



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Prof Vincenzo Salvatore
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London, 27 July 2012
Doc. Ref: EMA/11733/2012
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Dear Prof Salvatore,

I am writing in response to your e-mail dated 27th June 2012 responding to Ms Frances Nuttall's letter of 22nd June 2012 in which she sought additional details of the activities that you notified to the Agency in accordance with Article 16 of the staff regulations. This request followed receipt of a memo from you and an application for authorisation to engage in an occupation after leaving the EMA sent on 16th June, the day after the expiry of your contract.

In this respect, I can inform you that the Joint Committee has now reviewed these activities and provided me with an opinion which I have adopted in the form of a decision and which is attached to this letter.

I would further like to take this opportunity to express my personal disappointment and dismay at the way that you have handled your departure from the European Medicines Agency after over seven years of excellent service.

While I am assured that you will, in accordance, with your legal obligations, adhere to the lifelong commitment to confidentiality as set out in Article 17 of the staff regulations, and I note your commitment to refrain from liaising with former colleagues at the Agency in any form that might be considered abusive or inappropriate in consideration of your former role, I regret that you did not, in a spirit of trust and openness, see fit to inform me in advance of the full details of your planned activities, so that we could have taken appropriate measures to ensure the interests of the service.

Having been intimately involved with activities of the Agency of a sensitive and personal nature over the last seven years, and having worked extremely closely with me, following my appointment as Executive Director for the past six months, you, more than almost any other staff member were fully aware of the difficult challenges facing the agency with respect to perceptions of conflicts of interest and the associated reputational impact.

You were intimately aware of my personal goals for increasing transparency and openness and for seeking to rebuild the reputation of this Agency. You were also in the best possible position to be able to judge the border between appropriate and inappropriate behaviour, beyond which is required by administrative procedures.

You had also been closely involved in the Article 16 application of the former Executive Director and were fully aware of the impact this procedure had had on the Agency's reputation.



I regret that you did not, in the full spirit of the staff regulations, notify the Agency of your detailed intentions to engage in the activities you describe in your application and memo of 16th June and subsequent e-mail of 27th June, until *after* you had left our services.

It was my understanding and the understanding of your colleagues that you were obliged to return to Italy to resume your former post as full professor of international law, and that you were returning to Italy for family reasons. As represented to me at the time, I did not see any potential for a conflict of interest, and in fact I had sympathy for your stated motivations.

By allowing this misunderstanding to persist, and even if you had no formal obligation to do otherwise, you have breached my trust and the trust of your colleagues and you have left the Agency open to accusations of conflicts of interest with respect to some of your recent activities. This I find most regrettable.

Based on this experience I intend to revisit the current process we operate for staff leaving the Agency in order to better define the collective understanding of the "interests of the service", through the development of a Best Practice Guide and revised procedures, which may in some cases include a "cooling-off period".

I have also felt it necessary to send a message to all staff, many of whom were deeply concerned by the press release issued by the American law firm you joined immediately following your departure without waiting for the outcome of the Article 16 procedure. I reminded them that a central part of any human relationship, including in a professional environment, is reciprocal trust. I expressed my dismay on reading the media reports concerning your post-Agency activity and the potential impact on the level of trust of both our external stakeholders and the collective trust and confidence we expect as staff members.

As you will be aware, I am committed to doing whatever I can in my power to defend and restore the confidence and trust of our external stakeholders.

Nonetheless I wish you success in your future activities and am confident that you will, as you have assured me, continue to comply fully with the strict ethical and conflict of interest rules of your profession.



Guido Rasi
Executive Director



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Decision under Article 16 of the Staff Regulations (Following consultation of the Joint Committee)

Notification by Mr Vincenzo Salvatore of activities after leaving the service

THE EXECUTIVE DIRECTOR,

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;

HAVING REGARD to the obligation of staff members to behave with integrity and discretion after leaving the service and as regards the acceptance of certain appointments or benefits;

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;

WHEREAS, on 16 June 2012, Mr Vincenzo Salvatore submitted an application form for authorisation to be engaged in occupational activities after leaving the service, in the context of which he informed the Agency of intention to return to his previous role of professor of international law in the University of Insubria, Varese, Italy, for an indefinite period of time. In addition, he indicated that he would practice as an independent self-employed lawyer, he would be an external consultant to the Italian Medicines Agency (AIFA) and that he would be senior counsel to the law firm Sidley Austin LLP providing service as an independent lawyer on a broad array of aspects related to EU laws and regulations.

HAVING REGARD to the opinion issued by the Joint Committee on 16 July 2012 pursuant to Article 16 of the SR;

CONSIDERING the factual circumstances and the information provided so far by the former member of staff;

CONSIDERING the high importance that the European Medicines Agency gives to the proper management of potential conflict of interest and the assurance of public confidence in the work of the Agency;

issues the following



Decision

1. Holds that Mr Vincenzo Salvatore has provided to the authority authorised to conclude contracts (AACC) sufficient information for the purpose of Article 16 of the SR;
2. Holds that the activities identified by Mr Salvatore in the application for authorisation submitted on 16 June 2012 are authorised subject to the restrictions outlined below. Due to the special nature of Mr Salvatore's role within the Agency's organisation as former head of legal service for a period of over 7 years, this former role has been taken into specific consideration when assessing the interest of the service vis-à-vis the nature of the activity that the former member of staff intends to be engaged in after leaving the service.
3. Holds that Mr Salvatore, in the course of his professional activities may not engage in any activity, whether gainful or not, which concerns any legal case involving the EMA or any case that is connected to the EMA, with which he was previously involved with, directly or indirectly as former head of legal services. This restriction shall apply indefinitely.
4. Holds that Mr Salvatore, for a period of two years from 16 June 2012, shall refrain from holding any kind of managerial or executive role in pharmaceutical companies, whether gainful or not, and also from providing legal guidance or advice with regard to any procedure concerning product development, assessment, supervision and evaluation, or otherwise falling within the remit and the area of responsibilities assigned to the European Medicines Agency. In relation to these activities, Mr Salvatore shall refrain from individually liaising with any member of staff of the European Medicines Agency or attending any administrative or product related hearings or meetings involving the Agency for a period of 2 years from 16 June 2012.
5. Holds that Mr Salvatore should be reminded of his duty to behave with integrity and discretion after leaving the Agency and consider the impact that his public communication concerning the European Medicines Agency may have on the reputation of the Agency.
6. Reminds Mr Salvatore of his duty of lifelong 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 two year period of time after his leaving the service.

Done in London on 27 July 2012



Guido Rasi
Executive Director