



The European Medicines Agency's refusal to give public access to parts of a clinical study report concerning a drug for the treatment of schizophrenia and bipolar disorder

Case 444/2022/MIG - Opened on 07/03/2022 - Decision on 20/06/2022 - Institution concerned European Medicines Agency (No maladministration found) |

The case concerned a refusal by the European Medicines Agency (EMA) to grant full public access to a clinical study on the safety and efficacy of a medicine. In refusing access, it invoked an exception provided for under the EU legislation on public access to documents, arguing that disclosing the remaining information could undermine privacy of the individuals concerned. Specifically, the complainant was dissatisfied that EMA refused to disclose the personal data of the patients, notably, their gender and the pseudonyms used for the patients during the clinical trial. The Ombudsman found that it was reasonable for EMA to have withheld the personal data concerned. She therefore closed the inquiry finding no maladministration.