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EMA should support the international research community by publishing Clinical Study Reports on medicine and vaccine trials at the time of marketing authorisation

Dear Professor Rasi,

The current 2019 coronavirus disease (COVID-19) pandemic is the greatest health care and economic crisis Europe and many other parts of the world have faced in several decades. As a result, unprecedented research efforts are underway to develop or identify effective medicines and vaccines. Researchers from all over the world have joined forces to identify or develop, test and evaluate medicines and vaccines to fight the pandemic.

Regulatory agencies will have a crucial role in deciding which of these medicines and vaccines will be made available to patients and the public. To support the regulatory decision-making process, regulatory policies require submission of detailed and well-organised evidence packages in the form of Clinical Study Reports (CSRs).

In recent years, the European Medicines Agency (EMA) has been a pioneer of data transparency among regulatory agencies. EMA's policies on access to documents and proactive publication of CSRs have made extensive clinical trial information publicly available. EMA has defended this transparency before the Court of Justice of the European Union. It is exactly this transparency that is currently needed.

Because of the severity of the current situation, regulators are aiming to accelerate the marketing authorisation process. First treatments have already been evaluated by regulators, as recently seen with the fast emergency use authorisation of the antiviral remdesivir by the US Food and Drug Administration (FDA). EMA has also started a "rolling review" of remdesivir. This acceleration effort is understandable and to be welcomed in this exceptional situation. To achieve sustainable effects in health care, this effort must also include the publication of CSRs to make the full information on any new medicine or vaccine publicly available as soon as possible.

We therefore call for the publication of all CSRs on all COVID-19 medicines and vaccines on the day of marketing authorisation.

The international research community is undertaking coordinated efforts (e.g. the Living mapping and living systematic review of Covid-19 studies) to compile all emerging information on COVID-19 medicines and vaccines to ensure the optimal planning and conduct of research

and to inform treatment decisions. To assess these products further and to accelerate the development of additional products, the fast and full public availability of the information submitted to regulators is of utmost importance. Transparency is also vital to maintain public trust during the crisis. With its established processes, EMA is in a unique position to make a difference in the worldwide fight against the pandemic.

Yours sincerely,

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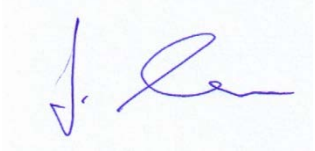

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