Minutes: Steering Board meeting 19 and 23 February 2021

1. Meeting with AstraZeneca – Update on Delivery Schedule

AstraZeneca representatives updated the Members of the Steering Board on the:

1. European Public Assessment report update, where the company outlined:
   - AZ COVID-19 vaccine indication;
   - the vaccine efficacy for incidence of first SARS-CoV2 virologically confirmed COVID-19 occurring ≥ 15 days post second dose in the pooled analysis set ;
   - elderly: the baseline characteristics for SD/SD seronegative efficacy analysis sets, 4-12 week dosing interval;
   - SARS-CoV-2 antibody levels by age – immunogenicity analysis set.

As a summary of the presentation, AZ underlined that:

- AZ COVID-19 vaccine has been shown to be safe and effective in preventing symptomatic COVID-19:
  - 100% protective against severe disease, hospitalisation and death , more than 22 days after the first dose;
  - 76% effective three weeks after the first dose that is maintained to the second dose;
  - for individuals vaccinated with second dose between 8 and 12 weeks, demonstrated efficacy at 72%
  - efficacy increased to 82% with longer inter-dose interval of at least 12 weeks or more
- over 50 countries approved the AZ COVID-19 vaccine.

2. Q1 and Q2 supply update, where AZ outlined:

I. The estimated dispatch schedule to Member States for February and March – AZ outlined:

- the number of doses for the weeks 5 to 13;
- two additional .

Furthermore, AZ outlined:

-

II. The estimated dispatch schedule to Member States for **Q2** .where AZ outlined:

The foreseen number of doses) similar to the previous update:

-

Furthermore. AZ outline it was:

-

2. Meeting with Curevac- Variant and pandemic preparedness – Proposal of an integrated European approach

Curevac representatives attended the SB meeting to present their proposal for an integrated fast response network. in line with the HERA incubator initiative to address COVID-19 variants.

In this context. Curevac proposed a solution that integrated all elements of the pandemic response value chain to ensure preparedness. scale and fast reactions. focusing on:

(i)

(ii) [redacted]

(iii)

This would allow to prepare for emerging variants

To support this, Curevac presented in detail its proposal and outlined in their presentation, *inter alia*, that:

- variant vaccine development than the original Wuhan strain and explained how Curevac's approach would deliver :
-

Curevac concluded

The company informed that it was waiting for conditional market authorisation and informed and also that [redacted].

Members of the SB welcomed the excellent presentation

Regarding questions on the timeline it filed for rolling submission

The company would attend the meeting on the 5 March to inform the SB on the .

1. **Meeting between the Steering Board and Janssen**

The representatives of Janssen provided a regulatory update as well as an update regarding the supply chain.

On the regulatory EU process, the company updated on:

- the submission and review process: EU approval expected for mid-March;
-
- and post approval :

Regarding the supply chain, the company outlined:

- the complexity of the manufacturing process of the Janssen vaccine;

- the specific requirements regarding the drug substance (DS) and the drug product (DP);
- its specialised precision filling requirements
  ;
- provided information on the Janssens network and sites selection
  in EU. The company outlined that due to global interconnectivity of Janssens' production and supply chain processes, one batch of Janssen vaccine would likely visit multiple countries through the course of various manufacturing stages.
- provided information of the availability of the delivery schedule:
  the delivery of a quarter, the company intends to provide the:
  - delivery schedule of the appropriate
  - expected volumes .

The company concluded

- that manufacturing and supply chain process for vaccines was time consuming and highly complex;
- it takes time to identify and activate new sites globally for production and fill and finish;
- once set up, the production process remains meticulous and is subject to stringent quality checks at every stage.

The Members asked about:

- concrete volumes for the company will start the first deliveries
  tressed that it
  would do its utmost to deliver as soon as possible
  The company hoped to be able to provide a schedule : and

- whether the EU would be delivered . The company stressed that the

The Commission called for fairness

In conclusion, the Commission and the Members expressed concerns the uncertainty for deliveries and asked the company to provide information on when and how much the MSs would be delivered.

2. **Ordinary Steering Board**

COVAX – state of play and nomination of EU candidates to co-chair the Shareholders Council

The Commission informed that:

- following the departure of that assured the interim of the COVAX Shareholders Council, all COVAX Self-Financing Participants were invited to nominate one or several candidates to co-chair the Shareholders Council;
- the Co-chairs will be selected from among Council members.
- the Co-chairs should normally comprise one Co-Chair from a high-income economy and one from an upper- middle income economy
- a final decision would be taken on 18 March.

Therefore, the Members were invited to suggest names and to agree on representative(s) that would be supported by the 27 MSs.

Several Members made some suggestions. The Members were invited to make further suggestions by Tuesday 23/02 cob in view of a decision at the next SB meeting.

Update on the allocation of doses (Bazaar) activities

Only two tables were open: **Valneva** and **Novavax**.

SOS doses- Members were asked: (i) to help MSs that have clusters and a very high death rate and (ii) borrow collectively a small number for each, that would be returned in April.

It was agreed that those MSs willing to borrow to indicate the numbers to the Commission.

Update on ongoing negotiations and on discussions with other companies

Valneva- based on the high interest of the MSs, the SB agreed to go for (the).

Moderna- one MS indicated that it had a public holiday during the opt out period.

Novavax- discussions on the contract were ongoing.