



## How the European Medicines Agency (EMA) dealt with concerns raised about a medicine

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

The complainant contacted the European Medicines Agency (EMA) with concerns about the safety of a medicine, the medical studies underlying EMA's assessment of the medicine and those involved in the assessment. The complainant was dissatisfied with how EMA had dealt with the concerns she raised, and turned to the Ombudsman.

The Ombudsman acknowledged that the complainant holds genuine concerns about the medicine, but found that EMA had provided reasonable and appropriate answers to the questions she raised. The Ombudsman therefore closed the inquiry, with a finding of no maladministration. However, she urged EMA to reply as soon as possible to the complainant's pending request for public access to documents.