

## Decision in case 2169/2020/LM on how the European Medicines Agency (EMA) evaluated a tender for carrying out a study on the safety of SARS-CoV-2 vaccines

Decision

**Case 2169/2020/LM - Opened on 15/01/2021 - Decision on 15/01/2021 - Institution concerned** European Medicines Agency ( No maladministration found ) |

Dear Professor,

On 18 December 2020, you submitted a complaint to the European Ombudsman against the European Medicines Agency (EMA). You argue that EMA has misunderstood essential aspects of your tender and that the original evaluation committee should have dealt with your complaint against the evaluation of your tender. You contend that appointing a new evaluation committee was detrimental to the evaluation because the new committee might not have received one or more documents and it might not have been made aware of the observations you submitted in your complaint against the first evaluation.

After a careful analysis of all the information you provided with your complaint, we regret to inform you that **the Ombudsman finds no maladministration by EMA** .

It is not the role of the Ombudsman to re-evaluate the tender that you submitted to EMA. The Ombudsman would question the substantive assessment of a tender only in case of an indication of a manifest error of assessment.

EMA has provided you with a comprehensive reply as to why your tender was not selected and we find no indication of a manifest error of assessment in that regard. Given, in particular, that two different evaluation committees came to very similar conclusions on your tender, there is nothing to indicate a manifest misunderstanding of your tender.

There is no indication of procedural errors or any evidence that the rules governing the procedure have been violated. Nor there is reason to assume that the new committee did not receive the full documentation.

According to the applicable rules, the tendering institution may suspend the signature of the contract to carry out additional examinations, if this is justified by the requests or comments



made by unsuccessful or aggrieved tenderers [1] . Based on the comments you made on the first evaluation, EMA decided to carry out such additional examinations. The role of these examinations is to make sure that the evaluation committee has not made any factual error in evaluating the tenders. The method for re-evaluation chosen by EMA - having all the tenders re-evaluated by a new evaluation committee - guarantees complete impartiality of the evaluation process and is in accordance with the applicable rules.

An evaluation committee can base its decision on the information provided with the tender only. To take into account the clarifications or additional information provided by a tenderer risks constituting unequal treatment of tenderers, as this would entail a modification of the original tender.

Based on the above, the Ombudsman has closed the case. [2]

We understand that you may be disappointed by this decision, but we hope that the above explanations are nevertheless helpful.

Yours sincerely,

Tina Nilsson Head of the Case-handling Unit

Strasbourg, 15/01/2021

[1] See point 35, Annex I to the Financial Regulation, available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1046> [Link]

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