Minutes

COVAX FACILITY ADVANCE MARKET COMMITMENT ("AMC") ENGAGEMENT GROUP MEETING

17 March 2021
Virtual meeting

1. Welcome and Introduction

1.1 Finding a quorum of members present, the meeting commenced at 13.02 Geneva Time. Minister Retno Marsudi, COVAX Advance Market Commitment (AMC) Engagement Group Co-Chair, opened the session.

1.2 Co-Chair Marsudi welcomed the AMC Engagement Group participants and thanked Gavi donors and partners for their support. She highlighted the importance of ensuring equitable access to COVID-19 vaccine for all, and noted the progress achieved so far. The Co-Chair highlighted key challenges and emerging questions, including supply constraints; the impact of COVID-19 variants; logistical bottlenecks; vaccine safety issues; vaccine export restrictions and the cost-sharing mechanism.

1.3 Co-Chair Lia Tadesse recognised the encouraging COVAX achievements and the important role of the AMC Group in identifying the critical challenges faced by countries.

1.4 Co-Chair Karina Gould acknowledged the progress achieved since the last meeting in January 2021, with vaccine deliveries to many countries, but noted the importance of addressing the remaining challenges and hearing from countries.

1.5 Brenda Killen, Director of Governance, proposed that the agenda item on External Communication be postponed to the next meeting, to allow more

discussion time on important COVAX updates. This was accepted by the meeting.

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2. COVAX Facility updates

2.1 Seth Berkley, CEO, provided updates from the COVAX Facility since the last AMC Group meeting. He noted that COVAX is undertaking what is expected to become the largest deployment of vaccines in history. In less than three weeks, and at the time of the meeting, COVAX deliveries had reached 42 participants and delivered 28.35 million doses. He highlighted the magnitude of this collective effort and thanked the donors for their generosity which made these achievements possible.

2.2 Dr Berkley stressed the need to maintain transparency while dealing with challenges, amongst them the recent suspension of the AstraZeneca (AZ) vaccine roll-out in multiple countries. COVAX is actively monitoring this situation and awaiting news from WHO's Global Advisory Committee on Vaccine Safety (GACVS). At the time of the meeting, the benefits of the AZ vaccine continued to outweigh potential risks, in line with current guidance from the European Medicines Agency (EMA) and WHO. COVAX is committed to the safety of all vaccines in its portfolio - and those it is considering bringing into the portfolio - and is continuing to track developments on all COVID-19 vaccines very closely.

2.3 Dr Berkley highlighted that 43 days after the first UK vaccination, COVAX had delivered doses to India, the first country where the COVID-19 vaccine was approved, followed by Ghana and Cote d'Ivoire. A first wave of small quantities of the Pfizer vaccine had been allocated to 18 countries. Of the AMC92 economies, 86 have submitted their National Deployment Vaccine Plan (NDVP) for review. He briefly touched on Indemnity and Liability (I&L), the No Fault Compensation scheme, allocation and supply, as well as the Memorandum of Understanding (MoU) with Novavax for 1.1 billion doses. He recognised the importance to countries of predictability and noted that the Facility endeavours to provide the best available information, given the constant changes at the global level.

2.4 Dr Berkley highlighted recent pledges, including Euro 980 million from Germany and Euro 500 million from the European Union, in addition to support from the US, bringing the total AMC funds raised to US$ 6.3 billion. He concluded by referring to the fast moving and changing agenda, noting that COVAX will continue to consider all vaccines that meet the standards, and will strive to deliver as many vaccines as possible to countries.

2.5 Aurélia Nguyen, Managing Director, Office of the COVAX Facility, provided an update on supply and deals. On the pipeline of COVID-19 vaccines, she noted that the number of candidates entering clinical development keeps growing, with up to 81 candidates at the time of the meeting. COVAX is engaging with the majority of the most advanced candidates that are being

assessed for inclusion in the portfolio by the Independent Product Group (IPG).

