

Steering Group meeting, 10 July 2020

Administrative aspects (request for access to documents, update on the scientific meeting with Moderna)

Member States were informed by the Commission of a request for access to documents, concerning the Decision approving the Agreement with Member States on procuring Covid-19 vaccines on behalf of the Member States, to which the template for the Agreement itself is annexed. The Commission did not see any reason to refuse this request and intended to respond positively to the request. Member States with any concerns about this were invited to contact the Commission to discuss.

The Commission invited the Member States to attend the meeting with Moderna, where the company will present their scientific data. The meeting will take place on Wednesday, 15 July, at 15:00 CET. The interested participants were asked to submit their contact details to _____@ec.europa.eu by Monday, close of business. Any non-members of the Steering Board should sign and submit the confidentiality agreement.

Update on AstraZeneca contract

The representatives of the Inclusive Vaccines Alliance (IVA) presented the main elements of the deal that the four countries (France, Germany, Italy and the Netherlands) concluded with AstraZeneca in order to procure the vaccine against COVID-19 for the European population, as fast as possible. Currently, the Oxford AstraZeneca vaccine is the most advanced in the clinical development, being in the third phase of studies in different regions in Europe.

_____ emphasised that it is important to prepare the production capacities in the EU, in order to have the vaccine available by the end of the year. The deal covers _____ doses with an option for _____ extra doses for Europe, for a non-profit price.

In order to implement this initiative, the Commission has to sign a purchase agreement with AstraZeneca, on behalf of all Member States.

The Commission is working on the specific procedure in order to sign the contract with AstraZeneca as soon as possible, having the defence of the EU financial interest as a guiding principle.

The co-Chair concluded that based on the initial estimates provided by the Member States, the current need would be to vaccinate _____ people in the EU, which might be covered by the AstraZeneca contract.

As regards the participation of the EEA countries _____ raised by MS, the Commission underlined that the ESI instrument does not include the non- EU Member States.

In response to the questions from the Member States, the Commission confirmed that the allocation of vaccine agreed in the Agreement between the Commission and MS will be taken into consideration in the contract with AstraZeneca. The Member States will have five days to opt out of the contract if they do not wish to participate in the APA.

Update on ongoing negotiations with producers, including liability

The Commission is currently negotiating with multiple vaccine producers, in order to consolidate its portfolio.

The Commission updated the Member States on the ongoing negotiations with the other vaccine producers:

- Johnson & Johnson - the discussion on the liability clause [REDACTED];
- Sanofi - discussions are still continuing on [REDACTED] liability. The Commission mentioned that the vaccines will be available [REDACTED] 2021.
- CureVac - despite several discussions, Curevac [REDACTED] requested by the Commission.
- Moderna - a number of meetings had taken place. Moderna's original proposal did not [REDACTED] EU scheme: the Joint Negotiating Team worked with Moderna to get [REDACTED] A discussion on liability was planned for early next week.

As a general point, the [REDACTED]

[REDACTED] Commission noted that it was important that Member States make it clear whether or not they wanted to consider these vaccines within the scope of the EU procurement scheme and, if so, the volume they were interested in purchasing and the price they were willing to pay. Without this information it would be difficult to make progress in these negotiations.

The Commission reiterated that a diversified portfolio of vaccines would allow the Member States to purchase the needed quantity of vaccines from the producer with a successful vaccine. [REDACTED]

The Commission made a short point on liability, mentioning that the indemnification clause works when the use and deployment of the vaccine occurs on the basis of a market authorisation. There are three situations:

- If Member States temporarily authorise the distribution of a medical product which has not yet received market authorisation, the product is not put into circulation following the intention of the producer; [REDACTED]

- [REDACTED]

with the exception

- After the market authorisation has been granted, may not be necessary, as the rationale for it is no longer applicable.

Update on meetings held with smaller producers

The Commission is working with a number of other vaccine producers to shape their proposals for the Commission vaccine scheme. Producers are being asked to provide material presenting their vaccine, available data, clinical trials plans, and manufacturing plans. These will be circulated to the Steering Board. The Commission will update the Steering Board with more details during the next Steering Board meeting, with the aim of having a discussion on how to handle these proposals. Although some of these producers may be operating at a smaller scale, it was noted that we might consider boosting the overall capacity of the EU by supporting some of them.

Tour de table on update/completion of estimated numbers of people for vaccination

The co-Chair pointed that several Member States already submitted their estimates for vaccines, however some data were missing.

There was a little *tour de table* of Member States, providing additional missing data, as presented in the table below:

Member State	Number of priority group	% of priority groups accept vaccination	Estimated number of people for vaccination
Austria			
Belgium			
Bulgaria			
Croatia			
Cyprus			
Czech Republic			
Denmark			
Estonia			
Finland			
France			
Germany			
Greece			
Hungary			
Ireland			
Italy			
Latvia			
Lithuania			

Luxembourg					
Malta					
Netherlands					
Poland					
Portugal					
Romania					
Slovakia					
Slovenia					
Spain					
Sweden					
ESTIMATED TOTAL. (status of 10th July 2020)					

The co-Chair encouraged the Member States to revise the priority groups and to submit the final estimates on vaccines. The estimated total should be considered as a minimum quantity for the negotiation contracts.

In reply, the Commission mentioned that the quantity of vaccine has a ceiling and will be distributed to the Member States based on a pro rata.

Update [redacted] on GAVI and COVAX

The representative of [redacted] provided a presentation on the COVAX facility managed by GAVI.

The COVAX facility has two parts: for self-financing, high income and upper-middle-income countries and for lower-middle-income and low income countries.

The participating self-financing, high income and upper- middle-income countries (which would include EU countries) have to commit to purchase doses for [redacted] % of their population and to contribute with data to the global repository. Additionally, they would have to provide [redacted] payment of [redacted] % of their commitment, based on which the facility would enter into the agreement with the manufacturers on behalf of all countries.

Following a round of questions and discussions, the co-Chair emphasised the importance of respecting the EU commitment under ESI instrument, the commitment of the Members States towards the Agreement on the Covid-19 vaccines and the need for a common approach of the Member States to GAVI and COVAX facility.

The Commission encouraged Member States to be mindful and supportive of the external dimension, in particular as regards support to least developed countries. Nevertheless, in terms of negotiating process, the Commission stressed the importance of avoiding [redacted] and parallel negotiations with the same companies for the same beneficiaries (the EU population).

Presentation by [redacted] on principals of pricing philosophy

Due to an exhaustive discussion of the other points of the agenda, this presentation has been postponed to the next meeting.