European Ombudsman

Emily O'Reilly
European Ombudsman

Professor Guido Rasi
Executive Director
European Medicines Agency

Strasbourg, 29/07/2020

Subject: Transparency and independence of the work of the European Medicines Agency in supporting the development and evaluation of COVID-19 medicines

Dear Professor Rasi,

We are experiencing a global health emergency of proportions that we have not seen for generations. I am conscious of the efforts being made by the European Medicines Agency (EMA) to conduct its evaluation work as quickly as possible, without compromising the quality of the safety and efficacy assessment. You confirmed your commitment to this mission before the European Parliament recently.[1] In the context of the work my Office is conducting on the response of the EU administration during the COVID-19 crisis, I am writing to you with this request for information.

Among the measures taken by EMA to respond to the COVID-19 pandemic is the establishment of the COVID-19 EMA pandemic Task Force (COVID-ETF)[2]. The role of the COVID-ETF is to help EU Member States and the European Commission to take quick and coordinated regulatory action on the development, authorisation and safety monitoring of medicines intended for the treatment and prevention of COVID-19. The COVID-ETF will assist COVID-19 medicine developers by providing guidance and advice.[3] Such interactions can be of vital importance for the speedy development of safe and effective vaccines and treatments.

However, it is important to ensure that an appropriate balance is struck between providing the best possible advice and assistance, while guaranteeing the independence of any subsequent evaluations. I understand that the COVID-

[1] Speech of 12 May 2020 in the European Parliament's committee on environment, public health and food safety (ENVI): https://www.europarl.europa.eu/committees/en/product/product-details/20200506CAN55006.
[2] Press release: https://www.ema.europa.eu/en/news/ema-establishes-task-force-take-quick-coordinated-regulatory-action-related-covid-19-medicines.
[3] Activities of the COVID-ETF include, among others: i) providing guidance on development plans of COVID-19 medicines when formal scientific advice is not yet feasible; ii) the review and requesting of data from developers and engaging with them in preliminary discussions; iii) contributing to scientific advice procedures as advisor to SAWP/CHMP, including on a rolling basis; and iv) providing feedback on development plans of COVID-19 medicines when formal rapid scientific advice is not feasible.

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ETF's membership includes the experts that draft EMA's evaluation report for COVID-19 medicines (the 'rapporteurs and co-rapporteurs')[4].

My Office has worked with EMA in recent years to improve the transparency and independence of its actions. I have no doubt that every effort is being made to apply the improved standards that have resulted from that work to EMA's current efforts to tackle the COVID-19 pandemic. With this in mind, I would be grateful if EMA could confirm that it intends to:

1. apply the principles agreed in the context of my inquiry into EMA's pre-submission activities[5] (OI/7/2017/KR) as regards the work of the COVID-ETF;
2. ensure transparency of its COVID-19 related activities, including the possibility of rapidly publishing clinical data for the products in question.[6]

I would be grateful if you could reply by the **end of September 2020**, if possible. Any question in the meantime may be sent to Mr Diesmer de Jonge, who can be reached on +32 (0) 22 83 07 84, and at diesmer.dejonge@ombudsman.europa.eu.

Thank you for your continued engagement on these matters. I wish EMA every success in these challenging times.

Yours sincerely,

Emily O'Reilly
European Ombudsman

[4] COVID-ETF rules and procedures: https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-covid-19-ema-pandemic-task-force-covid-etf_en.pdf.
[5] The European Ombudsman's inquiry into how EMA engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the EU (OI/7/2017/KR), see: https://www.ombudsman.europa.eu/en/decision/en/116683. This inquiry emphasised the need to ensure that the experts that have a prominent role in advising medicine developers in so-called pre-submission activities are not the same experts that are subsequently prominently involved in evaluating the safety and efficacy for the same medicine.
[6] See: https://www.ombudsman.europa.eu/en/letter/en/57622.