Decision in the case 1450/2022/NK on how the European Medicines Agency (EMA) handled a request for public access to documents containing information on clinical study data for the Comirnaty Covid-19 vaccine

Decision
Case 1450/2022/NK - **Opened on** 15/09/2022 - **Decision on** 15/09/2022 - **Institution concerned** European Medicines Agency (No maladministration found) |

Dear Ms X,

You recently submitted a complaint to the European Ombudsman against the European Medicines Agency (EMA) concerning its decision on your request for public access to documents. [1] You asked for documents containing individual participant data of study C4591015 for the Comirnaty Covid-19 vaccine . You are concerned that EMA has failed to identify the documents to which you are seeking public access.

After a careful analysis of all the information you provided with your complaint and subsequent correspondence, we have decided to close the inquiry with the following conclusion:

There is no evidence to indicate that there was any maladministration by the European Medicines Agency. [2]

EMA informed you that it is not in possession of documents containing individual patient data from participants in study C4591015. Furthermore, EMA explained to you that no individual patient data from participants of study C4591015 has been submitted by the manufacturer to the Agency yet. According to EMA, the submission of the final clinical study report in which individual patient data is expected to be presented is currently planned for 30 April 2023.

The right of public access to documents applies only to documents in the possession of an institution. [3] According to EU case-law [4] , where an institution says that it does not hold documents requested under Regulation 1049/2001, it must be presumed that this is true, unless the applicant puts forward evidence that unequivocally calls this into question.

We note that, according to the assessment report of the Comirnaty COVID-19 mRNA vaccine,

the study in question is still ongoing and the final clinical study report must be submitted by 30 April 2023. [5] We therefore consider that EMA's reply - that no individual patient data from participants of study C4591015 have been submitted by the company to the Agency yet and that the submission of the final clinical study report where individual patient data are expected to be present is currently planned for 30 April 2023 - is plausible.

You argued that the Risk Management Plan for the vaccine was updated in February 2022 and that it shows that there was a change in the scope of the trial, as less participants were enrolled than initially announced. However, these arguments are not sufficient to demonstrate that EMA held, at the time of your request, any documents containing patient data from participants to study C4591015.

In light of the above, the Ombudsman considers EMA's position in its decision on your request for access to documents to be reasonable. We have therefore closed the case. [6]

We appreciate this may not be your desired outcome but we hope you find these explanations useful. Thank you for having contacted the European Ombudsman.

Yours sincerely,

Rosita Hickey Director of Inquiries

Strasbourg, 15/09/2022

[1] Under Regulation 1049/2001 regarding public access to European Parliament, Council and Commission documents: https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32001R1049 .

[2] Full information on the procedure and rights pertaining to complaints can be found at https://www.ombudsman.europa.eu/en/document/70707 .

[3] In accordance with Article 2(3) of Regulation 1049/2001.

[4] See, for example, judgment of the General Court of 11 June 2015, McCullough v Cedefop, T-496/13: https://curia.europa.eu/juris/document/document.jsf?text=&docid=164964&pageIndex=0&doclang=EN&

[5] Assessment report on extension of marketing authorisation of 25 November 2021 (EMA/719541/2021), title 2.7.2: https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-x-0077-epar-assessmer .

[6] This complaint has been dealt with under delegated case handling, in accordance with the Decision of the European Ombudsman adopting Implementing Provisions.