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Steering Board meeting, 31 July 2020

The started the meeting inviting all Member States to finalise their national procedures related to the approval of the Agreement on the Covid-19 vaccines, and prepare for the conclusion of the Advance Purchase Agreements.

The Commission expressed the gratitude to all Member States for co-operation and added that there is only one Member State which has to conclude the national procedures in order to approve the Agreement.

Member States were encouraged to communicate as soon as possible the contact details for the secured emails. If any of the contact representatives will change, the Member States have to inform the Commission well in advance.

The Commission asked the Members of the Steering Board to respect the confidentiality of the information on the potential vaccine candidates shared during the Steering Board meetings.

Scientific Committee with independent experts on the potential vaccine candidates

The Steering Board representative invited the Member States to participate in the Scientific Committee, where will be presented the scientific opinion of the independent experts on the potential vaccine candidates. Member States are invited to nominate their independent academic experts and leaders of the scientific boards, which might provide relevant expertise on the Covid-19 vaccines platforms.

At the first meeting of the Scientific Committee, which took place on 27 July, the experts from , and the presented their opinion on several vaccine candidates. The Steering Board representative mentioned that the experts from and expressed their interest to share their expertise in the next meeting of the Scientific Committee, which will take place on .

The Steering Board representative invited the independent researchers and the lead experts to provide a written opinion, which will be further circulated to the Member States by secured emails, in strict confidentiality.

Addressing the questions of the Members of the Steering Board, the Commission noted that Member States can delegate their experts to the meeting of the Scientific Committee, if they have signed the declaration of confidentiality and absence of conflict of interest.

The Commission confirmed that meeting with the Scientific Committees will take place before concluding the Advance Purchase Agreements with the manufacturers.

Update on AstraZeneca contract

The Commission received a proposed draft Advance Purchase Agreement from AstraZeneca and proposed some further amendments. The Commission is currently discussing some liability aspects with the company.

The Commission emphasised that the access to vaccine doses will be allocated to Member States based on a pro rata, according to the population distribution key. The Member States, which accept to participate in the purchase of the AstraZeneca vaccine, can receive as a maximum the corresponding population pro-rata percentage of the total purchased quantity. Should they decide they do not want the vaccine, they will need to opt out explicitly.

The Commission confirmed that the upfront payment for AstraZeneca will be covered by the ESI fund. Two important aspects of the contract with AstraZeneca remain to be clarified:

- ✓ the logistics (the company plans to have only distribution hubs in the EU and ways of distribution);
- ✓ the , which might slightly without exceeding a .

In this regard, the Commission requested the company to provide a possible to the Member States. In turn, AstraZeneca underlined the importance of its capacity to produce in Europe, as a vaccine manufacturer, and addressed for support to the Member States.

The Commission noted that the vaccine regimen of AstraZeneca will consist of 2 vaccine doses and the distribution schedule is already .

Addressing the questions of the Members of the Steering Board, the Commission reiterated that in case a Member State does not agree with the conclusion of an APA or the terms of the contract, it has the right to opt out within 5 working days from the Commission's communication that it intends to conclude the APA with the vaccine manufacturer. According to the Article 4, the Member States which decide to accept the Advance Purchase Agreement have to communicate the number of doses of the vaccine they intend to purchase.

The Commission encouraged the Member States to consult their independent experts and to actively participate in the meetings of the Scientific Committee with the independent experts and with the vaccine producers. In this context, Member States requested to receive the written scientific opinion of the independent experts before the draft APA is proposed to the Member States.

Member States will receive the draft APA with AstraZeneca in the following , as soon as it will be concluded.

Update on ongoing negotiations with vaccine producers

The Commission and the representatives of the Joint Negotiation Team updated the Member States on the ongoing negotiations with the other vaccine producers:

- Sanofi – further to a constructive discussion, the Commission and the company reached on the .
  The representative of the Joint Negotiation Team highlighted that the Sanofi vaccine complements the potential vaccines of the other candidates, in terms of technology and risk diversification. The technology platform used by the vaccine candidate is well

known, and its efficacy has been proven. The potential vaccine is still under development and will be finalised at a later stage.
For the Member States, there is no financial commitment or obligation to buy the vaccine at this stage. The Commission will pay an upfront payment from the ESI fund, . According to the Article 3, Member States will have the opportunity to decide if they are interested in the vaccine candidate only after the results of the clinical trials. If interested, Member States will pay the the vaccine price.

Update as of 4 August 2020: The Commission has prepared and has sent it to the vaccine manufacturer. The Commission is expecting the contract from Sanofi by 10 August 2020 and more details will be presented on the Steering Board meeting on Friday, 7 August.

- Johnson & Johnson – further to a meeting on liability clause, the discussions will continue on . The vaccine manufacturer has started the clinical trials in several countries.
  The remaining points will be discussed further to an agreement on the .

- BioNTech- a constructive discussion on the liability clause had taken place. The uncertainties concerning the have to be addressed during the next meetings.
  The Commission noted that the company is offering a .
  Member States would be asked to communicate to the Commission the number of doses they would like to reserve. As emphasised in the Article 4, Member States will have 5 days to opt out, if they do not agree with the conclusion of an APA.
  The Commission noted that

- Moderna - several meetings had taken place. Moderna proposed a More details on the discussions with the vaccine manufacturer were previously submitted by email to the Members of the Steering Board.
  The vaccine manufacturer proposed a detailed comment on the liability clause, which has to be further examined by the Commission. A meeting on the delivery schedule was planned .
  The potential contract corresponds to the Article 4, representing a commitment to buy the vaccine.
- CureVac- a meeting with the company to discuss their offer was planned .
  More details will be presented at the Steering Board meeting on 7 August.

There was a discussion about how a portfolio might be constructed, the co-Chairs agreed that the Member States have to consider the timeline and the quality of the vaccines candidates, as well as the differences in prices and the records of the companies.

The Commission suggested to the Member States to reflect on their potential vaccine portfolio.

As agreed by the Steering Board, the Commission started the negotiations with Valneva and The Commission invited the companies to present their proposals for the vaccine candidates. Further discussion with the companies were planned .

provided more details on their clinical development plan. The Commission will schedule a separate meeting with the vaccine producer.

Concerning the question related to the conditional marketing authorisation, the Commission noted that almost all the companies will have the conditional marketing authorisation compliant with the delivery schedule of the vaccine. In case of the Commission asked for additional details on the regulatory approval.

Following the discussion in the Steering Board, the Commission contacted the other interesting candidates: . The Commission is not ready yet to enter into the negotiations with these companies. Nevertheless, it will keep a close co-operation with the vaccine producers.

The Commission contacted two promising candidates and Novavax. Novavax would be available to attend a Scientific meeting with the Member States. Both companies will analyse their distribution capacity for the EU and confirm it to the Commission by early September.

An Excel file including the companies which contacted the Commission and a few details on the vaccine candidates was sent to the Member States.

Update on GAVI and COVAX Facility

reassured the Member States that the EU is fully committed on the COVAX Facility, on both sides: research financing aspects and AMC, following the governance pillar of COVAX Facility in the GAVI Board.

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Estimated numbers of people for vaccination

The latest state of play is presented in the table below:

Member State	Number of priority group	% of priority groups accept vaccination	Estimated number of people for vaccination
ESTIMATED TOTAL (status of 4 August 2020)			