Nuttall Frances

From:	Vincenzo Salvatore <[redacted]
Sent:	27 June 2012 17:05
To:	Rasi Guido
Cc:	Nuttall Frances; Pott Andreas; Ron Irene
Subject:	Re: Letter - Article 16

Dear Professor Rasi,

I am writing to you, in response to the message below, in your role of legal representative of the authority authorized to conclude contracts (AACC) and the person responsible for the legitimacy of the activity of the European Medicines Agency.

Upon leaving the Agency and pursuant to Article 16 of the Staff Regulations, on 16 June 2012 I lodged a duly filled in form containing details of the occupational activities I intend to engage, with an attached memo providing additional information and clarifications at this regard.

On Friday 22 June I received via email a letter from Ms Nuttall, Head of HR, requiring additional information to be provided to the Agency by 17.30 UK time 27 June 2012.

With regard to the concerned requests, I am pleased to further inform you of the following:

* My private practice activity as independent self-employed lawyer, both under my own law firm in Varese (at "Studio Legale Salvatore") and in my role as senior counsel at Sidley Austin LLP started on 18 June 2012.

* My activity as external consultant to the Italian Medicines Agency (AIFA) has not started yet. I was informed that I was appointed as an AIFA expert by the Director of AIFA on 24 May 2012. Contractual arrangement is still pending for finalization.

* For all the identified occupational activities I will undertake cases falling within my area of expertise, i.e. European Union Law, including litigation before the European Court of Justice and national jurisdictions, regulatory procedures in the life science field (e.g. food and drugs, medical devices, clinical trials, compliance, cosmetics, healthcare, etc.), contract and procurements, environmental law, transparency and access to documents, data protection, EU staff cases, etc.

* It is difficult to predict the percentage of the time I will spent in each of the identified activities: apart from AIFA where I will have to provide guidance and advice if and when requested, I have just returned to private practice and I have not dealt with any case so far.

* The percentage of time devoted to private practice will have in any case to be compatible with my academic commitments. I am full professor of international law at the University of Insubria in Varese (Italy), where I teach both European Union Law and International Trade Law. I will have to dedicate to University activities two days a week on average.

* As to contracts, I am prevented from providing you with documents governing the professional relationship with my clients as this will constitute an infringement of the rules governing the practice as set by applicable legislation and ethic rules established by the Bar association ("Ordine degli avvocati").

I take also this opportunity to clarify that legal practice is governed by law in Italy (as in other EU member States) and the Bar association ("Ordine degli avvocati") as the authority empowered to impose conditions or limitations on lawyers' activities.

I would also like to draw your attention that many legal colleagues formerly employed by EU institutions or bodies have moved (or return, as in my case) to private practice after leaving the service, without any restriction, condition or limitation being imposed on them by their respective institution or body.

Since I was recruited at the European Medicines Agency, three former colleagues joined life science groups of different law firms upon leaving the service relying on their pharmaceutical law expertise, and another one accepted a job offer made by a pharmaceutical company in consideration of her pharmaceutical law expertise. I am not aware of any Agency's decision nor consultation of the Joint Committee affecting any of them.

It has in addition to be noted that I was recruited by the Agency when I was 41 and I left at 48, without maturing any pension right and that I will return to do exactly what I used to do at the time when I joined the Agency, relying on the same expertise (i.e. robust knowledge of EU law and EU pharmaceutical legislation, experience in litigation before the EU Court of Justice) that in 2004 made the Agency to offer me the job for which my position was advertised.

Eventually, I would like to ensure you that I am fully aware of and strongly committed to comply with the relevant provisions concerning conditions and limitations to legal professional activity, as set by the law and ethical rules governing legal practice.

I trust the above answers the questions I was addressed.

