Minutes: Steering Board meeting, 6 November 2020

1. Update on the vaccination documentation

[redacted] indicated that while all Member States had a vaccines registers, it might be important for Member States to ensure digital/electronic documentation of vaccine and that interoperability of vaccination documentation (for travelling, etc.) was crucial. [redacted] seems to have a solution in place, which could be explored with the other Member States.

The Commission informed that [redacted] gave a presentation in the Health Security Committee on electronic COVID-19 testing and vaccination certificates, a project in collaboration with WHO to facilitate international travel. The project included a first pilot on digital and verifiable international vaccination certificate. The Members were informed that the app was very user friendly and could be used by other Member States.

The HSC or the E-health Network will follow up with collecting reactions from countries on this app also to ascertain what kind of certificate or format of certificate would be useful and what is used in other countries.

The Members were also informed that the eHealth Network had a first discussion on the vaccination passport that raised several questions, including on the free movement of persons in the absence of such passport.

Depending on the implementation architecture, there could be [redacted], as well as the possibility of involving countries outside EU/EEA.

[redacted]

It was agreed that this topic would be further discussed with the experts in the eHealth Network, [redacted].

[redacted].

[redacted]

3. **Update on other contracts [redacted] / discussions with other companies**

BioNTech/Pfizer- work on the contract was advancing towards completion. Some technical issues still needed to be solved but there were no legal obstacles to conclude the contract.
The Commission explained extensively and comprehensively the liability and indemnification clause.

Moderna - work on the contact is ongoing. The members were updated of the discussions on key aspects: such as liability, delivery schedule, termination rights etc.

Curevac - the members were informed that new data was presented during a third scientific presentation on the 3 November that was welcomed by the independent experts who expressed a favourable opinion.

[redacted] as discussions with the company were concluded, the Steering should decide on launching the contract process.

Novavax - the Members were updated on discussions on liability and indemnification.

Valneva - there are [redacted] on indemnification and liability, [redacted] on the structure of the contract, on price, delivery and payment schedules and options.

4. **Joint procurement for the supply of medical equipment for COVID-19 vaccination**

The Commission provided a short update from last Steering Board meeting on the state of play regarding the **Joint procurement for the supply of medical equipment for COVID-19 vaccination**, for which the evaluation of the tender evaluation was ongoing.

The Commission recalled that the evaluation to be finalized by [redacted] (largely depending on the quality of offers and reactivity of companies), while the orders could be

placed [redacted] ensuring that supplies are available in time for national deployment of COVID-19 vaccines.

5. Update from AstraZeneca on Clinical trials, manufacturing and approval

In a dedicated session, AstraZeneca provided an update on clinical trials, manufacturing and approval.

In a very comprehensive presentation, Members were provided with:

- an update on the clinical development;
- explanations regarding the technology behind the vaccine candidate and that the vaccine [redacted];
- a full picture on the global clinical development plan;
- explanations of the results of the clinical trials so far.

The Members were also updated on the **regulatory and release process**. During the presentation, the company presented the standard regulatory and release process and provided an extensive explanation of the COVID vaccine accelerated development, appraisal and release process.

The company outlined the different phases in the pre-approval and post approval and explained how the parallel procedures could shorten the usual development process keeping the standards as high as during a normal process.

An update on the **supply** was also provided. Members were informed that:

- all order forms and binding allocation were received;
- [redacted] Member States still needed to provide distribution hub details;
- an updated preliminary delivery schedule would be provided during November;
- detailed plans were being updated as process development continues and more information becomes available regarding production, testing and release timelines become clear .
- Member States were asked to provide as soon as possible the outstanding Customer Set Up Forms ([redacted] received so far).

A **Q&A session** followed where the Members of the Steering Board were able to ask all relevant the questions (eg. vaccine platform, clinical trials, shelf life, price, distribution etc.)

6. AOB

[redacted] stressed that (i) a clear **communication** was necessary regarding the different stages of the market authorisation and that (ii) any vaccine outside the portfolio that the Members might want to purchase outside the portfolio can only be used if a **market authorisation** will be granted in Europe.

[redacted] informed that new **mutations** have been identified in SARS-CoV-2 strains from Danish **mink** - these strains have also infected humans. [redacted] These mutations have been detected because for [redacted] of all PCR positive patients in [redacted] virus strains are consistently whole genome sequenced. Several of these mutations are well known and part of what is expected of coronavirus infections.

There was a request to verify how vaccine manufacturers are judging the situation, particularly how effective the newly developed vaccines would be in conferring immunity to the mutated virus identified.

Exceptional meeting of the Steering Board on Pfizer/BioNTech contract 9 and 11 November

Two exceptional Steering Board meetings were held on:

- **9 November** to inform Members on the state of play of negotiations with Pfizer/BioNTech and last steps ahead of the adoption of the contract;
- **11 November**, the day of the adoption of the contract by the Commission, to inform the Members on the contract and of the next steps.

In both these session the **key elements of the contract** were presented and explained in great detail to the members. Elements illustrated include:

- number of doses [redacted] plus an option to request up to a further [redacted]);
- price [redacted]
- delivery schedule;
- [redacted] clause;
- liability and indemnification provisions;
- delivery [redacted]

Members were informed that, as set out in the Agreement, Member States have the right to opt-out no later than 5 working days after the Commission has communicated its intention to conclude the APA. In the case of this contract, therefore, the deadline to exercise the right to opt-out will expire on **18 November.**

Discussions on the [redacted] carried in both these meeting and revised tables were distributed reflecting the feedback from the MSs [redacted].

[redacted] r.

In light of the good work already carried out in the Steering Group and the early start of the [redacted], the Members were invited to complete the **Vaccine Order** forms with the **number of doses** [redacted] **by the time the opt-out period runs out** (i.e. **18 November**).

This would allow the Commission to complete the order procedure [redacted]
