

The European Medicines Agency's handling of the so-called referral procedure of a particular pharmaceutical product

Case opened

Case 1475/2016/JAS - **Opened on** 05/12/2016 - **Decision on** 16/10/2017 - **Institution concerned** European Medicines Agency (No maladministration found) |

In October 2016, the Ombudsman received a complaint alleging that the European Medicines Agency had not dealt properly with a so-called referral procedure related to a pharmaceutical product and alleging a lack of transparency. The complaint does not concern the safety of the product.

After an initial examination of the allegations, the Ombudsman decided to ask EMA for a meeting. A meeting between EMA and Ombudsman staff took place on Wednesday, 7 December 2016.

The steps the Ombudsman has taken in response to the complaint solely concern administrative and procedural issues. To that end, the Ombudsman is looking into whether EMA has procedures in place that ensure that all the relevant evidence is available to its scientific committees and whether EMA has been sufficiently transparent about how its committees reach their scientific conclusions. The Ombudsman's staff have not identified any deficiencies to date.

The Ombudsman is not in a position to question scientific conclusions made by the competent scientific bodies.

Strasbourg, 05/12/2016