Letter from the European Ombudsman to the European Medicines Agency (EMA) on its refusal of public access to documents relating to the manufacturing of mRNA vaccines against COVID-19 - EMA reference number ASK-82701

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

Head of Legal Department

European Medicines Agency

Dear Mr X,

The Ombudsman has received a complaint against the European Medicines Agency (EMA). The complaint concerns EMA's refusal to provide public access to documents relating to the manufacturing of mRNA vaccines against COVID-19.

In January 2021, the complainant asked EMA for public access [1] to documents concerning the quality of raw materials contained in the Module 3 of the Common Technical Document (CTD) for Comirnaty (Biontech/Pfizer) and Covid-19 Vaccine Moderna. EMA replied in March 2021, refusing access to the requested documents.

The complainant requested a review of this decision. EMA said that since the access request concerned a large number of documents, it would split it and process the confirmatory application in batches. In July 2021, EMA informed the complainant about its decision to refuse access to two documents, namely **document '3.2.S.2.3 control-of-materials-raw** ' [2] and **document '3.2.S.2.3 control-of-materials-starting-lonza-visp'** [3] (batches 1 and 2). EMA based this decision on the need to protect commercial interests.

We have decided to open an inquiry into the complaint against EMA's decision to refuse public access. At this stage, the Ombudsman's inquiry concerns only EMA's refusal to provide access to **document '3.2.S.2.3 control-of-materials-raw** ' and **document '3.2.S.2.3 control-of-materials-starting-lonza-visp'.**

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:

i. the two documents at issue;

ii. the consultations between EMA and the third party, at the confirmatory stage.

We would be grateful if EMA could provide us with copies of these documents, preferably in electronic format through encrypted e-mail, [4] by 27 August 2021. If more time is needed, we would be grateful if you could let us know.

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.

EMA's position has been set out in its confirmatory responses. However, should EMA wish to provide additional views, to be taken into account by the European Ombudsman during this inquiry, we would be grateful if they could be provided to us within fifteen working days from the receipt of this letter, that is, by 10 September 2021. We would be grateful if EMA could also submit a translation of such additional views (if any) in German, which is the language of the complaint.

If you have any questions, please feel free to contact the inquiries officers, Ms Oana Marin or Ms Michaela Gehring.

Yours sincerely,

Rosita Hickey Director of Inquiries

Strasbourg, 20/08/2021

[1] In accordance with Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32001R1049

[2] Confirmatory decision EMA/330164/2021 Rev.1

[3] Confirmatory decision EMA/386372/2021

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