



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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17 June 2016  
EMA/397114/2016  
Deputy Executive Director

Dear Prof Gøtsche

Subject: Your letter of complaint dated 26 May 2016 to the European Medicines Agency (EMA) over maladministration at the EMA.

I refer to your [letter of complaint](#) sent to Prof Rasi relating to maladministration at EMA. This reply only deals with point 4 of the section "Conflicts of interest" and a number of allegations on page 17 in the section "Final remarks" in your complaint letter. A reply to the other issues you have raised in your complaint letter is being finalised and will be provided to you within the next few days.

In your complaint you allege that Prof Rasi may have a conflict of interest, stemming from his previous contacts with industry, and which you claim he failed to declare. Without prejudice to any response and defence that Prof Rasi may wish to forward to you directly, EMA would like to refute your unsubstantiated allegations in the strongest possible terms, for the sake of transparency owed to the general public and to the EU regulatory network of which EMA is an important member.

The Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of staff members of the European Medicines Agency and candidates before recruitment (EMA/622828/2013(revised)) describes the interests in pharmaceutical industry to be declared by the Agency's staff. Amongst other things, EMA staff members are required to declare in their declaration of interests (DoI) any ownership of a patent held for a period of 5 years prior to the start of employment with the Agency.

As you may be aware (see for instance [European IPR Helpdesk](#)), the inventor mentioned on a patent is the creator of the invention and is always entitled to be designated on the patent, regardless of who files the patent application or owns the patent. An inventor remains an inventor throughout the term of a patent, but he is not necessarily the owner of the patent, e.g. the ownership rights may be vested originally upon, or subsequently assigned to, a subject other than the inventor/s. Only the owner of a patent can enjoy economic rights with regard to that particular invention. Therefore, neither the applicable rules, nor considerations of common sense oblige EMA staff to declare in their DoI any patents for which they are the inventor/s, but not the owner/s, unless the inventor is entitled to financial benefits (e.g. lump-sum or royalties) stemming from the exploitation of the invention.



The same principle is applicable to European experts. According to the EMA policy on the handling of declarations of interests of scientific committees' members and experts (EMA/626261/2014, Corr. 1), the definition of financial interests encompasses intellectual property rights relating to a medicinal product, including patents. An expert is required to declare such an interest if the patent is owned by the individual or if the individual is directly a beneficiary of the exploitation of the patent. If the expert is the inventor of the patent, but not the owner or beneficiary, there is no obligation to declare it.

The Agency's Executive Director Prof Rasi is indeed mentioned on a number of patents, even beyond those referred to in footnote 15 of your complaint letter, but only as inventor, not as owner of the patents. Prof Rasi does not own any patent together with Sigma-Tau. He is named as inventor on 2 patent families for which Sigma-Tau is named as applicant or patentee. He is not even the beneficiary of those patent families. Hence there was and there is no obligation for him to declare these patents in his DoI as EMA staff member in accordance with EMA's proceedings on the handling of DoIs.

We would also like to clarify that Prof Rasi has never worked with or for Sigma-Tau and that no former Sigma-Tau employee joined EMA since 2011 with the exception of Mr S. Marino, who was indeed the former General Counsel at Sigma-Tau, as publicly announced by EMA when he was hired after a very rigorous competition run by a selection panel featuring also external members from the Legal Service of the European Commission. Prof Rasi was not part of that selection panel and he did not know Mr Marino when he was still working in industry. The statements appearing at page 17 of the Nordic Cochrane complaint against EMA have therefore no foundation.

We trust that the information provided in this letter has adequately addressed the points raised in your complaint letter. Taking into account the seriousness of the accusations made via the Internet and the echo that these allegations have had worldwide, EMA reserves the right to protect its reputation through all appropriate means. Please also note that EMA will publish this reply for the sake of transparency.

Yours sincerely,

[Signature on File]

Noël Wathion  
Deputy Executive Director

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