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EMA speaking points for update on COVID-19 vaccines

Informal videoconference of the Ministers of Health, 2 December 2020, 10.00-12.30

[allocated time: ~5 minutes - current text: 733 words]

Dear Chair,

Honourable ministers,

My thanks to Minister Spahn for giving EMA the opportunity to participate again in your Council meeting, and it is a pleasure and honour for me to (virtually) meet you all since I took over from my predecessor Guido Rasi 2 weeks ago. I was invited today to update you on the status of the scientific evaluation of COVID-19 vaccines.

Yesterday we came a step closer to the authorisation of COVID-19 vaccines. Two developers – i.e. Pfizer/BioNtech and Moderna - have submitted to the EMA their marketing authorisation applications for two mRNA vaccines, the first authorisation applications for COVID-19 vaccines received by the Agency so far. These applications are the result of many months of work and dialogue with these developers, during which EMA's Pandemic Task Force, together with EMA's scientific committees gave scientific advice on the development programmes. Over the last months, EMA has already started to evaluate data in a 'rolling review', a practice whereby data is reviewed on an iterative basis as they become available while development is still ongoing.

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This rolling review allows us to expedite the final scientific assessments as a large amount of data has already been reviewed before a formal marketing authorisation application is submitted.

EMA will now assess all the additional data submitted yesterday as part of the application for marketing applications and, depending on whether they are sufficiently robust and complete, an EMA opinion for their marketing authorisation in the EU could be issued within weeks. With regard to the mRNA vaccine developed by BioNTech and Pfizer, our scientific committee for human medicines (CHMP) plans to conclude its assessment during an extraordinary meeting scheduled for **29 December** at the latest. As regards the Moderna Covid-19 vaccine, EMA's CHMP currently plans to conclude its assessment during an extraordinary meeting scheduled for **12 January 2021** at the latest. However these timelines may be subject to change as evaluation proceeds.

Also yesterday we have announced the start of a rolling review for the adenovirus vector-based vaccine for COVID-19 developed by Janssen Vaccines. This is the fourth EMA's rolling review on COVID-19 vaccines, after the ones for the AstraZeneca/Oxford University candidate which started on 1 October and the ones I have already referred to for Pfizer/BioNTech and Moderna.

Since the COVID-19 vaccines currently under evaluation will be given to millions of people in the EU we are keenly aware of the huge responsibility we have to get our assessments and our recommendations right to protect the European population. I would therefore like to assure you that our scientific assessment will be fully independent and our recommendations will be based on the strength of the scientific evidence on a vaccine's safety, quality and efficacy, and nothing else. Authorisation will be granted only when the evidence convincingly shows that the benefits of vaccination are greater than any risks of the vaccine. We are in close scientific collaboration with our international colleagues, including the US FDA and we note the decision of the UK authorities to temporarily authorise specific batches of the Pfizer/BioNTech vaccine.

We understand there are many concerns by citizens and we need to understand and find ways to address them. To this end we are organising a public meeting on 11 December to inform European

citizens about the EU regulatory processes for the approval of COVID-19 vaccines and to listen to the concerns and questions from the public.

We have also committed to extra transparency on the evaluation of COVID-19 treatments and vaccines and, we will be publishing the full public assessment report within 3 days of European Commission decision and the full clinical trials results underpinning the marketing authorisation as soon as possible following the Commission decision after redaction of commercially confidential and personal data.

Following the first authorisations, safety and effectiveness monitoring by the companies but also by EMA, ECDC and national authorities will be critically important. We will use all the tools we have available to monitor the safety of these vaccines in as close to real-time as possible so that we can take swift action, if needed.

Finally, as you are preparing for vaccinations in your countries, please let us know how EMA can best support you. The only way to bring the pandemic under control is through our joint efforts, each from our own perspective, and we need to be as integrated as possible to save lives and to allow EU citizens and business go back to normal.

Thank you again for the invitation and I look forward to continuing working with you.