2.6 She noted that three vaccines had been granted WHO Emergency Use Listing (EUL), namely: the AZ/University of Oxford vaccine; the Pfizer/BioNTech mRNA vaccine; and Janssen's adenoviral vector vaccine. These are already part of the COVAX portfolio which includes seven candidates, with signed Advance Purchase Agreements for 1.3 billion doses, and signed MOUs that will bring the portfolio to at least 2 billion doses across 2021 and 2022. The Novavax vaccine candidate has been added to the portfolio. Novavax has committed to equitable access and engaged in a technology transfer partnership with the Serum Institute of India (SII) to collectively supply COVAX with 1.1 billion doses.

2.7 Additional candidates are being assessed for inclusion in the portfolio and being sourced from the COVAX Research and Development (R&D) portfolio, which is managed by the Coalition for Epidemic Preparedness Innovations (CEPI), and directly from the approximately 30 manufacturers that responded to the UNICEF/PAHO request for proposals. Discussions with three of these manufacturers about supplying an additional 600 million doses to COVAX are ongoing. On the global supply forecast for 2021, she noted that approximately 100 million doses would be available in the first quarter; almost 500 million doses by the end of the first half; and almost 2.3 billion doses by the end of the year.

2.8 Furthermore, she noted that the approximately 255 million doses available by the end of May 2021 from the first wave have now been allocated among all eligible participants. The allocation of Pfizer vaccines doses for the second quarter of 2021 would be communicated the week following the meeting. The Facility has sight of approximately 1.8 billion doses for AMC countries by the end of 2021, which would significantly exceed the 20% coverage if delivered. Of the 1.8 billion doses, current AMC funding will support the procurement of about 1.3 billion doses, leaving approximately 500 million additional doses that could go to AMC participants, depending on future AMC fundraising or the ability of AMC countries to cost-share. She highlighted that the longer-term forecasts are not risk-adjusted, and that such factors as changes in deal terms, manufacturing performance and yields, regulatory success and delivery timelines must be taken into account.

2.9 Finally, she noted that all buyers are facing delays to supply schedules due to regulatory, manufacturing and delivery issues. Given these uncertainties, COVAX cannot operate with the level of accuracy and predictability that Gavi countries expect from Gavi's regular non-COVAX programmes. The Facility is actively monitoring developments, including possible export bans out of India, and using all possible levers to unblock bottlenecks and ensure supply to participants as quickly as possible, while maintaining transparency.

2.10 Claudia Nannei, Senior Technical Officer, WHO, outlined four allocation milestones, noting that available products had already been allocated, and allocation was in progress for products awaiting WHO EUL. Indicative figures were made available in January for the amounts countries can expect to receive in the first 6 months of 2021.

2.11 She noted that the first wave, which included the allocation of a small number of Pfizer vaccines to 18 participants, was largely a learning experience. The second round, from January to May 2021, will allocate 250 million doses of AZ and SII products to 142 countries. She highlighted that doses are allocated to countries willing to receive and ready to deploy vaccines. Discussions are ongoing with the IPG on the allocation of the Pfizer vaccine that could be made available for the third round. The number of doses and participants are still to be confirmed.

2.12 Ann Ottosen, Senior Manager, UNICEF**,** provided an outline of the supply chain from vaccine allocation to in-country shipment. A number of requirements must be fulfilled by AMC economies, including I&L agreements (for the first allocation of each vaccine to that country), regulatory approvals, and import licenses, before UNICEF and PAHO can place an order with the manufacturer. Other key steps include provision of export licenses by governments and freight arrangements.

2.13 Currently, vaccines have a six-month shelf life which means that, in the event that an allocation has been made but no purchase order placed within a certain time limit, doses could be re-allocated to other countries. Ms Ottosen provided an outline of vaccine delivery on the global level and plans for shipments in the next 7 days, noting that the number of countries changes on a daily basis and can be tracked on UNICEF's website.

