

THE SHAREHOLDERS COUNCIL MEETING ("THE COUNCIL")

18 March 2021

Virtual meeting

1. Welcome and Introduction

- 1.1 Finding a quorum of delegates present, the Shareholders Council meeting commenced at 13.00 Geneva time on 18 March 2021. Ms Sarah Goulding, Gavi Board Vice-Chair, chaired the meeting.
- 1.2 The Chair welcomed the Council members and speakers and introduced the agenda. After paying a customary Australian tribute to the Indigenous peoples, she invited Seth Berkley, Gavi CEO, to present his opening remarks.

2. COVAX Facility Updates

Developments since last meeting

- 2.1 Dr Berkley thanked the Council members for their contributions to a significant milestone in what is expected to be the largest deployment of vaccines in history, with the delivery of approximately 30 million doses of COVID-19 vaccines to 51 countries across 5 continents through the COVAX Facility to date. He updated participants on progress since the January meeting, namely, the approval of allocations to the Advance Market Commitment (AMC) economies; the introduction of the No Fault Compensation scheme for these countries; signed agreements with manufacturers and further ongoing negotiations; and assessment of additional candidates for inclusion in the COVAX Facility portfolio.
- 2.2 Dr Berkley addressed the concerns around the AstraZeneca (AZ) vaccine, stating that current guidance from the European Medicines Agency (EMA) and WHO is that the benefits continue to outweigh the risks. He concluded by thanking the donors for their recent pledges to the Advance Market Commitment (AMC), bringing the total funds raised to US\$ 6.3 billion.

Update on Supply and Deals

- 2.2 Aurélia Nguyen, Managing Director of the COVAX Facility, updated the Council on the supply and vaccine portfolio. It currently includes seven vaccine candidates with signed Advance Purchase Agreements for 1.3 billion doses and MOUs to secure at least 2 billion doses across 2021 and early 2022. She reported ongoing work to include new vaccine candidates in the COVAX portfolio, sourced from the CEPI R&D portfolio and directly from manufacturers, and the increasing number of regulatory approvals granted by the WHO for Emergency Use Listing (EUL).
- 2.3 Ms Nguyen reminded the meeting that 255 million doses of the AZ vaccine from the Serum Institute of India (SII-AZ) and the Pfizer/BioNTech vaccine would be allocated by the end of May 2021. Based on current forecasts, the COVAX Facility would be able to secure approximately 485 million doses, in line with the original demand expressed by Self-Financing Participants (SFPs). The delays in supply schedules that have been observed are linked to regulatory requirements and manufacturing and delivery issues, but the Facility is monitoring these developments and ensuring that adequate mitigation measures are put in place.

Allocation and Shipment

- 2.4 Kate O'Brien, Director, Department of Immunization, Vaccines and Biologicals, WHO, briefed the Council on the two allocation rounds and key milestones since January 2021.
- 2.5 Ann Ottosen, Senior Manager, Vaccine Centre, UNICEF Supply Division, walked the Council through relevant activities, processes and milestones that take place once allocated doses are communicated and vaccines become available in a country. The economies are required to enter into an indemnification liability agreement with the manufacturer. Participants can procure directly or through UNICEF or PAHO. In either scenario, to be able to import and deploy the doses, the economies need to demonstrate their readiness and ensure that necessary regulatory approvals are granted, import licenses issued, purchase orders placed with the manufacturer, freight booked and insurance provided.
- 2.6 Ms Ottosen presented the UNICEF <u>COVID-19 Vaccine Market Dashboard</u>, a live document showing the map of countries and vaccine supply information. She acknowledged the ongoing learning process to accelerate delivery of doses in countries and that up-to-date information and effective communication are critical. The WHO has developed the <u>COVID-19 vaccine introduction toolkit</u> to support the economies with deployment of COVID-19 vaccines in country.

New variants

2.7 Melanie Saville, Director of Research and Vaccine Development, CEPI, presented the emerging COVID-19 variants, which may impact the effectiveness of vaccines, transmission and severity of COVID-19. These are

- being carefully monitored by the COVAX partners and their impact on the COVAX 2021-2022 Strategy assessed. Ms Seville noted that the WHO Strategic Advisory Group of Experts (SAGE) currently recommends the continued roll-out of existing vaccines.
- 2.8 Dr O'Brien outlined the usual process of vaccine safety surveillance, and the additional measures taken during a pandemic. COVID-19 requires real-time assessment of safety, with daily intelligence reviews, digital scanning of press and social media, expert committee review and assessment, communication through public briefings and policy recommendations through SAGE.
- 2.9 Dr O'Brien commented on the recent suspension of AZ vaccinations by several countries. She reassured the Council that the WHO remains in close contact with the European Medicines Agency (EMA) on vaccine safety and reiterated the WHO recommendation to continue AZ vaccinations, the benefits outweighing the risks.

Finances

- 2.10 Santiago Cornejo, Director, Country Engagement, Office of the COVAX Facility, reminded the Council about the overall financial structure of the COVAX Facility.
- 2.11 Ian MacTavish, Director, Finance & Chief Accounting Officer, presented a financial update, the COVAX Facility reporting mechanism and the latest information on the utilisation of the upfront and down payments.

