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Re: Complaints 1475/2016/JAS and 1606/2016/JAS

Dear Ombudsman,

further to our complaint dated 10 October 2016 (complaints 1475/2016/JAS and 1606/2016/JAS), we would like to bring to your attention some of the content of the attached document which has been recently passed to us.

We think the content is highly relevant to the matter of our complaint. From pdf page 85 there is an exchange of emails from the summer of 2014 between the Danish regulator (Danish Health and Medicines Authority – head of pharmacovigilance), Mr Henrik G Jensen, and representatives of the market authorisation holder (MAH) for Gardasil, Sanofi Pasteur MSD.

The regulator requests an explanation of why the MAH concluded that none of the reports of the possible cases of POTS provided to the MAH by the Danish regulator fitted the diagnostic criteria for POTS (pdf page 93). In effect the regulator is asking for details of the methods used by the MAH and is openly critical of the MAH's conclusions and dismissal of the work of the Danish Syncope Centre at Frederiksberg Hospital.

In addition the regulator states that the search terms used by the MAH to identify possible cases of POTS in their pharmacovigilance database were too restrictive and failed to identify the cases notified by the same regulator.

At the end of the letter dated 24th of July 2014 (pdf page 95) the regulator states: "Please note that the PRAC rapporteur has received a copy of this letter," which listed the regulator's concerns. The MAH had also sent a copy of their original response dated 11 June 2014 with the search results to the "Swedish rapporteur" (pdf page 111) criticised by the regulator.

We can find no mention of the Danish regulator's concerns in the PRAC papers, nor any critical assessment of the searches carried out by both MAHs in coordination with each other. Indeed, knowledge of the previous regulatory concerns over the grossly insufficient search strategy used by Sanofi Pasteur MSD did not lead to publication of the search strategy used in the searches performed by the MAHs' that were requested by the EMA.

We deduce from this that the Danish regulator's concerns were not taken seriously by the PRAC, also because we could find no discussion of this issue in relation to the searches performed by the MAHs in their databases, neither in the long internal 256-page report nor anywhere else.

In your admissibility letter to us dated 8 November 2016 (your references 1475/2016/JAS and 1606/2016/JAS), you state that "The Ombudsman may, however, seek to assess whether EMA has

procedural safeguards in place which ensure that the scientific advice it receives is independent of outside interests and reliable".
We believe that the emails show that the advice received by the EMA from the PRAC was uncritical and unreliable and did not take into account the concerns clearly expressed by the referring Danish regulator.

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