Letter from the European Ombudsman to the European Medicines Agency closing of the Ombudsman's Strategic Initiative SI/5/2020/DDJ

Correspondence - 08/03/2021
Case SI/5/2020/DDJ - **Opened on** 29/07/2020 - **Decision on** 08/03/2021 - **Institution concerned** European Medicines Agency |

Ms Emer Cooke

Executive Director

European Medicines Agency

Strasbourg, 08/03/2021

Subject: Closing of the Ombudsman's Strategic Initiative SI/5/2020/DDJ

Dear Ms Cooke,

In this unprecedented public health crisis, the European Medicines Agency (EMA) continues to play a leading role. Your agency has quickly and effectively adapted its working methods to meet the challenges it is facing.

I am grateful for the reply I received from your predecessor on 30 September 2020 to my strategic initiative regarding the transparency and independence of EMA's work in supporting the development and evaluation of COVID-19 medicines (SI/5/2020/DDJ).

The reply confirmed that EMA is determined to safeguard the independence of its evaluation of medicines and that this applies to the work of the COVID-19 Pandemic Task Force (COVID-ETF). The letter also set out the transparency measures put in place by EMA.

I note that EMA organised stakeholder meetings ahead of the approval of the first COVID-19 vaccines to inform the public and answer questions from concerned individuals and organisations. EMA also put in place additional transparency measures regarding its regulatory activities on treatments and vaccines for COVID-19.

EMA has published the European Public Assessment Reports (EPARs) of approved COVID-19 medicines in a timely manner, including a description of the involvement and activities of the COVID-ETF and other relevant information regarding the pre-submission and evaluation phases.

Public trust, as we discussed and agreed on when we met some time ago, is of the utmost importance in addressing the challenges that the COVID-19 crisis has presented, and I commend EMA for having upheld high transparency standards in relation to the development and authorisation of COVID-19 medicines.

I hereby close this strategic initiative and thank you for EMA's continued commitment to these important matters.

Yours sincerely,

Emily O'Reilly European Ombudsman