Professor Guido Rasi
Executive Director
European Medicines Agency

&

Mrs Emer Cooke
Designated Executive Director
European Medicines Agency

Brussels, 29th October 2020

Dear Mrs Cooke, dear Professor Rasi,

EURORDIS-Rare Diseases Europe and the European Patients' Forum (EPF) would like to invite the EMA to organise one major or several multi-stakeholder meetings open to the public on vaccines to prevent SARS-CoV-2 infection.

On the EMA 25th anniversary, Mrs Cooke, as designated Executive Director, you said "*EMA's role in the pandemic response is key - evaluating COVID-19 vaccines and therapeutics. More than ever we require multi-stakeholder approach and strong coordination and collaboration from all parties involved. Information sharing, transparency and communication are essential to gain efficiency and importantly to maintain public trust and confidence*".

We fully agree. We believe that pro-active vaccine communication and campaigns are crucial to help reduce the impact of the pandemic on population segments more at risk of infection, due to age, certain professional exposure, socio-professional or economic status, and on people affected by health conditions which increase their risk of a severe form of COVID-19. When one or several vaccines are eventually approved and rolled out, lack of trust from the public and healthcare professionals is a major risk; numerous surveys point strongly to this concern. New scientific techniques, accelerated timelines, and high media attention are all potent ingredients for controversy and resistance.

EURORDIS and EPF feel that the EMA, as the European scientific authority responsible for the evaluation and the surveillance of these vaccines, is best placed to organise such a multi-stakeholder meeting(s) open to the public.

The EMA can play a crucial role in helping build the trust of professionals and the public at large on the future SARS-CoV2 vaccines. We are all aware that high numbers of EU citizens are concerned by vaccines in general, and together with the ECDC, the EMA is promoting actions to inform the public on how vaccines are developed and evaluated. This was debated extensively at a dedicated joint meeting with the Patients' and Consumers' Working party, and the Healthcare Professionals' Working Party in October 2019. And we are looking forward to the PCWP/HCPWP meeting on 16 November dedicated to a COVID-19 pandemic update.

In this context, the scientific and technological challenges in the development of effective, safe and high-quality vaccines against SARS-CoV-2, and solutions to address these, should be openly discussed with the General Public. As responsible organisations, all stakeholders recognise the importance of excellent communications from the onset. There are few windows of opportunity to set the right tone and build knowledge and awareness that will create trust and confidence and pave the way for campaigns at national level.

Building on the successes of previous and numerous multi- stakeholder meetings and workshops led by the Agency in recent years (not to mention EMA's Public Hearings held in the context of PRAC) EURORDIS and EPF believe that such an event (or events) will play a vital role in shaping public opinion.

An issue to be discussed in this context is the development of a world class pharmacovigilance system to aggregate and analyse real world data, reported directly by people experiencing adverse events. The Web-RADR mobile application to report suspected side-effects, now promoted by WHO and implemented in several countries in the world, could support this. EURORDIS, as a partner in Web-RADR, funded by IMI, would be pleased to explore this further with EMA.

Large trials are recruiting significant numbers of patients, up to 30,000 for some, but this will not provide the information for all patients. In particular, people who match phase III trials exclusion criteria will not necessarily have the information on efficacy/safety when they will receive a vaccine. Special pharmacovigilance measures are needed to collect data from their experience. This is particularly true for people living with a rare disease or other chronic diseases, as there will not be information available to enable them or their healthcare professionals to take critical decisions. In order to address this gap, post-authorisation measures will be needed, as vaccines cannot be delayed whilst additional studies are undertaken in specific population cohorts.

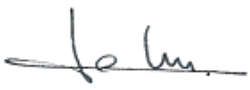
We also need to explore patient rights linked to adverse events. EPF and EURORDIS are advocating for a fair, transparent European approach to compensation, that avoids lengthy delays, and complex, cumbersome and gruelling processes at national level.

The organisation of a public meeting (or meetings) reflects EMA's mission to foster scientific excellence in the evaluation and supervision of these vaccines and the EMA would become the first regulatory agency in the world to engage with all its stakeholders in a public, transparent, scientific and high-quality debate.

EURORDIS and EPF understand the challenges in organising such a (virtual) meeting, in terms of logistics and preparation; however, we trust that there is sufficient time to do this well, if a decision is made rapidly. EURORDIS and EPF are ready to support the mobilisation of patient organisations to participate.

We look forward to an opportunity to discuss with you and your colleagues in the near future.

With our best personal regards,



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