European Ombudsman

Decision of the European Ombudsman concerning complaint 2123/2020/VS on how the European Medicines Agency dealt with concerns raised about a medicine

Decision
Case 2123/2020/VS - **Opened on** 26/02/2021 - **Decision on** 26/02/2021 - **Institution concerned** European Medicines Agency (No maladministration found) |

Dear Ms X,

On 3 December 2020, you submitted a complaint to the European Ombudsman against the European Medicines Agency (EMA) concerning how it dealt with your concerns about the safety of a medicine, containing the active substance pregabalin [1] , the medical studies underlying EMA's assessment of the medicine and about the independence of EMA staff, management and experts.

We would first like to acknowledge how challenging the situation that you experienced in relation to the medicine in question must have been and to emphasise the importance of the matters you have raised with EMA.

We would also like to explain why it took some time to reply to your complaint. We first needed to wait for the copies of your exchanges with EMA on the questions raised in your complaint. Normally, these are submitted to us directly by the complainant along with the complaint. In this case, EMA helpfully provided them. We then needed some time to review carefully all the material submitted to us.

We identified several issues in your complaint. You contend that:

1. The clinical studies on which EMA's authorisation of the medicine was based were not sound.

2. EMA did not provide you with a precise answer to your question if there were long-term studies based on which the medicine was authorised and which measured the withdrawal symptoms for a period of at least one month after having stopped the treatment.

3. EMA did not provide you with the full text of the study underlying EMA's assessment of the

medicine.

4. EMA did not reply to your request of 23 October 2020 to disclose a list of EMA product leads, the medical authorisation application for the medicine, the names of the assessment team members for the medicine and their declarations of interest (DOIs), and the DOIs of six members of EMA's Committee for Medicinal Products for Human Use (CMPH).

5. EMA did not provide you with concrete answers concerning potential conflicts of interest of several EMA experts.

After a careful analysis of all the information submitted to us, our assessment is as follows.

It is important for our Office to have a clear idea, from the outset, of how we could help a complainant. In this case, given the limitations on the Ombudsman's mandate, and the extent to which EMA has engaged on the matter, it is not possible for us to identify what we could achieve for you.

First, as regards your primary concerns about the medicine's clinical studies and the result of EMA's scientific assessment, it is important to note that the European Ombudsman cannot take a view on a question of medical science. We are not in a position to call into question the result of EMA's medical assessment. [2]

On the question of whether EMA provided a clear answer to your question about a long-term study measuring withdrawal, our view is that EMA has in substance replied to this point. In particular, EMA's reply of 18 November 2020 noted that while the clinical studies on which the initial authorisation was based were relatively short, they were in line with the relevant guidelines. The Ombudsman is not in a position to call into question the adequacy of these medical guidelines. On the basis of the data from the trials, the medicine was found to cause withdrawal symptoms, which, as EMA clarified, is duly reflected in the product information. [3]

Regarding your concern that EMA did not provide you with the full text of the study underlying the assessment of the medicine, we note that on 16 March 2020 you lodged a confirmatory application, asking to be provided with the patients' names from the clinical study. EMA's reply of 14 April 2020, that EMA does not hold the information and that in any event patients' names constitute personal data that could not be disclosed, is reasonable. [4]

Finally, you contend that EMA did not provide you with concrete answers concerning potential conflicts of interest. On the basis of a review of the exchanges [5] , we consider that EMA answered to your general and concrete questions. In particular, EMA explained the principles and policies that apply and provided details on a large number of topics, such as EMA's budget, clinical trials, EMA's institutional and operational set-up, competing interests and staff code of conduct. We find that EMA provided reasonable and appropriate replies, clarifications and information, explaining its policies and why it considered that there were no conflicts of interest. The information provided to us does not suggest that EMA erred in reaching this conclusion.

We note however that your request for public access to documents of 23 October 2020, concerning the list of EMA product leads, the medical authorisation application for the medicine, the names of the assessment team members for the medicine and their DOIs, and the DOIs of six members of CMPH, is - according to the latest information available to us - still 'in queue' in EMA's system. While we have found that EMA's practice of placing 'in queue' certain requests for public access to documents is appropriate [6] , we have asked EMA, if it has not done so in the meantime, that they now reply to your request as soon as possible.

Given these considerations, we have not identified any possible maladministration on the part of EMA in its handling of the matter to date. [7] We say this in the knowledge that you hold genuine concerns about the medicine in question. However, our assessment of the matter is that any further inquiries by the Ombudsman would not serve a useful purpose.

We understand you may be disappointed with this outcome but we hope you find these explanations useful.

Yours sincerely,

Rosita Hickey Director of Inquiries

[1] https://www.ema.europa.eu/en/medicines/human/EPAR/lyrica [Link]

[2] See the Ombudsman's decision in case 107/2020/EWM: https://www.ombudsman.europa.eu/en/decision/en/131637

[3] EMA reiterated this information in its subsequent reply to you dated 30 January 2021.

[4] See the Ombudsman's decision in case 1602/2016/JAS, §§ 24-31, where the Ombudsman found that transparency requirements do not extend to disclosing patients' data:

https://www.ombudsman.europa.eu/en/decision/en/89507

[5] Your requests and EMA's replies to them dated 22 June 2020, 24 July 2020, 17 September 2020, 21 September 2020 and 18 November 2020.

[6] See the Ombudsman's decision in case 1608/2017/MIG: https://www.ombudsman.europa.eu/en/decision/en/111254

[7] Full information on the procedure and rights pertaining to complaints can be found at https://www.ombudsman.europa.eu/en/document/70707 [Link]