Euroopan oikeusasiamies

Euroopan lääkeviraston kieltäytyminen antamasta yleisön tutustuttavaksi osia kliinisen tutkimuksen raportista, joka koskee skitsofrenian ja kaksisuuntaisen mielialahäiriön hoitoon tarkoitettua lääkettä

Tutkimus aloitettu
Kanteluasia 444/2022/MIG - **Tutkittavaksi otetut kantelut, pvm** 07/03/2022 - **Päätökset, pvm** 20/06/2022 - **Toimielin, jota kantelu koskee** Euroopan lääkevirasto (Ei hallinnollista epäkohtaa) |

Head of Legal Department

European Medicines Agency (EMA)

Dear Mr X,

The Ombudsman has received a complaint against the European Medicines Agency.

The complaint concerns EMA's refusal to give public access to parts of a clinical study report concerning the drug Zyprexa. EMA has given the complainant wide access to the report, subject to the redaction of certain personal data. Specifically, EMA refused to disclose the ID number and gender of the patients enrolled in the clinical trial in question. It considered that disclosure of this information would risk the indirect re-identification of the patients and that the complainant had not put forward a necessity in the public interest for the transfer of this data.

The complainant would like EMA to disclose this information. He argues that, due to the passage of time, it can be assumed that relevant additional data that would allow for the identification of the patients concerned has been deleted. In addition, he considers that the redacted data is relevant to fully understand the findings of the study and that this data should be disclosed to put the public in a position to verify the safety and efficacy of the drug.

We have decided to open an inquiry into the complaint against EMA's decision to refuse public access to parts of the clinical study report under Regulation 1049/2001.

Regulation 1049/2001 states that applications for access should be handled promptly. It is in

line with this principle that the Ombudsman also seeks to deal with cases such as this as quickly as possible.

As a first step, we consider it necessary to review the redacted parts of the clinical study report at issue. We would be grateful if EMA could provide a copy of the relevant pages of the report, preferably in electronic format through encrypted e-mail, [1] **by 15 March 2022** .

The documents subject to the public access request will be treated confidentially, along with any other material EMA chooses to share with us that it marks confidential. Documents of this kind will be handled and stored in line with this confidential status and will be deleted from the Ombudsman's files shortly after the inquiry has ended.

We also consider that it would be helpful to schedule a meeting between EMA and the Ombudsman inquiry team at which we can discuss this case. The inquiries officer responsible for the case, Ms Michaela Gehring, can be reached to arrange the details of this meeting, ideally to take place **before 1 April 2022** .

Yours sincerely,

Rosita Hickey Director of Inquiries

Strasbourg, 07/03/2022

[1] Encrypted emails can be sent to our dedicated mailbox.