Discussion

- 2.12 The Council members congratulated the COVAX Facility on its successful rollout of vaccines and reiterated their commitment to equitable access to COVID-19 vaccines. Numerous questions and some concerns were raised by participants, prompting the following clarifications by speakers:
 - Allocation: The Secretariat reported that the next allocation round for Pfizer/BioNTech doses would be communicated within the coming weeks. Current allocation of AZ doses is until May 2021, with the next allocation round to be communicated in due course.
 - The COVAX Facility is bound by the principle of fair and equitable distribution of COVID-19 vaccine across all participants, with dose allocation proportionate to the country population size. The allocation algorithm takes into account equity, consistency of vaccine products and vaccine preferences but also has to factor in minimum shipment sizes. The proposed allocation is reviewed by the COVAX Independent Allocations of Vaccines Group, to ensure that the process is fair and does not disadvantage any countries.

- Delivery schedules and logistics: In response to concerns about deliveries, the Secretariat explained that the new AZ supply chain had experienced some teething problems causing logistical bottlenecks but that vaccines should be delivered to all pending participants within the next 3 weeks. Acknowledging the acute pandemic, the Secretariat reported ongoing dialogues with those countries that have not yet received their allocated doses. Availability of flights remains a key factor in determining the sequence of shipments.
- Vaccine expiration: In view of the 6-month expiration of vaccines, the
 importance of early operational planning and country readiness was
 stressed, especially for the AZ vaccine which requires an 8 to 12-week
 interval between doses. Countries were advised to consider using all
 doses for the first round across a wider population, rather than reserving
 stock for a second dose based on the public health benefit.
- COVAX Facility Strategy: The Secretariat welcomed the proposal to review the future strategy of the COVAX Facility at the next Shareholders Council meeting in May.
- Partnerships: In response to a question about how governments might support the Get One Give One initiative, the Secretariat reported that it had already initiated discussions to explore how this might be leveraged for the COVAX Facility. These initiatives encourage people who have been vaccinated to make donations to others.
- Export restrictions: Dr Berkley called upon all countries to play a role
 in advocating the free flow of vaccines, to facilitate the export and supply
 of vaccines worldwide and to encourage manufacturers to ensure an
 equitable vaccine supply.

3. COVAX Facility Design

Dose-Sharing

3.1 Ms Marie-Ange Saraka-Yao, Managing Director, Resource Mobilisation, Private Sector Partnerships & Innovative Finance, presented the dose-sharing mechanism. It was launched in December 2020 to fast-track access to vaccine doses, accelerate and deepen coverage by supplementing already funded doses, redistributing excess doses and bringing additional doses to countries in an equitable and efficient way. Ms Saraka-Yao expressed her appreciation to the countries already engaged in the operationalization process of the dose sharing mechanism.

COVAX Exchange

3.2 Aurélia Nguyen introduced the principles underlying the COVAX Exchange, a mechanism for redistribution of doses that provides participants with an

avenue to further optimise their allocations of vaccine through mutually agreed transactions. The launch of the COVAX Exchange is foreseen in Q3 2021 subject to favourable feasibility and proof-of-concept studies.

COVAX Humanitarian Buffer

3.3 Sanne Wendes, Lead, Design & Operationalisation, Office of the COVAX Facility, provided a brief update on the COVAX Humanitarian Buffer, a last resort mechanism, designed to ensure access to COVID-19 vaccines for high-risk populations in humanitarian settings. She presented the eligibility criteria for the Buffer, which aims to make available 5% of COVAX doses and AMC funding to eligible populations, pending Board approval.

Discussion

- 3.4 The Council members congratulated the Facility on the remarkable results achieved though the COVAX AMC and on the doses delivered to date. In response to the questions raised by the Council, the Secretariat provided the following clarifications:
 - Dose-sharing: Several participants applauded the mechanism and encouraged firm commitments to doses sharing as early as possible. The Secretariat accepted the UK's offer to convene a working group for this purpose.
 - COVAX Exchange: The members welcomed the COVAX Exchange mechanism, recognized its value but sought further clarification on how it would work, who would be conducting the studies and how the Council would be involved. There was a proposal to consider various options for in-kind exchange and to maintain flexibility in terms of participation and exchange conditions, ensuring that multilateralism would be central to Exchange efforts.
 - COVAX Buffer: Members were reminded that the COVAX Buffer is a measure of last resort for those priority populations that were not included under national deployment and vaccination plans.

External Communication

3.5 In the interest of time and prioritisation of agenda items, the Chair proposed that this item be deferred to the next meeting of the Shareholders Council. This was accepted by the members.

4. Closing remarks

4.1 Following a summary of the meeting 'take aways' by Aurelia Nguyen, Dr Berkley reflected on the complexity of the global COVAX efforts and

- anticipated a move to a much larger scale of operations before the next Council meeting in May.
- 4.2 The Chair extended her thanks to the Council participants and partners for their collaboration to support the goal of equitable access to safe and effective COVID-19 vaccines through the COVAX Facility, recognising that significant work and challenges lay ahead. After determining that there was no further business, the Chair closed the formal meeting.
