EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mrs Emily O'Reilly
European Ombudsman
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30 September 2020
EMA/516771/2020
European Medicines Agency

Dear Ms O'Reilly,

**Subject: Reply to the European Ombudsman's letter concerning transparency and independence of the work of the European Medicines Agency in supporting the development and evaluation of COVID-19 medicines**

Thank you for your letter of 29 July 2020 in which you asked about transparency and the independence of EMA's activities in relation to the COVID-19 pandemic.

Since the start of this unprecedented global public health crisis, EMA has been working with EU national competent authorities (NCAs) and the European Commission to harness expertise from across the EU to aid the development and evaluation of COVID-19 medicines. As you rightly point out, EMA has been taking measures so it can conduct evaluations of COVID-19 medicines as rapidly and efficiently as possible while maintaining high standards of safety, efficacy and quality. As of today, EMA has recommended the authorisation of one medicine, Veklury (remdesivir), for COVID-19 and has also endorsed the use of dexamethasone medicines.

EMA's COVID-19 Pandemic Task Force (COVID-ETF) has played a crucial role in coordinating EMA's pandemic activities, including facilitating discussions with developer about medicines still under development.

As we deal with this crisis, EMA and the rest of the European regulatory network are fully committed to upholding not only the scientific rigour of our regulatory processes, but also our long-standing commitment to the principles of openness, transparency and independence. I welcome your questions about these matters, particularly as we have worked cooperatively to strengthen them over the past few years. Please see my responses below:

1) **Will EMA apply principles agreed in the context of the European Ombudsman's inquiry into EMA's pre-submission activities (OI/7/2017/KR) as regards the work of the COVID-ETF**

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Your enquiry into EMA's pre-submission activities concluded that EMA should, to the greatest extent possible, ensure that there is a separation between those responsible for providing scientific advice to a medicine developer and those subsequently involved in evaluating a marketing authorisation application for the same medicine. To this end, we have introduced measures to ensure a separation of these roles where possible.

These measures apply equally to COVID-19 medicines, as mechanism for providing scientific advice and for evaluating an application for marketing authorisation is the same as for other medicines.

EMA established COVID-ETF to help the European regulatory network take quick and coordinated actions in the wake of the COVID-19 pandemic. Its activities include providing guidance on development plans of COVID-19 medicines when formal scientific advice is not yet feasible; reviewing and requesting data from developers and engaging with them in preliminary discussions; and contributing to scientific advice procedures as an advisor to the Scientific Advice Working Party(SAWP)/Committee for Medicinal Products for Human Use (CHMP).

In accordance with its mandate, no member of the COVID-ETF exercises a leading or prominent role in the pre-submission phase. The COVID-ETF works in collegial manner with shared responsibilities, while the prominent roles are reserved for the Coordinators in the SAWP and the CHMP Rapporteurs.

You also recommended in your previous enquiry that EMA should attach to the European Public Assessment Report (EPAR) a detailed log of all relevant pre-submission activities, including the names of the experts involved. I can confirm that such logs will be provided for COVID-19 medicines in the same way as for other medicines. If EMA had provided scientific advice for a COVID-19 medicine, we will apply the same level of transparency with regard to the coordinators and the scope of the advice. We will also take the opportunity of your current query to consider how to best include information in the EPAR about any involvement of the COVID-ETF in the pre-submission phase.

Finally, in line with our commitment to openness and engagement with civil society, EMA has now appointed two representatives and two alternates to represent patients and healthcare professionals. These new members are expected to start joining COVID-ETF meetings in the first week of October and they will bring a unique perspective to the discussions.

**2) Will EMA ensure transparency of its COVID-19 related activities, including the possibility of rapidly publishing clinical data for the products in question.**

Transparency and the provision of timely information about medicines, including clinical data, is more relevant than ever in the present circumstances. In addition to meeting an unprecedented public demand for information, transparency in relation to COVID-19 medicines will support global research and allow for public scrutiny.

EMA is therefore implementing exceptional measures with regard to medicines for COVID-19, speeding up standard publication timelines and providing more information than is usually the case. These measures include:

a) Publication of the product information with details of the conditions of use at the time of the CHMP's positive opinion on the marketing authorisation application.

b) Expedited publication of the full EPAR, within 3 days of authorisation by the European Commission.

c) Publication of clinical data submitted to EMA in support of the applications for COVID-19 medicines after the authorisation of a medicine and once personal data have been anonymised

and any commercially confidential information redacted. The first set of clinical data that EMA will publish for a COVID-19 medicine will be those of remdesivir. We expect to publish the data in the coming weeks. (EMA suspended publication of trial data in August 2018 in the context of EMA's Brexit Preparedness Business Continuity Plan but announced in June 2020 that it will restart this activity for COVID-19 medicines as a priority.)

d) Publication of the full risk management plan (excluding annexes) for authorised COVID-19 medicines. (EMA usually only publishes a summary.)

e) Publication of news announcements within 1 day of the start of initial rolling reviews or the evaluation of new or extension of indication applications for COVID-19.

More information about these measures is available in a dedicated COVID-19 section on EMA's website. In addition, the EU clinical trials register provides publicly available summary information on clinical trials conducted in the EU (and paediatric trials conducted outside the EU that are part of paediatric investigation plans). This is the publicly accessible part of the EU clinical trials database (EudraCT).

I trust this letter reassures you of the continued scientific rigour and independence of our regulatory processes as well as our commitment to transparency, openness and data sharing, particularly in relation to COVID-19, where public trust will be of utmost importance for controlling the pandemic and saving lives.

Yours sincerely

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Guido Rasi
Executive Director