The European Medicines Agency's (EMA) refusal of public access to documents relating to the manufacturing of mRNA vaccines against COVID-19

Case 1458/2021/MIG - **Opened on** 20/08/2021 - **Decision on** 10/11/2021 - **Institution concerned** European Medicines Agency (No maladministration found) |

The complainant sought from the European Medicines Agency (EMA) public access to documents concerning the raw materials used in manufacturing mRNA vaccines against COVID-19. In processing the request, EMA refused access to two documents, arguing that disclosure would undermine the commercial interests of the company in question. Having inspected the documents, the Ombudsman found that they contain commercial information. Given the high public interest, information relating to the safety and efficacy of a medicine (for example the results of clinical trials) should always be disclosed, and EMA has indeed provided increased transparency about its regulatory activities on treatments and vaccines for COVID-19. However, the same does not normally apply to detailed information relating to how a medicine is manufactured. The Ombudsman thus found that EMA was justified in withholding access and closed the inquiry, finding no maladministration.