

Minutes: Steering Board meeting, 23 October 2020

1. Implementation of the Astra Zeneca Contract- Order Forms

The Commission informed the Members that all the Order forms were sent to AstraZeneca Alliance Manager.

At the time of the meeting the Commission was still waiting for:

- replies from [redacted] MSs on whether they [redacted] hubs. [redacted]
- replies from [redacted] MSs on the [redacted].

2. Update on Johnson & Johnson contract [redacted]

The Commission informed that the contract was signed and that all Member States, except for [redacted], opted for the Johnson & Johnson contract.

[redacted]

[redacted]

3. Update on other contracts in the [redacted] discussions with other companies

BioNTech- [redacted] was constituted. Work on the contract was ongoing. A technical meeting to discuss the contract took place in the course of the week. A revised version was awaited from the company [redacted].

The Members of the SB were encouraged to ask questions on logistics during the special session organised later during the day.

[redacted].

The Commission recalled the contractual provisions according to which :

- the Commission should send the binding allocation to the company [redacted] [redacted];
- from this date the MSs will need to in fill in the Order Form [redacted] [redacted].

Curevac – the Members were reminded that a second scientific presentation took place, followed by a discussion with the independent experts. A third scientific presentation/discussion will be organised on the 3 November.

Moderna –work on the contact is ongoing. [REDACTED]

[REDACTED] advancement of the negotiations.

Novavax- discussions with the company continue. The Members were informed on discussions on pricing, proposed number of doses, schedule delivery, liability and logistics.

The Chair proposed a strategic discussions on the mRNA vaccines at the next Steering Board meeting.



5. Pfizer/BioNTech contract- Logistics

Pfizer/BioNTech presented key elements on the logistics, as outlined below:

1. Vaccines storage options at the point of vaccination:

- Ultra low temperature freezer – storage for [REDACTED];
- Thermal shipper designed for temporary storage- storage [REDACTED];
- 2 to 8 degrees refrigerator- storage [REDACTED].

2. Unpacking and re-Use General schematic

Instructions were explained, in the case of:

- receipt [redacted] at the point of vaccination
- a [redacted] how to transfer trays [redacted]
- [redacted] temporary storage ([redacted])

3. Dry ice Guidelines- Safe storage, use and handling

4. Re-icing instructions and recommendations

5. Vaccine preparation and administration- explanations were provided on how to:

- remove the vials to thaw;
- dilute the vaccines;
- prepare the syringes;
- vaccine administration.

6. Vaccine Order management timing and customer order:

- orders would be created in the Pfizer IT system [redacted] prior the shipping date with the requested quantities;
- [redacted] will be performed [redacted] prior to the shipping date ;
- [redacted] to be made if needed [redacted] prior to then ship date;
- [redacted] in advance of shipping , in support of the [redacted] receiving preparations;
- [redacted] finished good quality release, [redacted].

Following the presentation a series of **questions** were raised by the Members, namely on:

- whether the price of the vaccine would include [redacted]
- who will be in charge of the return of boxes. [redacted]
- whether the diluent and the syringes used for dilution [redacted].
- if the company expected updated stability data for storage option at 2-8°C [redacted]

- where would the safety features (UID code and ATD) be present on the packaging.
[REDACTED]
- clarifications were asked on the type of diluent used. The company indicated that normal saline should be used, more specifically 0,9 sodium chloride injection, insisting on the fact that it must be used for one time dilution, regardless of the volume of the locally sourced diluent vial.
- whether there were any problems storing the vaccine with other vaccines in the ultra cold freezer. The company stressed that there were no problems as long as the GMP procedures were respected.

The company noted that it is possible that the final preparation and logistical requirements may change in light of forthcoming data on dosing, stability, manufacturing and shipping requirements.

The Members were invited to contact Pfizer directly for further questions of clarifications.

The Members also called for a Q&A to be distributed by the company.