



COVAX

THE SHAREHOLDERS COUNCIL MEETING (“THE COUNCIL”)

14 October 2021

Virtual meeting

1. Welcome, Introductions and Headline Updates

- 1.1 Noting that the meeting had been duly convened, the Shareholders Council meeting commenced at 13.00 Geneva time on 14 October 2021. Dr Chrysoula Zacharopoulou chaired the meeting.
- 1.2 The meeting did not have quorum. In accordance with the COVAX Shareholders Council Operating Procedures, the meeting could proceed at the option of the Co-Chairs, however no decisions could be made.
- 1.3 Dr Zacharopoulou welcomed the Council members and speakers and introduced the agenda, which included an update on the latest COVAX developments from Seth Berkley, CEO; the revised country participation model for self-financing participants for 2022; as well as the latest vaccine development strategy, advice on booster doses and the COVAX 2022 strategy.
- 1.4 The Chair invited Dr Gabriel Mesa Nicholls, Adviser on COVAX to Shareholders Council Co-Chair Minister Fernando Ruiz, to say a few words on behalf of Minister Ruiz who was unable to join the meeting due to an unavoidable commitment. Dr Mesa Nicholls indicated that following consultation with the Upper Middle Income country grouping, his constituency had brought several messages to the Gavi Board at its meeting on 28 September 2021 including on challenges, such as the lack of timely communication, delays in deliveries of doses, and the need to increase accountability. He also highlighted opportunities for COVAX for the future, including the importance of: i) safeguarding flexibility of the mechanism to allow response, ii) advancing in the creation and strengthening of local production, and iii) guaranteeing supply through redistribution via donations, exchange and resale scenarios.
- 1.5 He encouraged countries to work towards the global 70% COVID-19 vaccine coverage target but flagged that supply management was an ongoing issue and booster doses were still a matter to consider.

- 1.6 He also noted the continued need for COVAX and WHO to address the lack of global recognition of vaccines within the COVAX portfolio that had been approved for Emergency Use Listing (EUL) by WHO and the impact of this on population confidence.
- 1.7 Dr Zacharopoulou summarised the points that she had made to the Gavi Board on 28 September 2021. First, on dose sharing, she highlighted the intensification of countries participating in this mechanism and gave the example of the European Union, but noted this effort still needs to be accelerated. She also indicated that COVAX despite being a major procurer of doses had been deprioritised by manufacturers. She expressed her wish that COVAX and Self-Financing Participants would act to influence industry to prioritise COVAX. She also noted the need to coordinate with other regional actors such as the Africa Vaccine Acquisition Task Team (AVATT) to ensure that doses are directed where they are needed most.
- 1.8 On the participation model, she had highlighted to the Board that the COVAX Facility should remain inclusive for all countries wishing to participate.
- 1.9 In terms of manufacturing, she had insisted to the Board that COVAX work together with other key players in manufacturing, including the European Union and United States, on matters relating to production of vaccines and ancillary materials, particularly with respect to any new Task Forces working on this issue.
- 1.10 Seth Berkley, CEO, welcomed the participants and provided some high-level updates on the COVAX Facility progress, noting that, to date, the Facility has raised US\$ 10.9 billion, and had signed agreements with 11 vaccine candidates. He noted that COVAX is expected to allocate 1.43 billion doses for delivery by the end of the year.
- 1.11 He noted that dose sharing has been successful, with 400 million doses delivered, but the challenge has been getting adequate shelf life for those doses.
- 1.12 On delivery, he noted delays in meeting the target, with only 94% of participants having received their first shipment of doses against the June 2021 target of 100% of participants. He explained that over 364 million doses were delivered by the end of September 2021, making September the month with the highest number of doses shipped by the Facility to date.
- 1.13 He noted there was continued risk to the supply pipeline for 2021. He highlighted that India is expected to resume export of COVID-19 vaccines towards the end of October 2021 which would be critical to increase the supply base. However there is still uncertainty around timelines for some key regulatory approvals.

- 1.14 In relation to allocation rounds, Dr Berkley explained that the remaining November-December portion of confirmed Q4 supply is presently being run as rounds 8 and 9, and outcomes will be announced shortly.

