
10 October 2016

Follow-up on our complaint to the European Medicines Agency (EMA) over maladministration at the EMA related to safety of the HPV vaccines

On May 2016, we submitted a [Complaint to the European Medicines Agency \(EMA\) over maladministration at the EMA](#) related to safety of the HPV vaccines.

The replies we received from the EMA came in three parts:

1. On 17 June, Noël Wathion, the EMA's Deputy Executive Director, addressed conflicts of interest issues related to the EMA's Executive Director, Guido Rasi ([2 pages](#)).
2. On 1 July, Noël Wathion sent the EMA's response to the other issues we had raised ([17 pages](#)).
3. Starting on 8 July and ending on 30 September, Carter-Ruck solicitors in London sent a total of 8 letters to us on behalf of their client, Guido Rasi, which we responded to.

The EMA's replies to us did not fully address our concerns. Some of our concerns were not addressed at all, and several of the EMA's statements were either wrong or seriously misleading, or irrelevant for the criticism we had posed. We have therefore today submitted a [Complaint to the EU ombudsman over maladministration at the EMA](#) related to safety of the HPV vaccines.

The EMA has made us aware that we have misinterpreted some of the information that was available to us in relation to conflicts of interest issues and we therefore make corrections here as well as in our [Complaint to the EU ombudsman over maladministration at the EMA](#) related to safety of the HPV vaccines. We have included the entire correspondence between Wathion and Rasi's law firm and us in an Appendix to our complaint to the ombudsman, as we believe it has considerable public interest.

About the EMAs executive director, we wrote in our complaint to the EMA:

"We noticed a Guido Rasi's name associated with patents for inventions and wonder whether this is the same person who is the EMA's director. If so, we believe Rasi has failed to declare his conflicts of interest."

"a Guido Rasi, which we assume is the same person, holds a number of patents, some of which were filed or approved in 2012 or 2013, and where the applicant was a drug company (Applicant: SciClone Pharmaceuticals, Inc.; Inventors: Guido Rasi, Enrico Garaci, Francesco Bistoni, Luigina Romani, Paolo Di Francesco) (15). As they go back less than five years, we believe he should have declared them, according to the EMA's regulations concerning the handling of declared interests of its employees (16)."

“the EMA’s director, Guido Rasi, has brought in a number of people from the drug company Sigma Tau that include Stefano Marino, his head of legal affairs. Rasi has worked with this company for many years and apparently owns several patents together with the company (15).”

“the EMA’s director, Guido Rasi, declared on 20 July 2015 that he had no conflicts of interest (14). On a form called ‘EMA Public Declaration of Interests,’ he replied ‘none’ to all four questions, also to question 4, which is: ‘Other interests or facts whether or not related to the pharmaceutical industry⁴ which you consider should be made known to the Agency and the public, including matter relating to members of your household⁵.’”

The EMAs deputy executive director, Noël Wathion, has informed us that:

“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.”

“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 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 apologize for our mistakes.

We were not aware of the legal subtleties and assumed that an inventor of a patented technology is also an owner of that patent, as it is unusual that inventors give away their patents to drug companies without benefiting from them and without having any working relationship with that

particular company. Noel Wathion has explained to us that Professor Rasi is not the owner of the patents for which he is named as inventor.

As concerns the employment of people, there are legal procedures to follow, but it is also common that the employer contacts people informally, encouraging them to apply for the post. The EMA has stated to us that Professor Rasi did not bring anyone to EMA from Sigma-Tau and that Stefano Marino was recruited according to the ordinary, rigorous EU selection procedures and received no favourable treatment at all.

About the EMA's rapporteur, we wrote:

"We also believe that the rapporteur for the EMA's report, Julie Williams (2), has failed to declare her conflicts of interest."

We apologize for this mistake, which stems from the limited information that was available to us. In the material from the EMA that we had acquired, we could not see where this person worked and therefore looked her up on the Internet. Unfortunately, we found the wrong person, another Professor Julie Williams. Therefore, what we wrote about Julie Williams in our complaint to the EMA should be disregarded, apart from this sentence, which is correct:

"in Williams' 'Public declaration of interests' on the EMA's homepage from 21 November 2015 (13), no conflicts of interest are declared."

Sincerely,



Peter C Gøtzsche, Professor, Director of the Nordic Cochrane Centre, Rigshospitalet, Denmark
Karsten Juhl Jørgensen, Deputy Director of the Nordic Cochrane Centre, Rigshospitalet, Denmark
Tom Jefferson, Honorary Research Fellow, Centre for Evidence Based Medicine, Oxford, UK
Margrete Auken, MEP (The Greens/European Free Alliance)
Louise Brinth, PhD, MD, Danish Syncope Unit, Frederiksberg, Denmark