our client's responsibilities as Executive Director. Our client's advice will mainly be based on his experience and knowledge gained, prior to joining the Agency, at the Stockholm School of Economics and during his appointment by the Swedish Government to the committee that established the Swedish HTA authority TFL. His advisory services are not product based and he has made it clear to the company that he will not be involved in any product specific business on the regulatory side of NDA's business or any business where it directly or indirectly gives advice to companies about ongoing activities related to the Agency or European Commission*". They also clarified that "*Our client is not employed by the company*".

Additional information and clarifications on Mr Thomas Lönngren's involvement in Essex Woodlands and Cbio Limited were submitted as follows:

"***2. Essex Woodlands***

Our client's limited engagement is presently concerned with understanding the nature of the company and its business which invests in the wider health care sector. In due course, his role will involve providing strategic advice regarding business plans and investment opportunities in the healthcare sector generally. This activity is not related in any way to his role as Executive Director or the mandate of the Agency and there is no conflict of interest. By way of further clarification, the majority of new investments by this company are outside the scope of the matters and interests covered by the Agency. In order to avoid any conflict arising, our clients has made it clear to the company that he cannot be involved in any way regarding any target investment company that has any ongoing application or issues with the Agency or European Commission.

Our client is not employed by the company.

3. Cbio Limited

Our client has accepted a Non-Executive Directorship with this Australian research company. His role is one of an independent director and he will not have an operational role in the company. His role is to provide advice regarding corporate plans, budgets and strategic management. This company is not under the jurisdiction and control of the Agency or the EU and it does not presently produce commercial medicinal products or, in fact, deal with any medicinal products which have been approved or are subject to approval in the EU. The company is at several years away from making any application for marketing authorisation within the EU or otherwise. There is no conflict of interest regarding these activities".

Winckworth Sherwood LLP furthermore maintained that in their view "*Article 16 of COES is concerned with "occupational activity" and therefore does not cover other non-occupational activities such as memberships or networks and not for profit organisations and attendances at summits and conferences*".

III. THE JOINT COMMITTEE'S ASSESSMENT

The Joint Committee first of all considers that, pursuant to the wording of Article 16 of the SR, its opinion has to be based on the information provided by the former member of staff.

The Joint Committee relies on Mr Lönngren having fulfilled his responsibilities to have provided full and complete information for the purpose of Article 16 of the SR.

The Joint Committee acknowledges the top managerial role of Mr Thomas Lönngren within the Agency's organisation as he was Executive Director of the European Medicines Agency for ten years. This former role has to be taken into specific consideration when assessing the interest of the service vis-à-vis the nature of activity the former member of staff intends to be engaged in after leaving the service.

Whilst, in the light of the relevant provision set by the Agency's Code of Conduct, it would be illegitimate to prevent a former member of the Agency's staff from using the skills acquired in the course of their employment at the Agency so long as such use does not interfere with his obligation of confidentiality, the Joint Committee recommends to the authority authorised to conclude contracts that approval of Mr Lönngren undertakings after his departure from the service should be subject to certain conditions in order not to undermine the interest of the service.

In particular, the Joint Committee considers that Mr Lönngren, in the course of his professional activities, should refrain from holding any kind of managerial or executive role in pharmaceutical companies or industry associations, whether gainful or not, and also from providing any kind of guidance or advice with regard to any procedure concerning specific medicinal products development, assessment, supervision and evaluation, or otherwise falling within the remit and the area of responsibilities assigned to the European Medicines Agency.

The Joint Committee takes the view that the above mentioned conditions and limitations may be lifted after two years of Mr Lönngren's leaving the service.

On the other hand, the Joint Committee maintains that it cannot be considered in conflict with the interest of the service any occupational activity that Mr Lönngren intends to be engaged in as far as it relates with sectors which do not fall within the European Medicines Agency's remit or area or responsibilities.

In the light of the above and based on the information and clarifications provided by Mr Lönngren, the Joint Committee holds that the activities numbered 1-3 inclusive in the memorandum submitted by Mr Lönngren to the authority authorised to conclude contracts in attachment to his communication dated 10 February 2011, do not conflict with Article 16 of the SR to the extent that the above mentioned conditions and limitations are adhered to.

Furthermore, the Joint Committee holds that the activities numbered 4 and 6 do not fall within the scope of Article 16 of the SR, as they relate to membership of networks and not for profit organisations, to the extent that Mr Lönngren's involvement will not imply influence or interference with the Agency's remit or area of responsibilities.

The Joint Committee is not in the position to formulate its opinion on activity numbered 5, in relation to Mr Lönngren's involvement in the Tapestry network, and recommends that further information is provided by Mr Lönngren on the scope of his involvement.

The Joint Committee also recommends that the authority authorised to conclude contracts, when taking its decision at this regard, remind Mr Lönngren of his duty of confidentiality and of his obligation to immediately inform the authority authorised to conclude contracts of any change in circumstances affecting his professional activities as this will be subject to additional prior authorisation by the authority authorised to conclude contracts if it occurs within the timeframe set by Article 16 of the Staff Regulations. This will have to be taken into specific consideration with regard to activities identified under number 7 in the letter Mr Lönngren addressed to the Agency on the 10 February 2011.

Done in London, on 8 March 2011

Vincenzo Salvatore

Chair of the Joint Committee

Frances Nuttall

Member of the Joint Committee

Noël Wathion

Member of Joint Committee

Monika Benstetter

Member of the Joint Committee

Jaki Oliver

Member of the Joint Committee