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From: 5.1.2e
Sent: Thur 11/12/2020 10:48:08 PM
Subject: RE: COVAX - consultation of Member States- ddl.16/11 at 12h00
Received: Thur 11/12/2020 10:49:32 PM

Dear 5.1.2e

Thank you for sharing.

SE supports your proposed position on governance and representation.

In addition, on vaccine candidates, we want to point out that some mRNA vaccine candidates seem to be stable under regular cold storage conditions, and that some producers (eg Pfizer/BioNTech) have developed transport solutions that should work for many COVAX countries. SE agrees that mRNA vaccines should be part of the portfolio, albeit with practical/planning challenges.

/ 5.1.2e

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Regeringskansliet

Från: [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>
Datum: torsdag 12 nov. 2020 6:39 em
Till: [redacted]@sozialministerium.at <[redacted]@sozialministerium.at>, [redacted]@gesundheitsministerium.gv.at
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<[redacted]@ec.europa.eu>, [redacted]@ec.europa.eu <[redacted]@ec.europa.eu>
Ämne: COVAX - consultation of Member States- ddl.16/11 at 12h00

Dear Member States representatives,

Thanks to all Member States that took part at the first meeting of the COVAX Shareholders Council on 2 November. As discussed in that meeting, participants are invited to comment on three issues:

1- **Opting in or out from three vaccine COVAX portfolio candidates: AstraZeneca, Sanofi/GSK and BionTech/Pfizer**

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2- **Nomination of co-chairs and participants in the Executive Committee under the COVAX Shareholders Council**

The Executive Committee, a sub-group of the Shareholders Council is set up with 12 participants, 3 per WHO region. The Shareholders Council invited each of the four WHO regions to nominate three participants. The EU represents the biggest part of the European region and is the largest donor to Covax. The Shareholders Council has also been invited to nominate two co-chairs.

EU proposed position:

a) Confirm the nomination of **Sir Andrew Witty (UK)** and **Mrs Ngozi Okonjo-Iweala (Nigeria)** as co-chairs of the Shareholders Council, position they are holding provisionally since the first meeting.
b) Nominate three European participants in the Executive Committee as follows: the EU Presidency (Germany), the **European Commission** and **Norway**.
c) To request **increasing the number** of the Executive Committee representatives **to four per region** plus a an extra participant to set an uneven number bringing the **total number to 17**. Should the Shareholders Council agree to increase by one participant per region, we propose a representative from the **Western Balkans** (Serbia has expressed interest).

3- **M-RNA vaccines in COVAX portfolio**

At the Shareholders Council meeting on 2 November, participants received information on cost, regulatory approval and logistical implications of m-RNA vaccines in the COVAX portfolio (so far BionTech/Pfizer and Moderna). Participants were invited to express support or reserves about m-RNA vaccines in COVAX portfolio. Background information in the e-mail below from Gavi.

EU proposed position

Being fully aware of the costs and logistical implications of m-RNA vaccines, the EU supports a diversified COVAX portfolio including different technologies, time availability and manufacturing capacity. In this context the EU supports continuous assessment of all safe, efficacious vaccines that receive regulatory approval based on sound scientific evidence. M-RNA vaccines should continue be assessed in the COVAX portfolio.

Member States are invited to comment on the proposed line to take in COVAX and send any comment **by Monday 16 November at noon** to the **EC Vaccines mailbox (cc** 5.1.2e **.**

Best,
EC Vaccines team

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From: 5.1.2e < 5.1.2e @gavi.org>
Sent: Thursday, November 12, 2020 12:01 PM
Subject: *** Board update November 2020

You will all have seen the exciting clinical results released by Pfizer/BioNTech earlier this week indicating a more than 90% efficacy of its COVID-19 vaccine based on the first interim efficacy analysis from its phase 3 study. Pfizer/BioNTech is the first vaccine manufacturer to release results from a phase 3 trial. This news from Pfizer has implications not only for the Pfizer vaccine, but for mRNA vaccines more broadly and the power of vaccines to end the pandemic. Importantly, this news also demonstrates that vaccine induced protection from SARS-CoV-2 is possible and that the pre-fusion spike protein used in most other vaccines under development is an appropriate antigen. Of course, many questions remain. This analysis was done with 94 confirmed cases of COVID-19 in trial participants; the trial will continue until they reach the 164 cases originally planned. This will give more detailed analyses including some critical subgroup analyses. The vaccine appears to be well tolerated. Safety data will continue to be accrued; a critical requirement for submission of an emergency use authorization will be accumulation of safety follow up data on half of the participants for a median of 2 months. This is expected to be available by the third week of November. Additionally, we have no data on duration of protection and on protection against different severity of disease.

This news has many asking when the vaccine may be available for use. Under the absolute best case scenario, the earliest we could expect first emergency regulatory approval for the Pfizer vaccine is mid to late December, with an aspiration of a very quick PQ/EUL to follow—but this will be dependent of rolling submissions to the regulatory agencies being shared with WHO—and with authorization for use in LMICs at the end of January or early February of 2021. We are expecting interim results from Moderna, another mRNA vaccine, as soon as the end of this month, and from AstraZeneca potentially in December. This puts Pfizer potentially slightly ahead of the other vaccines, subject to regulatory approval. We also do not know how efficacious these other vaccines (as well as the Pfizer vaccine) will prove to be especially in different age/risk categories.

We had our first Shareholder's Council meeting last Monday and our AMC Engagement Group meeting is scheduled for next week. For both, we had on the agenda a question about the demand for the mRNA vaccines given the logistical challenges and cost. The early positive data of Pfizer (and potentially mRNA vaccines more broadly) carries substantial implications for our delivery efforts. The Pfizer vaccine with a two-dose regimen requires ultra-cold chain capacity (storage of -60 to -80 degrees Celsius) which comes with a number of costs. The Alliance has some experience with this in a limited capacity with the rollout of the Merck Ebola vaccine, but no one has yet delivered an ultra-cold chain vaccine on a global scale. There is also going to be a very limited supply of the vaccine to start, likely focusing initial efforts on reaching healthcare workers. Equity is our driving force at Gavi – ensuring access to a safe and effective COVID-19 vaccine globally at the same time it is rolling out in HICs – and we are carefully working through the important trade-offs posed by the inclusion of the Pfizer vaccine or any vaccine in the COVAX portfolio. It is also important to note that this is the first time an mRNA would be approved for use in humans and so there are implications for increased pharmacovigilance and monitoring. We are in ongoing discussions with Pfizer/BioNTech which has expressed interest in supplying the COVAX Facility.

Also, yesterday Russia announced 92% efficacy of its Sputnik V vaccine. We are watching this closely, especially given the very small numbers of cases in the analysis and have reached out for more details on the clinical data which will be analysed by the IPG, WHO and CEPI teams.

This is an exciting time as the vaccine trial results begin to roll in and we here at Gavi, in close collaboration with our COVAX partners, CEPI and WHO, are continuing to monitor the space very closely. As always, I would be happy to answer any of your questions.

Best,

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