

Letter from the European Ombudsman to the European Commission concerning the transparency of clinical trials data

Letter - 03/06/2014

Mr José Manuel Barroso President European Commission 1049 BRUSSELS BELGIQUE

Strasbourg, 3 June 2014

Re: Transparency of clinical trials data

Dear Mr President,

I have recently been in correspondence with Mr Guido Rasi, Executive Director of the European Medicines Agency (EMA), concerning the transparency of clinical trials data.

In his letter dated 22 May 2014, Mr Rasi refers to a "clear message" of the European Commission relating to the need to ensure compliance with national and international agreements, including, but not limited to, TRIPS and copyright legislation. I presume from the context that Mr Rasi means that a "clear message" has been conveyed by the Commission to EMA.

In order to help me understand the development of EMA's policies, it would be helpful if you could inform me of the contacts that the Commission and its services have had with EMA since July 2013 regarding the transparency of clinical trials data, including all relevant letters and emails sent and received and all relevant meetings. Please also provide me with copies of any minutes of such meetings and of the relevant correspondence.

Please also inform me if the Commission has given its agreement, pursuant to Article 80 of Regulation 726/2004, to the proposed EMA policy to publish proactively clinical study reports. I understand that policy is to be submitted to the Management Board of EMA on 12 June 2014.

If the Commission has given its agreement to the proposed EMA policy to publish proactively clinical study reports, please provide me with a copy of the document communicating that agreement to EMA.

I should be grateful to receive the above information and documents from the relevant



Commission services as rapidly as possible and in advance of a formal reply. The person to contact in my office for this purpose is Mr João Sant'Anna ([tel]; [e-mail]).

Yours sincerely,

Emily O'Reilly

Cc: Mr Rasi, Executive Director of EMA Mr Kent Woods, Chairman of the EMA Management Board

Enclosures (2):

- Letter from the Ombudsman to Mr Rasi dated 13 May 2014
- Letter from Mr Rasi to the Ombudsman, dated 22 May 2014