

Minutes: Steering Board meeting, 18 September 2020

1. Update on the Sanofi contract

The Commission informed that:

- the signature of the contract took place on the 18 September ;
- the contract did not foresee an obligation to buy doses (and Art.3 contract);
- a press release would be published on the day of the signature.

The Commission recalled the Members of the Steering Board the payment milestones provisions of the two contracts signed so far (AZ and SANOFI), confirming that no payment would be required from the MSs before the end of 2020.

2. Bazaar/EEA+CH file- final status

The SE representative updated the Members on the state of play of the Bazaar file, following the feedback received from the Member States, recalling that:

- all Member States agreed to forego 3% of doses to EEA and CH;
- after the process of consultation there was a surplus of almost 7.5mio doses;
- as a consequence, the allocations could be adjusted and MSs were invited to go back to the original dose allocation (before the 3% deduction);
- the Member States that had not yet reacted in this respect were invited to do so as soon as possible;
- the final table would need to be produced and circulated quickly, in order to allow the Commission to send the binding allocation to AZ, which would trigger the ten-day timeframe for the Member States to complete their Order Forms.

3. Topping-up ESI- final status

The Commission and DE thanked the Members for the positive replies received so far from a majority of Member States expressing their willingness to top-up ESI.

The Commission underlined that the positive replies varied in terms of form and content:

- some were sent by a formal letter with the specific amount regarding the financial commitment;
- other replies were more vague – via letters (or even informal emails) agreeing to the top-up (i) either pending national procedures, or (ii) without mentioning specific amounts.

Regarding the replies covered by the latter point, the Commission highlighted that a more formal approach was needed and invited the Member States that have not done so, to confirm

their willingness to top-up ESI via a formal letter signed by a Minister mentioning the exact amount committed (according to then GNI table annexed to the original letter).

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

J&J and Curevac - work is progressing well, envisaging a possible signature of the two contracts in the next weeks.

Moderna - some elements of clarification (eg. headquarters, minimum share capital) were required from the company, in order to be able to continue with the process.

Novavax - key elements of discussions were outlined, such as: the number of doses, the delivery schedule, the payment proposal as well as flexibilities outlined by the company during the negotiation.

Valneva and Reithera- the Members were informed about key elements of exploratory discussions, such as: the price, delivery schedule, upfront payment etc.

5. COVAX

Short follow-up point to the COVAX dedicated meeting on the previous day, in order to inform the Members that the European Commission confirmed on the 18 September:

- its participation in the COVAX Facility for equitable access to affordable COVID-19 vaccines, following its expression of interest on 31 August and its announcement of a contribution of €400 million;
- that Team Europe (European Commission and the 27 EU Member States) would contribute with an initial €230 million in cash (equivalent to reserves or options to buy 88 million doses that would be transferred to eligible Advanced Market Commitment countries), contribution complemented with the remaining amount in financial guarantees from the EU budget.

The Commission informed the MSs that a press would be published on the same day.

6. AOB

The Members of the Steering Board were informed that the Commission and AZ appointed each an Alliance Manager and that a note would be circulated to Member States contract contact points explaining the roles of each Alliance Manager and information flow. In addition, the EC asked companies to provide information on logistics and injectable devices characteristics for each vaccine. Feedback will be shared with Member States via a secured transfer.

7. Liability and Indemnification

A special session was dedicated to the issues of liability and indemnification. The Members of the Steering Board as well as legal experts from the Member States were briefed on the matter and were able to seek clarifications in a Q&A session.

Through the session it was clarified that:

- the provisions regarding the liability and indemnification were not deviating from the legislative status quo;
- the Commission and negotiating MSs systematically resisted all requests which would have conflicted with the Product Liability Directive;
- liability incurred as a result of a defect in the use and administration of the vaccine stays with the company which must defend itself in court against claims due to an allegedly defective vaccine that would have caused adverse effects;
- negotiations and ultimately the contracts strike a reasonable balance between the need to fully uphold the applicable EU legal provisions and to incentivize pharmaceutical companies to accept to take up the corresponding risk allowing for a timely provision to the Member States of a vaccine against COVID-19, given that manufacturers are expected to develop safe vaccines in a much shorter lead time than the normal timeframe;
- in order to compensate for risks taken by manufacturers, the contracts provide for Member States to indemnify the manufacturer for possible liabilities incurred under specific and strict conditions. Indemnification cannot take place if the defect follows from certain unlawful actions by the manufacturer.
- the indemnification clause might only apply:
 - if the company cannot prove that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered (i.e. it was scientifically possible to detect the defect but it was just not de facto detected -it was hidden but detectable)
 - there is a causal link between the defect and the damage;
 - the company complied with all rules applicable to manufacturing the product.
- the provisions on liability and indemnification do not alter in any way the regulatory burden of proof borne by companies to demonstrate the safety and efficacy of its product before the EMA and the Commission.