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 four MSs on whether they would like AstraZeneca to cover the transport to the national hubs. Should this not be the case, those MSs would be responsible of picking up the doses from the producer.
- replies from five MSs on the designated distribution hub.

2. Update on Johnson & Johnson contract and the Bazaar

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

A preliminary Bazaar table was already circulated, but a revised one would be distributed with a deadline for the MSs to reply.

The MSs expressed preference for the opening of the Bazaar process in advance for the Pfizer/BioNTech contract.

3. Update on other contracts in the tendering phase/ discussions with other companies

BioNTech- the evaluation Committee 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 by the end of the day.

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

The Members agreed that the Bazaar process should be started in advance.

The Commission recalled the contractual provisions according to which :

- the Commission should send the binding allocation to the company within 15 working days from the date of signature;
- from this date the MSs will need to in fill in the Order Form within 10 working days.

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. The company hired a Belgian law firm, for a smooth 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.

4. Vaccine strategies

A special session was dedicated to a joint discussion with the Health Security Committee members on vaccines strategies.

The Commission informed the respective groups about the ongoing work of the HSC and the Steering Board.

The Commission outlined that the Health Security Committee:

- was mandated to reinforce the coordination and sharing of best practice and information on national preparedness activities;
- met on a regular basis;
- discussed national vaccination strategies;
- agreed on a Blueprint for an EU Vaccination Plan for COVID-19.

The importance of an effective communication (e.g. on the safety and availability of vaccines, prioritisation of groups etc.) was outlined.

The Member who took the floor:

- informed about ongoing work on the national vaccination strategies (e.g. prioritisation of groups) and
- outlined the importance for a strong coordination of national strategies and communication at EU level.

The Commission provided a state of play regarding **the Joint procurement for the supply of medical equipment for COVID-19 vaccination**, namely that:

- there were 27 participant countries: 23 MS (5.1.2a 5.1.2a), 2 EEA (5.1.2a) 5.1.2a

- the call covered 27 lots under six categories (vaccine carriers, waste containers, injecting devices, disinfection solutions, personnel protective equipment and anaesthetic consumables);

- the tender was launched on 28 September with the deadline for submission extended by one week- to 19 October. The evaluation preparatory meeting took place on 19 October in the afternoon and the evaluation has started immediately on 20 October.

- in total, 15 tenderers submitted 86 offers covering 26 lots (except for nasal catheters) and up to 20 times of the requested quantities

    - over 3.6 million waste containers were requested by countries; 4 offers submitted for this lot exceed this quantity by more than 3 times;
    - over 504 million needles were requested by countries; 11 offers exceed the requested quantities up to 4.5 times respectively;
    - over 1.25 billion syringes (with/without needle /1ml, 2ml, 3ml, 5 and 10ml) were requested by countries ; in total 39 offers were submitted between 2 and 7 offers per product; offered quantities satisfy and exceed the needs from 1,2 to 20,2 times (depending on product).

- the Commission anticipates the evaluation to be finalized by mid-November (largely depending on the quality of offers and reactivity of companies), while the orders could be placed as of December ensuring that supplies are available in time for national deployment of COVID-19 vaccines

All agreed on the importance of coordinating the schedules on supply of medical equipment (needles, syringes etc) with the vaccines calendar. Some MSs asked for an overview of a possible delivery vaccine schedule and distribution.

The Commission encouraged Member States prepare aspects linked to logistics, storage volume and capacity etc.

The Commission also asked the MSs to inform if they launched or signed national procurement on syringes and needles in parallel, information that could be relevant for adjusting the offer to the needs of the Member States.

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 6 months;
    - Thermal shipper designed for temporary storage- storage for 15 days ;
    - 2 to 8 degrees refrigerator- storage for 5 days.

2. **Unpacking and re-Use General schematic**

   Instructions were explained, in the case of:

   - receipt of the ULT thermal shipper at the point of vaccination
   - a ULT freezer available -how to transfer trays to the ULT freezer
   - the thermal shipper is used for temporary storage (replenish dry ice in thermal shipper in 24 hours of delivery)

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 8 weeks prior the shipping date with the requested quantities;
   - customer order sequencing will be performed 4 weeks prior to the shipping date ;
   - customer order adjustments to be made if needed 2 week prior to then ship date;
   - all customer order lines will be frozen 5 days in advance of shipping , in support of the Mfg site, logistics and customer receiving preparations;
   - inventory allocation to customer orders will occur immediately upon plant finished good quality release, for pick/pack.

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

- whether the price of the vaccine would include the delivery. The company confirmed this.
- who will be in charge of the return of boxes. The company would be in charge of the pick-up, upon information by the MSs.
- whether the diluent and the syringes used for dilution would be included in the price. The company infirmed this.
- if the company expected updated stability data for storage option at 2-8°C for longer than 5 days. The company stressed that test were ongoing and could not provide an answer for the time being.

- where would the safety features (UID code and ATD) be present on the packaging. The company indicated that they would be placed on the 2nd pack (pizza box).
- 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.