

Minutes: Steering Board meeting 22 January 2021

1. Update from AstraZeneca on the delivery schedule

AZ stated that they **expected an opinion by EMA next week.**

AZ went on to present the **updated delivery schedule**. Compared to the schedule presented in December, AZ is committing to the same number of doses, with one-month delay. AZ is working on options on how to further increase the numbers,

[REDACTED]

- [REDACTED]
- [REDACTED]

The Commission and Member States expressed deep disappointment and serious concerns with the updated delivery schedule, significantly lower compared to the estimated delivery schedule from the Advance Purchase Agreement.

Commission and Member States expressed deep concerns that with current figures, [REDACTED]

The Members of the SB asked to understand the reasons of delay and decrease of delivery numbers.

The company explained it was experiencing significant issue with production of drug substance in one of the EU plant: [REDACTED] which affects the delivery schedule.

[REDACTED]

The Commission reminded the Company that the Advance Purchase Agreement foresaw [REDACTED]

Furthermore, the Commission and the Members of the SB asked:

- for precise delivery schedule for the first releases;
- to reduce the long timeline between approval and delivery;
- for a clear chronogram and from where the doses would be shipped;
- for a clear presentation of the schedule to allow a precise planning for rolling out;
- for an improvement in figures for March;
- deplored the lack of earlier notification from the company on the decreased volumes;
- [REDACTED]

- [REDACTED]
- for clear volumes numbers for the production for the next quarters;
- [REDACTED]

2. Update on the implementation of contracts and deliveries

AstraZeneca

Following the meeting with AZ the Members further discussed and expressed concerns regarding the delivery of AZ vaccines in Europe.

3. COVAX

Latest updates were provided on COVAX, noting that on the 22 January:

- COVAX announced the signing of an advance purchase agreement for up to 40 million doses of the Pfizer-BioNTech vaccine; rollout to commence with successful execution of supply agreements.
- Additionally, COVAX announced that, pending WHO emergency use listings, nearly 150 million doses of the AstraZeneca/Oxford candidate are anticipated to be available in Q1 2021, via existing agreements with the Serum Institute of India (SII) and AstraZeneca.
- COVAX is therefore on track to deliver at least 2 billion doses by the end of the year, including at least 1.3 billion doses to 92 lower income economies in the Gavi COVAX AMC.

3.1 Pfizer-BioNTech

COVAX, the global initiative to ensure rapid and equitable access to COVID-19 vaccines for all countries, regardless of income level, announced on 22 January the signing of an advance purchase agreement with Pfizer for up to 40 million doses of the **Pfizer-BioNTech** vaccine candidate, which has already received WHO emergency use listing. Rollout will commence with the successful negotiation and execution of supply agreements.

3.2 AstraZeneca

In further support of its mission to expedite early availability of vaccines to lower-income countries and help bring a rapid end to the acute stage of the COVID-19 pandemic, COVAX also confirmed on the 22 January that it would exercise an option – via an existing agreement with Serum Institute of India (SII) – to receive its first 100 million doses of the AstraZeneca/Oxford University-developed vaccine manufactured by SII.

Of these first 100 million doses, the majority are earmarked for delivery in the first quarter of the year, pending WHO Emergency Use Listing. The WHO review process, which is currently underway, follows approval for restricted use in emergency situations by the Drugs Controller General of India earlier this month, and is a critical aspect of ensuring that any vaccine procured through COVAX is fully quality assured for international use. According to the latest WHO update, a decision on this vaccine candidate is anticipated by the middle of February.

COVAX also anticipates that, via an existing agreement with AstraZeneca, at least 50 million further doses of the AstraZeneca/Oxford vaccine would be available for delivery to COVAX participants in Q1 2021, pending emergency use listing by WHO of the COVAX-specific manufacturing network for these doses. A decision on this candidate is also anticipated by WHO in February.

3.3 Update on COVAX and common approach for donations

Regarding donations, there are already well advanced discussions with Moldova, Ukraine and the Western Balkan countries to help them to be prepared to receive the vaccines.

4. Update on ongoing negotiations and on discussions with other companies

CureVac

The Commission explained that the Allocation table had been sent to CureVac on [REDACTED]. The Commission reminded Member States to send their Vaccine Order Forms [REDACTED].

Novavax

The contract is drafted and shared with Novavax. The contract will be discussed with the Evaluation Committee [REDACTED]. The process could go relatively fast.

Valneva

The tender process was launched, [REDACTED]. A process similar to Novavax has been applied.

Janssen

A meeting would be organised next week to receive a scientific update and the regulatory and delivery schedule update.

5. Meeting with BioNTech-Pfizer -delivery schedule

Following the previously announced delay in delivery in week of 18 January, the representatives of BioNTech-Pfizer stressed that the company:

- had reviewed the scenario of the previous week and could accelerate the deliveries for the week of 18 January;
- plans to come back to the [REDACTED] delivery plan of trays in Q2 to accelerate the vaccination effort in the EU;
- the company would gradually equalize the initial reduced supply of doses by increasing the deliveries. [REDACTED]
[REDACTED]
- had been assisting countries in their transition to [REDACTED] doses/vial; the company explained they were working on a mechanism to support MS [REDACTED]
- BioNTech has reached out to support them with access to relevant needles/syringes;
- BioNTech would provide feedback on how the support mechanism will work next weeks.