EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

IQWIG
Im Mediapark 8
50670 Köln
Germany

28 May 2020
EMA/280976/2020
Executive Director

Dear Dr Wieseler, Dr Kaiser, Prof Dr Boutron, Prof Dr Devane, Prof Dr Gartlehner, Prof Dr Meerpohl and Prof Dr Ravaud,

Thank you for your letter of 14 May 2020 in support of our activities to increase transparency of medicines development and regulation.

I concur with you that we face an unprecedented global challenge with this pandemic and that scientists, researchers, pharmaceutical companies and regulators all have an important role to play. Close collaboration is essential to mitigate the devastating effects of the disease on our society. By pooling our efforts and resources we can more effectively advance science and bring to patients and citizens around the world much needed safe and effective therapies.

I can assure you that the European Medicines Agency and the EU Regulatory Network as a whole is fully committed to support and facilitate the development of new medicines for COVID-19. We will use every opportunity to gain efficiencies and speed up our evaluation procedures whilst ensuring that our high standards on quality, safety and efficacy continue to apply.

I also agree with you that transparency and timely information on COVID-19 related activities is more relevant than ever for the public in the present circumstances. As you note, the Agency was a pioneer in this area and has brought unprecedented levels of transparency to medicine development and regulation by making public the clinical data underpinning EMA's recommendations soon after the medicines' authorisation in the EU.

Our activities in relation to COVID-19 deserve the highest possible level of transparency and, in keeping with our commitment, the Agency will take appropriate action to share information publicly. We are currently discussing how to enhance the level of transparency for COVID-19 procedures, including the possibility of rapidly publishing clinical data for these products. The need for rapid evaluation during the current emergency will require us to depart from our usual procedures. In some cases, we will be evaluating evidence as it emerges (i.e. 'rolling review') and putting information in the public domain in these circumstances will be subject to additional challenges which we are currently looking to address.

As you may be aware, the Agency had to deal with the direct consequences of Brexit and the move from London to Amsterdam in recent years, involving a huge impact on staffing and other services.

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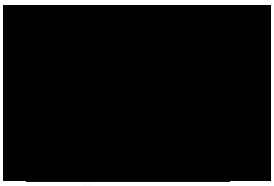
Inevitably, this disruption required the Agency to shift all its focus to core activities that are essential for public health. Regrettably, our efforts to publish clinical data had to be put on hold in these very trying circumstances.

In view of this and the extra effort needed to deal with COVID-19 related activities, I can't yet commit to reinitiate all activities related to clinical data publishing for medicines evaluated by the Agency. However, as stated above, COVID-19 related medicines deserve special consideration because of the overriding public interest and the need to support the international research community and foster the collaborative effort. Further information on the concrete proposals to increase transparency of COVID-19 related activities will be communicated once agreed within EMA and the EU Regulatory Network.

I hope this reassures you of our commitment to transparency, along the lines expressed in your letter and provides you with some insight on how we plan to apply this to our activities in response to this unprecedented global challenge.

Yours sincerely,



Guido Rasi
Executive Director