European Ombudsman

How the European Medicines Agency (EMA) organised a re-examination of an application for a marketing authorisation of a medicinal product for treating age-related macular degeneration

Case opened
Case 1851/2022/KR - **Opened on** 12/12/2022 - **Decision on** 18/12/2023 - **Institution concerned** European Medicines Agency (No maladministration found) |

Dear Mr X,

The Ombudsman has received a complaint against the European Medicines Agency (EMA). The Ombudsman has asked me to deal with the case on her behalf.

The complaint concerns the way in which EMA conducted the meeting of its Ad Hoc Expert Group (AHEG) on 16 February 2022, in relation to the review procedure for the medicinal product Y.

In sum, the complainant has raised three main concerns about:

1. EMA's handling of competing interests of AHEG experts;

2. The adequate level of expertise of AHEG members to scientifically evaluate the grounds for re-examination and the selection of the questions asked; and

3. The level of detail of the meeting minutes, in particular when it comes to the reporting on divergent opinions.

We have decided to open an inquiry into the aspects of this complaint which concern how EMA dealt with (risks of) conflicts of interest of the AHEG experts involved (point 1), and the manner in which EMA reported on the meeting of the AHEG on 16 February 2022 (point 3).

For the purposes of the Ombudsman's inquiry, we would be grateful if EMA could comment on these two aspects of the complaint.

In particular, could EMA please comment on its practices regarding the recording of divergent opinions expressed by experts in AHEG meetings? For example, could EMA explain why, in this

case, it did not provide details on which of the experts held the divergent views?

As regards the second aspect of this complaint (point 2), we note that questions relating to the adequate level of scientific expertise of AHEG experts, as well as the selection of questions to be discussed by the experts, are matters of science. The Ombudsman is not a scientific body and is not in the position to call such choices into question. We are therefore not inquiring into the second aspect of the complaint.

Please note that we are likely to send your reply and related enclosures to the complainant for comments [1] . We would therefore be grateful if EMA could submit a translation of the reply itself in Dutch, which is the language of the complaint. We may also decide to publish your reply.

The responsible inquiries officer is Mr Koen Roovers.

We would be grateful to receive the EMA's reply by 15 March 2023. If, in the course of this inquiry, EMA becomes involved in court proceedings concerning the same subject matter as this complaint, we would ask you to let us know.

Yours sincerely,

Tina Nilsson Head of the Case-handling Unit

Strasbourg, 12/12/2022

[1] If you wish to submit documents or information that you consider to be confidential, and which should not be disclosed to the complainant, please mark them ‘Confidential’. Encrypted emails can be sent to our dedicated mailbox. Information and documents of this kind will be deleted from the European Ombudsman’s files shortly after the inquiry has ended.