Minutes: Steering Board meeting, 17 and 18 December 2020

An extraordinary meeting of the Steering Board was convened on the 17 of December, in order to:
- provide the Members of the Steering Board with the latest information on BioNTech/Pfizer authorization process and timeline and
- present various scenarios for the Steering Board to decide on the

1. Planned timelines for the authorisation process and regularity flexibilities

The Commission explained in detail the planned timelines for the authorisation process of BioNTech/Pfizer COVID-19 Vaccine, aiming at a final decision no later than 22 December.

In view of the exceptional circumstances of the coronavirus pandemic, Members States were asked to be prepared to ensure an in depth but swift analysis and feedback to the written consultation, in order to accommodate the smooth advancement of the process.

A letter would be sent to Member States Ambassadors on the same day, explaining this process in order to ensure full information and transparency at all levels (technical and political).

Furthermore, the Commission provided extensive explanations of the regulatory flexibilities for COVID19 vaccines, which were agreed by the MSs as necessary to facilitate rapid deployment of the vaccine at large scale by:
- increasing production capacity,
- reducing transport costs and storage space,
- improving the distribution of the doses between Member States,
- limit possible impact on the production of other routine vaccines.

It was outlined that all flexibilities were temporary and time limited and would not affect the critical elements, which would not be exempted (e.g. full package leaflet information, expiry date etc).

Extensive explanations were also provided regarding the flexibilities on labelling which were discussed and agreed among the Member States in the Pharmaceutical Committee.

The Members welcomed the information provided and did not express any objection to this timeline.

2. EU Dose allocation/distribution and projected timelines post CHMP approval

In order to have the latest updates and to allow Members to take a decision on the distribution of the quantities and delivery timeline, the Commission
invited in a separate discussion representatives from Pfizer/ BionTech to explain and present different scenarios, allowing Member States to agree on the best / most suitable options for them.

The representatives presented the EU allocation and the various scenarios regarding its distribution \(\textit{with no implication on the overall volume}\), as follows:

- [ ]

This option was discarded by the Member States.

- [ ]

Members agreed unanimously on this last scenario.

The company presented also the projected timelines post CHMP approval including for shipment to all markets with a coordinated arrival on December 26\(^{th}\). The timeline presented reflects the Commission suggestion for a coordinated first shipment to arrive on same day in all MS, in order to support a consistent vaccination start date across all Member States.

This would indeed ensure a start of the vaccinations campaigns in all Member States as it was outlined by the President of the Commission.

To this end, all Members agreed to receive on the 26\(^{th}\) December a first shipment of in their hub and possibly in another hub of their choice.

This first shipment would, of course, be followed by others the following days, to ensure the distribution of the to all designated hubs.
The company:

(i) underlined that the market delivery locations needed to be ready to receive all day on 26th December and most importantly
(ii) drew the attention that not all MSs sent the Order Forms, and without the information provided (eg. national hubs) in these forms the delivery would be impossible.

The Commission encouraged

In order to anticipate and prepare for reception of deliveries the company will provide information with the quantities to be distributed per week and per country.

18 December

The discussions on the aspects outlined above were carried in the Steering Board the next day along the same lines.

At this ordinary session, other issues were also discussed:

1. Update on contracts and discussions with other companies

Novavax - the Members were informed that the Commission announced on the previous day the end of the exploratory discussions and the intention to go into the

Key elements of the envisaged contract were presented

Valneva - negotiations were over on the structure of the envisaged contract, on price, delivery and payment schedules and options. The Members were informed of the Commission’s intention

2. Update on the activities and implementation of contracts
Moderna:

- Members were informed that the allocation of initial and optional doses was communicated to Moderna;
- Members would receive after the meeting the template for the Vaccine Order Form;
- if MSs requested both initial and optional Doses, as reflected in the allocation table, they were requested to prepare two separate Vaccine Order Forms;
- Members were asked to send the filled and signed Vaccine Order Form to the EC Vaccines mailbox as soon as possible;
- the Commission will send it on MSs’ behalf.

The Commission will organize a meeting next week with the representatives of the company and the Steering Board members to explain elements related to medical information, logistics, regulatory aspects etc;

Pfizer/BioNTech:

- the Members would be invited to express their interest for optional doses;
- in this light a table would be circulated to the Members;
- it was outlined the importance of having a picture of the overall volume of the optional doses wanted by the Member States.

Curevac

- a number of doses still need to be attributed;
- Members were asked to send the filled and signed Vaccine Order Form to the EC Vaccines mailbox as soon as possible in order to be sent to the company by the end of the year.

Janssen

- Members were informed that the allocation per participating Member State for the base volume commitment has been communicated to Janssen;
- Members were asked to send the Vaccine Order Form to EC-VACCTNES@ec.europa.eu as soon as possible and at the latest;
- the Commission will send it to the company on MSs’ behalf.

The Commission (i) debriefed the Members on the meeting with AstraZeneca held during the week where the company provided a scientific/technical updates and (ii) informed Members about the company’s readiness to accommodate Member States’ request for optional doses.
The Members were informed about recent leaks in the press on elements from the contracts and were reminded about the very strict confidentiality rules that, expressed the support of to the initiative.

3. COVAX

An in-depth discussion was carried on COVAX and the common approach on donations.

The Commission debriefed the Members on the second meeting of the subgroup on donations where the participant were discussed the (i) state of play on donation allocation; (ii) ; (iii) vaccine donation in WHO and COVAX.

The Commission also debriefed the Members on the meeting with held on the previous day, where it was outlined:

- support for COVAX but also their uncertainty that COVAX would be able to supply all their needs;
- request for EU’s help not only regarding donations

The Commission also debriefed the Members meetings with the Commission where it was outlined that:

- COVAX was delayed in securing supplies of vaccine volumes;
- EU should further increase the percentage foreseen for donations
- WHO was working with a number or low income countries among which were identified as ready logistically to receive immediately doses of vaccines.

The Members outlined the very good portfolio secured by the EU and agreed that the EU should continue to support the rest of the world.