

Minutes: Steering Board meeting, 9 and 13 October 2020

1. Implementation of the Astra Zeneca Contract

The Commission informed the Members that the binding allocation was sent to AstraZeneca on the [redacted] of October.

This triggers the [redacted] Order Forms. The Commission informed that it would share an info note and guidance on how to fill in the Order Forms.

The Members States were asked about their preference on various aspects regarding the logistics [redacted]
[redacted]

In order to follow up on the delivery, the company asked the Member States to fill in the Order forms details regarding the national contact points.

Once the Order Forms filled, further discussions on the logistics will be carried bilaterally between the AstraZeneca [redacted] and the persons appointed by the Member States.

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

J&J –the Members were reminded that the contract had been sent to the Member States via the secured transmission and that they had five working days to express their intention to opt-out.

The Member States taking the floor [redacted] praised the quality of the contract, welcomed its adoption and called for solidarity on the portfolio.

Some MSs [redacted] indicated that a final decision would be taken within the five days period.

Once the opt-out period runs out , [redacted] process will be set in place by the Member States, aiming to accommodate the various needs [redacted] terms of number of doses, respecting, at the same time the contractual provisions.

Moderna – issues [redacted]

Curevac – the Members were reminded that a second scientific presentation took place, followed by a discussion with the independent experts.

Once additional scientific data is provided by the company, a third scientific presentation and follow-up discussion will be organised.

Novavax- discussions with the company continue.

BioNTech- the [REDACTED] was constituted.

[REDACTED] - the Members were informed that a scientific presentation took place on the previous day. The exploratory discussions were nearly finalized, leaving the next steps up to the Member States' [REDACTED]

Valneva - the Members were informed on the discussions regarding the supply and [REDACTED]. These elements will be further addressed in follow-up discussions with the company.

The Commission clarified some questions regarding the criteria and the legal base [REDACTED]. It was recalled that the discussions with the companies were based on the criteria set in the Agreement with the Member States, the Vaccine Strategy and the collective decisions by the Steering Board.

3. Press communication

Some Members asked when details of the contracts could be made public.

The Members were reminded that the contracts contained confidentiality clauses that could only be waived with the agreement of companies.

Furthermore, caution was called for not disclosing contract clauses while negotiations were ongoing, as companies may wish to 'cherry-pick' on the best conditions.

As a conclusion, disclosing elements from contracts once the negotiations were finalised required the agreement of the companies and ultimately of all Member States, as buyers of the vaccines.

4. Strategic discussion about expanding the current portfolio of 6+1

Following the reflection carried by the Member States, some key exploratory elements/principles were outlined regarding the way forward on expanding the current portfolio of 6+1, namely that:

- all EU Member States should have access to the EU portfolio;
- all EU Member States should benefit from the EU Vaccine Strategy ;
- Member States would need to express a written interest in a candidate upfront;

- Members States no having expressed interest, could opt-in at a later stage to the same conditions.
- forecast on volume and costs to make budgetary impact possible.

Regarding the latter point, key elements for reflection were outlined, such as: companies that could be added to the portfolio, type of vaccine and the technology used, total volume, upfront costs, ceiling price, payment milestones.

The Members of SB generally welcomed the elements presented, pleaded for a broader Portfolio and for the continuation of discussions and possible negotiations with companies beyond the 6+1.

The importance of finalising the current portfolio before proceeding with the expansion was outlined .

A state of play on the ESI [REDACTED] was also provided.

5. Exceptional Steering Board meeting on J&J contract- 13 October 2020

The objective of the exceptional meeting was to provide Member States with information and the opportunity to ask questions [REDACTED]

A representative from J&J made the following remarks:

- J&J had temporarily paused further dosing in all their COVID-19 vaccine candidate clinical trials, including the Phase III trial, due to an unexplained illness in a study participant, [REDACTED].
- Following internal guidelines, the medical data [REDACTED] was being reviewed and evaluated by the independent Data Safety Monitoring Board (DSMB) as well as the Company's internal clinical and safety physicians.
- Adverse events (illnesses, accidents, etc) even those that are serious (SAE), are an expected and normal part of any clinical study, especially Phase III studies involving large numbers of participants
- Clinical studies conducted by the Janssen Pharmaceutical Companies of Johnson & Johnson follow pre-specified protocols and guidelines. These ensure studies may be paused if an unexpected SAE that might be related to a vaccine or study drug is reported, so there can be a careful investigation and review of all of the medical information before deciding whether to restart the study. It was clarified that the study was paused by the company and not put on hold by the regulatory agency.

- AEs are not uncommon in clinical trials¹. Furthermore, as many trials are placebo-controlled and often subcontracted to third parties, it is not always clear from the outset whether a participant received a study treatment or a placebo. In reaction to queries regarding elements of [REDACTED]
- The company confirmed that they were screening their database of [REDACTED] subjects vaccinated with their adenoviral platforms for symptoms that resembled those of the case at hand.
- At the time, the company gave no indication as to the duration of the temporary pause although they would treat it as a high priority [REDACTED]

Several MSs [REDACTED] stressed that a [REDACTED] any clinical study, especially studies involving large numbers of participants.

Furthermore, those MSs outlined that:

- the main goal of this model of APA was to secure vaccines for Europe and the rest of the world by sharing risks on their development - contributing to build up capacity of manufacturing of medicines under clinical development implies that some of them may fail in the process;
- during the normal development of a clinical trial, the research may be stalled by adverse events, safety issues may arise, consequently the incident must be analysed by the DSMB, and, eventually, the trials should resume;
- this was a routine occurrence and part of the risk of purchasing therapies and vaccines at the current stage of development;
- closing an advanced purchase agreement during the conduct of Phase III trials will invariably be subject to such occurrences as temporary halts during large scale Phase III trials;
- negotiations for purchase should not be paused when this and other similar events are unfolding as it would be extremely disruptive to negotiations/deliveries to pause every time such an event occurred;
- [REDACTED]

Some MSs [REDACTED] underlined that the [REDACTED]

¹ https://www.who.int/vaccine_safety/causality/en/

Additionally to the [REDACTED], [REDACTED] raised a [REDACTED] stressing that the [REDACTED]

[REDACTED] outlined that the main goal of this model of APA was to secure vaccines by sharing risks on their development and that this was enshrined in the agreement with all the MSs.

The Commission clarified that the contract did not foresee any [REDACTED] [REDACTED] but reassured that MSs did not need to make any [REDACTED] before the market authorisation was granted, which would, of course, not be the case should the [REDACTED] not be solved.

The Members asked for common language on the LTTs regarding the [REDACTED] [REDACTED] for Johnson & Johnson.