2. Revised Country Participation Model

- 2.1 Santiago Cornejo, Director, Country Engagement, Office of the COVAX Facility, outlined key areas of focus for the Self-Financing Participant model for 2021 (SFP1) and the revised country participation model for 2022 (SFP2). He encouraged countries to sign a Framework Agreement if they wish to procure doses in 2022. He also presented key areas under consideration for economies who do not wish to procure but wish to continue engagement with COVAX.
- 2.2 Aurelia Nguyen, Managing Director, Office of the COVAX Facility, presented on the governance structure for COVAX following the Gavi Board's decision in June 2021 to continue with Gavi administering the COVAX Facility. She noted that through a consultation exercise following the Board, no major changes had been proposed to the COVAX structure.
- 2.3 She reviewed the changes that would be required to the Terms of Reference for the Shareholders Council to reflect the revised participation model and to guarantee inclusivity.
- 2.4 Ms Nguyen also noted that the Shareholders Council may wish to update its Operating Procedures to reflect the revised participation model, for example around frequency of meetings or use of closed sessions.

Discussion

- Council members expressed support for the proposed approach to the revised participation model.
- With respect to the proposed changes to the Terms of Reference, Council members noted these adhered to the discussions so far about building in inclusivity, flexibility and stability.
- One Council member indicated a special interest in holding a discussion at an upcoming meeting on best practice and lessons learned on approaches to immunisation policy.
- With respect to the use of closed sessions in 2022 to treat commercially sensitive information for procuring countries only, one Council member recognised these might be necessary for practical reasons but encouraged COVAX to be as open as possible with information, so all participants have the opportunity to make informed purchasing decisions. The Secretariat clarified the intention was to be as transparent as possible.

- Council members also queried when countries might have further information about delivery of doses and donations, and the terms associated with each, and about handling of unused funds. It was clarified that COVAX would be communicating shortly about additional doses available for November and December, and for early 2022. For doses that were allocated in 2021, the fulfilment would be according to the terms already signed.
- With respect to the documentation required to continue engagement as a non-procuring economy, it was clarified that there will not be a requirement to sign a new framework agreement. As part of the closure documentation for SFP1, there will be documentation about continued engagement in SFP2.
- One Council member asked for additional detail on the process to select Council members to sit on the Gavi Market-Sensitive Decisions Committee (MSDC). The current appointments end 31 December 2021 and there will be a process announced regarding reappointment.

3. COVAX Pillar 2022 Strategy

- 3.1 Kate O'Brien, Director, Immunization, Vaccines & Biologicals, World Health Organization, provided a recap of the COVID-19 global vaccination strategic vision. She referred to the COVID-19 vaccination targets to reach 70% coverage of the world's population by June 2022 noting that the first of the interim targets had been missed with several countries not having access to COVID-19 vaccines.
- 3.2 She presented the purpose of these targets and noted their stepwise approach, whereby older adults and high-risk populations are prioritised as a first step, moving to all adults and finally to adolescents. She noted that the strategy is a live document and would be updated as necessary.
- 3.3 She highlighted key challenges to achieving the coverage targets, notably: i) ensuring sufficient financial and programmatic resources for procurement & delivery, and ii) guaranteeing equitable access to COVID-19 vaccines by all countries across income groups.
- 3.4 On boosters, Dr O'Brien summarised the rationale that will be assessed by SAGE for boosters and additional doses including consideration of waning protection, inadequate protection, and the COVID-19 variants.
- 3.5 She presented the SAGE/WHO recommendations on providing additional doses for immunocompromised persons, and for older persons who received inactivated vaccines (Sinovac/Sinopharm) and referred to the WHO interim statement on boosters.

- 3.6 Noting that current COVID-19 vaccines maintain substantial effectiveness against severe disease with modest waning over 6 months, she concluded that, while data on waning effectiveness are still emerging, it should be expected that effectiveness against severe disease may wane further in the longer run.
- 3.7 Aurélia Nguyen, Managing Director, Office of the COVAX Facility, presented the COVAX pillar strategic priorities and ambition levels. She noted that building on the WHO strategic vision, the overall aim for COVAX in 2021 is to accelerate the end of the acute phase of the pandemic, while in 2022 the Facility is shifting to supporting participants' needs and ambitions to control the disease and reopen society.
- 3.8 She outlined the principles of the COVAX Facility coverage objectives for 2022 and noted that the Facility proposes to: i) support the participants ambitious goals of vaccination, ii) complement supply through bilateral and multilateral collaboration, and iii) pursue flexibility by continuing to invest in increased coverage and establishing a contingency pool to address risks and uncertainties in 2022.
- 3.9 She concluded by highlighting the Facility's focus areas for 2022 and reiterated that the collaboration and support from all stakeholders would be critical in helping the Facility achieve its targets and ambitions.

