Minutes: Steering Board meeting, 17 and 18 December 2020

An extraordinary meeting of the Steering Board was conveyed 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 [redacted]

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 (eg. 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** [redacted] **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 (with no implication on the overall volume)**, as follows:

- [redacted]

  This option was discarded by the Member States.

- [redacted]

- [redacted]

  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 26th**. 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 Members States** [redacted] as it was outlined by the President of the Commission.

To this end, **all Members agreed** to receive on the **26th December** a first shipment of [redacted] in their [redacted] 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 [redacted] to **all designated hubs.**

[redacted]

[redacted]

[redacted]

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 [redacted]

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** [redacted] **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 [redacted]
Key elements of the envisaged contract were presented [redacted]

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 [redacted]

2. **Update on the** [redacted] **activities and implementation of contracts**

[redacted]

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 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

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- 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-VACCINES@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, [redacted]

The session did not host an in-depth discussion on the vaccination strategies, however the Commission underlined the importance of the **unique code** (sort of IBAN), with minimal data sets on the **vaccination card**. [redacted] expressed the support of [redacted] 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) [redacted]; (iii) vaccine donation in WHO and COVAX.

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

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

The Commission also debriefing the Members [redacted] 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 [redacted] 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.