Yours sincerely,

Vincenzo Salvatore

On 22/giu/2012, at 17:28, Ron Irene <Irene.Ron@ema.europa.eu> wrote:

> Dear Vincenzo
>
> On behalf of Frances, please find attached a letter regarding Article 16 of the Staff Regulations which has also been sent by post to you today.
>
> Best regards,
>
> Irene Ron
> HR Assistant
> A-HR Personnel
> Ext. 6931
>
> ---
>
> This e-mail has been scanned for all known viruses by European Medicines Agency.
>
> ---
>
> <Letter to VS ARticle 16 -22 June 2012.pdf>

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Joint Committee Opinion n. 7/2012 of 16th July 2012

Present	Role
Emer Cooke	Chair
Noel Wathion	Member
Frances Nuttall	Member
Monika Benstetter	Member (appointed by the Staff Committee)
Tania Teixeira	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 Executive Director's decision of 19 June 2012 (Doc. Ref.: EMA/416754/2012) setting up the Joint Committee;

WHEREAS, with regard to Mr Vincenzo Salvatore's engagement in occupational activities after leaving the service, Ms Frances Nuttall, Head of Human Resources, requested the Chair to convene the Joint Committee pursuant to Article 16 of the Staff Regulations;

WHEREAS, the Joint Committee was convened and held its meeting to discuss the issue on 22nd June, 5th July and 16th July 2012, when this opinion was adopted;

HAVING REGARD to the information provided to the Joint Committee in the context of application for authorisation to engage in occupational activities after leaving the service submitted by Mr Salvatore and received by the Agency on 18 June 2012,;

HAVING REGARD to the additional information requested by the Joint Committee on 22nd June by letter from Ms. Nuttall and the e-mail response received from Mr Salvatore addressed to Dr. Guido Rasi on 27th June 2012;

CONSIDERING the information provided by the former member of staff and the relevant circumstances related to the performance of his duties whilst he was working at the Agency;

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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 content of the Joint Committee Opinion n. 7/2011 of 20th October 2011 and namely to the agreed principle stating that *"In principle, within the two years timeframe set by Article 16 of the SR, former Agency's managers (i.e. Executive Director, Heads of Unit, Sector and Section) can provide independent guidance or advice to pharmaceutical companies or industry associations (i.e. as an external consultant but not as an employee)".*

HAVING REGARD to the Agency Code of Conduct (Doc. Ref.: EMEA/6470/03/2368) and namely to the provision set out 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/her 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 has to 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 Vincenzo Salvatore is a former temporary agent of the European Medicines Agency, whose contract terminated on 15 June 2012.

During his 7 years and 7 months of service (from 16 November 2004 to 15 June 2012) at the Agency, he has been working as Head of the Legal Service Sector in the Directorate Unit.

In the application and accompanying memo received by the Agency on 18 June 2012, Mr Salvatore informed the Agency of his 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.

III. THE JOINT COMMITTEE'S ASSESSMENT

The Joint Committee holds that its opinions shall adhere to the principles of consistency and equal treatment amongst members of staff when assessing their activities after leaving the service and for this reason it considers that its former opinions delivered pursuant to Article 16 of the SR and the principles affirmed therein should be duly recalled and referred to. The Joint Committee also holds that over time experience has been accumulated and evolved and as a result, bearing in mind the particularities of each case, opinions may differ from previous opinions given.

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

The Joint Committee considers that it would be illegitimate to prevent a former member of the Agency's staff from using the skills and experience acquired in the course of their employment at the Agency so long as such use does not actually clash with a clearly identified interest of the service as it does not interfere with his obligation of lifelong confidentiality.

Nonetheless, the Joint committee acknowledges 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 to be 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.

In particular the joint committee considers 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 European Medicines Agency, with which he was previously involved with, directly or indirectly as former head of legal services. This restriction shall apply indefinitely.

In addition, for a period of two years from 16 June 2012, Mr Salvatore should 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.

The Joint Committee further requests, 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.

In the light of the above and based on the information provided by Mr Salvatore, the Joint Committee unanimously holds that the activities related to Mr Salvatore's activities identified above may be authorised subject to the restrictions outlined.

The Joint Committee also recommends that the authority authorised to conclude contracts, when taking its decision at this regard, remind 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 as ruled by Article 16 of the SR.

Done in London, on 16th July 2012

Emer Cooke

Chair of the Joint Committee

Andreas Pott
Deputy Executive Director

Noel Wathion

Member of the Joint Committee

Frances Nuttall

Member of Joint Committee

Monika Benstetter

Member of the Joint Committee

Tania Teixeira

Member of the Joint Committee