Discussion

- One Council member queried how the COVAX strategy ties in with the role of therapeutics in the pandemic response, and how to best equip countries to use a combination of vaccination and therapeutics to manage the impact of the pandemic. It was clarified that therapeutics are important components to the response, as are diagnostics, and that COVAX is carefully monitoring developments in both areas. It was noted that COVAX is using the Access to COVID-19 Tools Accelerator (ACT-A) coordination mechanism for this, but that it is already looking as though the interdependencies will be complementary.
- On the question of dose sharing, Council members discussed the possibility of establishing a dose sharing working group to consider efficiencies. It was acknowledged that having multiple vaccines available in country makes it very difficult to run an efficient programme. The Secretariat indicated that a working group on this topic would be welcome.
- One Council member advised that it would be important to include dose sharing in the COVAX strategy for 2022 given the considerable importance of donations to date. It was clarified that dose sharing has been included, but as a complementary component to the doses secured through Advance Purchase Agreements (APAs), given the important role of the latter in building in resilience and flexibility to the portfolio.

- With regard to the impact of boosters and additional doses on the market, it was clarified that COVAX will continue to focus on primary series, informed by WHO recommendations on boosters. It will be important to continue to actively manage the portfolio and make sure it retains flexibility to address developments in evidence and policy recommendations from WHO on this issue.
- One Council member shared the experience and evidence being generated in a cohort study of effectiveness of four different vaccines in Colombia that showed decline in protection in older populations across all vaccines. It was clarified that WHO is drawing on such emerging evidence as it become available.

4. Manufacturing Task Force

- 4.1 Matthew Downham, Sustainable Manufacturing Lead, Coalition for Epidemic Preparedness Innovations, presented on the work of the COVAX Supply Chain & Manufacturing Task Force.
- 4.2 He reviewed the vision, objectives and three key workstreams of the Task Force on: i) Supply Input Efficiency that is intended to facilitate global free flow of critical supplies for vaccine manufacturing, including through the creation of the COVAX Marketplace platform; ii) Maximising Mid-Term Supply Availability, which concluded work this month; and iii) Sustainable Manufacturing (in lower middle-income countries) to expand capabilities of existing manufacturers in lower- middle-income countries (LMICs) and establish sustainable capacity in regions with no significant capacity.

Discussion

- Council members acknowledged this is an ambitious effort and expressed support for the work of the Task Force.
- It was noted that the creation of the mRNA tech transfer hub in South Africa, with the engagement of the Medicines Patent Pool, is an important development.
- It was also noted that it will be important to have a holistic and global approach and to bring in all ACT-A stakeholders as appropriate in this work.
- One Council member queried what type of support might be needed from Council members. It was clarified that support would be useful moving forward in the area of training, of sharing of skills, and of free flow of goods of key consumables, and providing championing/political support.
- One Council member asked about the response that COVAX has had from manufacturers from requests for more transparency. It was clarified that

while in principle, manufacturers are supportive, it is still difficult to get that visibility on the supply schedule. It is one item that needs collective advocacy and action.

- On the COVAX Marketplace, one Council member asked whether there were more matches expected beyond the three that have taken place. It was clarified that several other matches are expected.
- One Council member commented that the governance of the mechanism within the region is linked to sustainability. It was flagged that this Task Force was founded by the COVAX partners, together with the Bill & Melinda Gates Foundations and three trade associations. They feed into the ACT-A vaccine manufacturing working group that adds to the governance and direction of the Task Force.

5. Summary, Takeaways and Closing Remarks

- 5.1 Aurelia Nguyen, Managing Director, Office of the COVAX Facility, provided a summary of the meeting ‘takeaways.’
- 5.2 In her closing observations, Dr Zacharopoulou thanked all stakeholders, with a particular expression of gratitude for José Manuel Barroso, Gavi Board Chair, for his facilitation of the request for more dialogue between COVAX and the Gavi Board.
- 5.3 The Co-Chair noted the next Shareholders Council is scheduled for 8 December 2021 with interim briefings and meetings to be scheduled as needed.
