Email to CEO from Guido Rasi

5 June 2014

Dear Ms Cann

Thank you for your mail of 28 May 2014 concerning the role of our Head of Legal Department and related matters. Please find my answers below:

1. The Head of the EMA Legal Department is responsible for managing the Legal Department and actively assisting the Management Board, the Executive Director and the Heads of Divisions and Departments in legal matters. Leading a team of other in-house legal advisors, he provides advice on all legal aspects of regulatory issues and other topics where legal assistance is required. He may represent the Agency in legal proceedings involving the Agency before the EU Courts.

2. At the Agency, we take conflict of interests very seriously. All staff members have an obligation to submit and then update their declarations of interests as soon as any new event requires to do so. There is also an annual monitoring and re-assessment by the relevant reporting officer of the declarations of interests submitted by the concerned staff member. The risk of a possible conflict of interests with regard to Mr Marino's previous role at his former employer's was duly assessed before appointing him and afterwards. It was decided to assign him a level 3 risk, which means that he cannot participate to any discussion/decision-making process concerning any interests of his former employer, Sigma-Tau of Italy.

3. On his first day of work at the EMA, the EMA published on its external web portal a brief profile of Mr Marino when his previous role as Chairman of the EFPIA Trademark Committee was duly mentioned. He is not a member of the Name Review Group dealing with proposed new invented names submitted by pharmaceutical companies, nor is he involved in any decision by the Name Review Group or the CHMP concerning invented names. For this reason, there cannot be any real or potential conflict of interests concerning his above mentioned previous role at EFPIA.

4. Your question raises the general issue of a "reverse revolving door" principle, i.e. whether it is appropriate for a public institution to hire somebody from industry. Let me be very frank in that regard: excluding experienced managers from the selections for vacant positions at the Agency, or refusing to hire them solely because they have been working for industry for a long time would be a highly discriminatory and disproportionate decision. The EMA can benefit from the experience of this category of managers, provided that the decision-making process is robust, that roles of team members are clear and that rules (including rules on the handling of declarations of interests and resulting restricted involvement where appropriate) are applied consistently. In this case, Mr Marino's professional conduct and absolute personal integrity reinforces my belief that, for once, the revolving doors have worked in favour of the EMA.

5. See Section 3 above.

6. The EMA's proactive publication of clinical trials draft policy is a project led by a multidisciplinary team where all delicate issues (scientific, regulatory, political, legal) have been assessed for months, also in light of more than 1300 comments received from many stakeholders, including EU institutions. This thorough analysis and debate has been coordinated by our Chief Policy Adviser, Noel Wathion, who took particular care in ensuring that all members of the team would offer their professional inputs with a view to reaching a collegial decision. Within this framework, Mr Marino's role was to review the draft policy from a legal perspective, also in light of some indications coming from the European Court of Justice both in our pending Court case(s) and in other cases concerning transparency and access to documents in the

European Union. He participated, together with several other colleagues, to various meetings with the stakeholders aimed at presenting the draft policy and receiving suggestions from them. In all serious organisations, and I am proud to say that this Agency is one of them, decisions are taken collegially and every manager who participated to the decision abides by the decision taken and receives a clear mandate to represent the institution's viewpoint on the subject matter of the decision. I am probably stating the obvious, but how could you reasonably argue that such a complex decision-making process would be driven or conditioned by one manager only?

7. For this question, I kindly refer you to two documents published meanwhile by the Agency on its web portal, i.e. the answer that I have recently given to the European Ombudsman and the press release concerning the publication of the new Clinical Trial Regulation.

8. These concerns are ill-founded. The decision-making process at the EMA is very solid and the decision is collegial; the process was coordinated by the Chief Policy Adviser, whose professional behaviour is out of discussion; I disagree with your characterisation of the Head of the Legal Department at the EMA as "unduly sympathetic to the concerns of the pharmaceutical industry on these issues". This is not supported by any facts and is rather a simplistic and gratuitous statement. After Mr Marino joined the Agency last year and under his guidance, first the Agency obtained an important victory by having the interim measures issued against the EMA in April 2013 set aside by the Court of Justice in appeal. Then, one of the plaintiffs withdrew from two of the interim and main cases. The Legal Department and his Head are still very committed to defend the Agency in the last pending Court case.

9. Please see above my answer to your question 4.

10. The Agency's commitment towards transparency cannot be reasonably disputed. The draft policy has been shaped in the absence of any specific provision mandating the EMA to publish on its web portal documents submitted to the Agency by third parties, as is instead the case for other EU Agencies. I am not aware of any other body providing this level of access to the documents on which important regulatory decisions are based. As ever, we are accountable for our decisions and are prepared to explain and defend them. We trust that you will appreciate our openness.

Kind regards

Guido Rasi

Guido Rasi

Executive Director

European Medicines Agency

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From: Vicky Cann
Sent: 28 May 2014 16:26
To: Rasi Guido
Subject: Urgent questions regarding Stefano Marino, his declaration of interest and related matters

Dear Mr Rasi

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 have a number of questions to ask you about EMA's employment of Stefano Marino as head of its legal department. 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 before the close of play on Friday 6 June.

1. What are the precise functions of the role of EMA's head of legal department?
2. Did EMA fully assess the risk of possible conflicts of interest relating to Mr Marino before it appointed him? If so, what form did this assessment take place?
3. Why does Mr Marino's previous role as the chairman of the trademark committee at the European federation of pharmaceutical industries and associations (EFPIA) 2005-2013 not feature on his EMA declaration of interest dated 19 June 2013?
4. When considering the risk of potential conflicts of interest surrounding EMA's employment of Mr Marino, did EMA fully consider not just his direct employment at Sigma-Tau and any direct conflicts which might arise concerning Sigma-Tau products (ie. Eurartism) and other interests, but also his role at EPFIA and the fact that Mr Marino has worked within the pharmaceutical industry for practically his whole career, a period of approximately 23 years?
5. In practical terms, what does EMA's categorisation of Mr Marino as a level 3 risk of conflict of interest mean? Are there issues or areas of work which he cannot get involved in; if so, what? What monitoring and oversight is there considering Mr Marino's risk level?
6. What is Mr Marino's precise role in the development of EMA's draft policy on the "publication and access to clinical-trial data"?
7. Why has EMA's draft policy on the "publication and access to clinical-trial data" been weakened since the publication of the initial draft of June 2013? 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.
8. How do you respond to concerns that the weakening of EMA's draft policy on the "publication and access to clinical-trial data" between June 2013 and May 2014 reflects the fact that Mr Marino is unduly sympathetic to the concerns of the pharmaceutical industry on these issues?
9. How do you respond to concerns that EMA's employment of Mr Marino after 23 years within the pharmaceutical industry provokes the risk, perception or actuality of conflicts of interest?
10. Do you have any other comments to make about these issues?

We are also writing in similar terms about these matters to Mr Marino himself.

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/
