Email to CEO from Stefano Marino
6 June 2014

Dear Ms Cann

Thanks for your mail of 28 May 2014. Please find my responses below, following the order of your queries.

Sincerely,

SM

1. As Head of the Legal Department, I am responsible for assisting the Management Board, the Executive Director and the Heads of Divisions and Departments in legal matters. I lead a small team of in-house legal advisors who provide advice on all legal aspects of a number of issues, such as regulatory matters, Staff Regulation, Contract Procurement, Litigation and any other topics where legal assistance is required. When needed, I represent the Agency in legal proceedings before the Union Courts.

2. If you refer to similarities existing between my activity as in-house legal advisor in private industry and at the EMA, there are certainly some analogies in terms of managerial tasks (leading a small team of professionals, preparing legal opinions and contracts, drafting pleadings for court cases etc.). These were the skills sets that the Agency advertised for when recruiting its new Head of Legal. Of more importance are the areas in which I no longer am active, such as trademarks/patents, as the EMA does not deal with those issues.

3. As soon as I joined the EMA last year, the Agency issued a press release announcing my appointment and detailing my experience. My previous role as Chairman of the EFPIA Trademark Committee is also clearly stated in the staff profile published on the EMA website. In that capacity I have been dealing in the past with trademark issues and also attended some stakeholders' meetings organised by the EMA Name Review Group (dealing with proposed new invented names submitted by pharmaceutical companies). At the EMA, I am not a member of the Name Review Group, nor am I involved in any decision by the Name Review Group or the CHMP concerning invented names. Therefore, there is no real, potential or reasonably perceivable conflict of interests in the context of our DOI rules that I should or should have declared in my DOI concerning my previous role of Chairman of the TMKC at EFPIA. In any event, both the Agency and I have been extremely open and transparent about this topic.

4. I am one of the members of the EMA multidisciplinary team, coordinated by our Chief Policy Adviser, created for the purpose of addressing all issues raised by the stakeholders in the public consultation of our draft proactive publication policy for clinical trial data. My task is to review the draft policy from a legal perspective. My inputs are, as all others, discussed within the team with a view to reaching a collegial decision. I also joined various meetings with the stakeholders aimed at presenting the draft policy and receiving suggestions from them. In short, I do not have a leading role in this project.

5. I strongly disagree with these allegations and in particular to the fact that I would be "unduly sympathetic" to industry. Please note that I have never taken part in any of the EFPIA working groups that prepared and submitted comments to the EMA after our ED announced in 2012 the Agency's

intention to go ahead with the preparation of a draft proactive publication policy. In addition, I have never been involved in access to documents issues until I joined the EMA in June 2013. On the contrary, I have devoted huge efforts aiming at setting aside the interim orders issued against the EMA decisions on access to documents in Spring 2013. I am proud to say that those efforts were successful as, on 28 November 2013, the ECJ set aside the interim orders. I am still actively pursuing together with my legal team the defence against Intermune in the pending Court case. As to your other comments concerning the differences between the first version of the policy and the one currently in preparation, a thorough analysis of all competing interests expressed by the stakeholders called for a serious attempt to try to strike a balance among all such interests. This is a duty of care that public institutions have to comply with when they launch a public consultation and receive thousands of comments expressing divergent views. In any event, the draft policy is subject to the scrutiny of the European Commission and to the Management Board of the Agency, where 28 Member States and patients' and healthcare professionals' representatives are also represented and can endorse or disagree with its contents.

6. The Agency was very transparent from the beginning about my career experience with pharmaceutical industry, as already stated above. There was never any intention to hide or otherwise redact this information. I act at all times with the utmost integrity and work to the best of my abilities to promote the sole interests of the Agency. In light of the above, any actual or perceived risks are, from my perspective, completely devoid of any foundation.

7. I cannot be involved in any issue concerning my previous employer's interests.

8. No.

-----Original Message-----
From: Vicky Cann
Sent: 29 May 2014 08:43
To: Marino Stefano
Subject: Re: Urgent questions about your declaration of interest and related issues

Thanks.

On 28/05/2014 19:43, Marino Stefano wrote:

> Dear Ms Cann
>
> Duly received. I will respond on or before 6 June.
>
> Kind regards
>
> SM
>
> Sent from my iPad
>
> On 28/mag/2014, at 16:24, "Vicky Cann" wrote:
>
> Dear Mr Marino,
>
> I work for an NGO called Corporate Europe Observatory which is a research and campaign group concerned with the access and influence enjoyed by corporations and their lobby groups in EU policy-making: http://corporateeurope.org/

I would like to ask you several questions about your move from Sigma-Tau to EMA. It would be very useful to understand more about this from your side before we consider publishing an article on this issue.

I would appreciate receiving a response from you as soon as possible and at least before the close of play on Friday 6 June.

1. What are the precise functions of your role at EMA as head of its legal department?
2. What overlaps do your perceive in your work for EMA vis a vis your previous work at Sigma-Tau?
3. Why do you not mention your previous role as the chairman of the trademark committee at the European federation of pharmaceutical industries and associations (EFPIA) on your declaration of interest dated 19 June 2013?
4. What is your precise role in the development of EMA's draft policy on the "publication and access to clinical-trial data"?
5. How do you respond to concerns that the weakening of EMA's draft policy on the "publication and access to clinical-trial data" which has taken place between the publication of the initial draft of June 2013 and the version which was shared with stakeholders in May 2014 reflects the fact that you are unduly sympathetic to the concerns of the pharmaceutical industry on these issues? The June 2013 draft proposed pro-active transparency of clinical data yet the documents which were shared with stakeholders in May 2014 propose allowing systematic censorship of data by pharmaceutical companies, impose strict confidentiality requirements and impose wide restrictions on the use of the data.
6. How do you respond to concerns that your move from the pharmaceutical industry to EMA provokes the risk, perception and / or actuality of conflicts of interest?
7. Have there been any specific issues which you have agreed with EMA that you will not work on because of the risk of conflicts of interest considering your previous career history within the pharmaceutical industry?
8. Do you have any other comments to make about these issues?

We are also writing in similar terms about these matters to Guido Rasi.

I look forward to hearing from you; thank you in advance for your time.

Yours sincerely,

Vicky Cann

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Vicky Cann
Lobbycracy campaigner
Corporate Europe Observatory
http://corporateeurope.org/