EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
The Director

Luxembourg
SANTE.DDG1.C.3/VP/tm (2020)5459002

Dear Petitioners,

Thank you for your letter to President von der Leyen and European Commissioner for Health and Food Safety Stella Kyriakides of 1 September 2020, regarding your search for information and "scientific explanation to the concentration of lethality differences due to the virus in the different countries and areas of Europe". We have taken note of your letter even though the European Commission is not a scientific body per se.

The European Commission is coordinating a common European response to the coronavirus outbreak. We are taking resolute action to reinforce our public health sectors and mitigate the socio-economic impact in the European Union. We are mobilising all means at our disposal to help our Member States coordinate their national responses and are providing objective information about the spread of the virus and effective efforts to contain it.

The COVID-19 pandemic is an unprecedented challenge, with far-reaching impacts not only on public health but also on our daily lives, social and economic well-being. The Commission continues to work closely with the EU Member States, together with the European Centre for Disease Prevention and Control (ECDC), to provide coordination, guidance and support. However, public health matters, notably the responsibility for the organisation of and the delivery of healthcare services, are the competence of EU Member States and it is Member States authorities that decide on the specific measures based on each country's epidemiological and social situation. Member States' public health authorities are also responsible for the continued surveillance and reporting of cases, including deaths.

Regarding your specific question on lethality (mortality), please see below a non-exhaustive analysis provided by the European Centre for Disease Prevention and Control.

> The COVID-19 mortality reported by EU/EEA Member States and the UK has varied significantly throughout the pandemic. Data from the European Mortality Monitoring system[1] shows the significant excess mortality disproportionately observed in some countries. There are multiple reasons for these differences:

[1] www.EUROMOMO.eu

Evolution of the pandemic and implementation of public health measures: countries were affected by the pandemic at different points in time. This meant that some countries were able to implement public health measures (such as lockdowns) early on, leading to lower transmission and fewer deaths in the spring, compared to countries, which were affected early on.

Testing capacities: Testing capacities have evolved over time, with large increases in testing rates observed in many countries particularly over the summer period. More widespread testing allows for appropriate isolation of cases and quarantine of contacts and is a key part of control of the pandemic. This may lead to reduced transmission and therefore fewer deaths.

In addition, when testing was limited in the first months, the focus was on patients with severe symptoms. This meant that the case fatality rate during the first months was high. As testing was expanded to patients with milder symptoms, and more recently even to asymptomatic persons in some settings, the number of deaths as a proportion of the number of persons testing positive decreased, leading to a lower case-fatality rate. These differences can also be observed across countries, with those countries having higher testing rates reporting lower case fatality rates. See the ECDC surveillance report for more details for example on the crude case fatality rates for hospitalised cases[2].

Definitions: During the first months of the pandemic, there were also differences in how countries classify and count deaths. For example, some countries counted deaths among probable cases (such as those deaths occurring among persons who are not tested but who have an epidemiological link to confirmed cases for example in a nursing home) and others counted deaths occurring within a specified number of days following diagnosis. There were also differences on whether countries counted cases occurring in the community as opposed to those happening in hospitals. These differences affected the reporting of deaths and overall case fatality rates. WHO introduced guidance on reporting of deaths on 20 April 2020, which ECDC endorsed[3]. Further data on reporting of deaths due to COVID across countries are available on our website[4].

Further to the above, it is not clear from your letter what assumptions you make to conclude that "this knowledge [on differences in mortality] is essential to determine if an *ad hoc* vaccine, with all the related risks, is really necessary…". It is not clear what you mean by an "*ad hoc* vaccine". An effective and safe vaccine against the virus is a strong tool to achieve a lasting solution to the pandemic. To help protect people everywhere, the European Commission presented a European strategy to accelerate the development, manufacturing and deployment of vaccines against COVID-19, you can find more here[5].

[2] https://covid19-surveillance-report.ecdc.europa.eu/#2_severity
[3] https://www.ecdc.europa.eu/en/covid-19/surveillance/surveillance-definitions
[4] https://covid19-surveillance-report.ecdc.europa.eu/#6_surveillance_system_description
[5] https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response/public-health/coronavirus-vaccines-strategy_en

The European Commission works closely with Member States and the European Medicines Agency (EMA) to facilitate the development and potentially the authorisation of COVID-19 treatments and vaccines. However, we would like to stress, that in accordance with the pharmaceutical legislation, a medicinal product, including a vaccine, will be authorised in the EU only if the quality, safety and efficacy data will allow for a positive conclusion on the benefit-risk related to its use. EMA has been in discussion with the developers of 38 potential COVID-19 vaccines and 158 potential COVID-19 treatments. The Agency published a public health advice on the use of chloroquine and hydroxychloroquine during the COVID-19 pandemic[6]. More information on EMA's COVID-19 work can be found on the Agency's web site[7].

Regarding your second point, on the need to establish a "common therapeutic protocol based on clinical experience written by a medical committee", the European Commission supports this proposal. I would recommend close cooperation with the relevant European Federation of Internal Medicine and Standing Committee for European Doctors as well as health authorities who have already published guidance[8]**.** It is certainly beneficial to harmonize the medical practices for treating the patients affected by the COVID-19 based on the experience acquired so far. The European Commission does not have the expertise and the competence to establish this protocol but we would be available to distribute the information to the relevant networks.

On the other hand, the European Commission is responsible to authorise medicinal products used to treat COVID-19 patients based on a scientific evaluation carried out by the European Medicines Agency. To date, the European Commission granted a conditional marketing authorisation for the remdesivir containing medicine Veklury for the treatment of COVID-19 in adults and adolescents from 12 years of age with pneumonia who require supplemental oxygen. Recently the EMA endorsed the use of dexamethasone in COVID-19 patients on oxygen or mechanical ventilation[9]. I would like to reassure you that the primary role of EMA is to promote human health in Europe. I can confirm that the European Medicines Agency has to ensure that its scientific experts do not have any financial or other interests that could affect their impartiality.

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[6] https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/public-health-advice-during-covid-19-pandemic#use-of-chloroquine-and-hydroxychloroquine-medicines-section

[7] https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19

8 Sciensano (Belgium) COVID 19 protocol. https://covid-19.sciensano.be/sites/default/files/Covid19/COVID-19_InterimGuidelines_Treatment_ENG.pdf
National Institutes of Health (US): https://www.covid19treatmentguidelines.nih.gov/whats-new/
NICE (UK): https://www.nice.org.uk/guidance/NG179
WHO Clinical Guideline on COVID https://www.who.int/publications/i/item/clinical-management-of-covid-19

[9] https://www.ema.europa.eu/en/news/ema-endorses-use-dexamethasone-covid-19-patients-oxygen-mechanical-ventilation

We would like to assure you that we are fully committed to taking all steps to protect the health of our citizens. You can find further information on the activities of the European Commission regarding the COVID-19 response on our corporate website[10].

Yours faithfully,

John-F RYAN

[10] https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response_en