2.14 Key lessons emerging from the first allocation round were presented. Finally, she referred to a COVID-19 vaccine introduction toolkit, a 'one-stop shop' for guidance, resources, tools and training, and provided a link to this toolkit for participants.

2.15 Kristine Rose, R&D Project Manager, CEPI provided an update on the emergence of new COVID-19 variants. She noted that COVID-19 mutations are to be expected, however WHO has designated three variants of particular concern. At this stage, the recommendation from SAGE is to continue with existing vaccines that have been proven safe and efficacious. She highlighted that vaccine manufacturers are beginning to evaluate second generation vaccines and boosters, and regulators are considering how these might be approved. COVAX partners are monitoring this issue carefully and the potential need to modify the COVAX portfolio.

2.16 Kate O'Brien, Director, Department of Immunisation, Vaccines and Biologicals, WHO provided a general brief on safety surveillance of vaccines. She noted that the risks associated with any vaccines are not fully known when granting full licensure or emergency-use listing. This is particularly true for COVID-19 vaccines that are granted EUL based on data

that is deemed sufficient for the vaccines to be deployed in the context of emergency use. As COVID-19 vaccines are being rolled out globally and being administered to elderly and frail persons, it is expected that there will be signals which require evaluation, and a proactive approach to safety monitoring.

2.17 She then presented in detail the process of vaccine safety surveillance in normal times, from the moment that adverse events occur, to actions required at all levels. She underlined that signals may relate to the product itself but also to its administration, such as contamination of vials. In the current pandemic context, additional measures have been put in place, including daily intelligence reviews, exchange and collaboration with regulatory networks around the world and real-time signal assessments conducted by WHO's GACVS. As assessments are performed and evidence continues to grow, safety signals are either resolved or continue to be closely monitored, which may lead to revised recommendations.

2.18 Dr O'Brien provided an outline of the WHO COVID-19 vaccine safety strategy, including the GACVS subcommittee reviews of emerging signals; the daily situation 'huddles', and the WHO global database. As of 14 March 2021, 250 safety reports had been submitted; however, it was important to note that a safety report is not necessarily a safety event.

2.19 With reference to thromboembolic events following vaccinations with the AZ vaccine, she noted that these reports are temporally associated with the vaccination but they are not necessarily associated with, or caused by the vaccination. Thromboembolic events are known to occur frequently, and venous thromboembolism is the third most common cardiovascular disease globally. WHO is in regular contact with the EMA and regulators around the world, and awaits the review and assessment of these safety events. However, WHO, along with the EMA, considers that the benefits of the AZ vaccine outweigh its risks and recommends that vaccinations should continue.

2.20 Marie-Ange Saraka Yao, Managing Director, Resource Mobilisation, Private Sector Partnerships & Innovative Finance, presented an outline of AMC fundraising, underlining the importance of advance capital to reserve and secure vaccine doses. She recalled that the COVAX AMC was launched at the Global Vaccine Summit in June 2020 and thanked the donors for providing immediate funds which allowed negotiations with manufacturers, helped secure vaccines and made developing enablers such as the I&L and the No Fault Compensation scheme possible.

2.21 She referred to the Group of Seven (G7) meeting which further garnered financial commitments to reach US$ 6.3 billion for vaccine procurement and US$ 778 million for delivery, which is critical and is complemented by support provided by partners and Multilateral Development Banks (MDBs) to support delivery. New challenges associated with the emergence of variants make it important for COVAX to continuously update its vaccine portfolio, improve the product pool and respond faster. COVAX is nearing

achievement of the first milestone towards reserving at least 1.3 billion COVID-19 vaccine doses, with an opportunity to access 500 million further doses in 2021.

2.22 She underlined the importance of having dynamic portfolio management, including different products with different pricing. With the goal of a fully funded AMC, the Secretariat will be bringing an investment opportunity in April 2021 to achieve full funding to cover all needs in 2021. She recalled that the AMC is a ten-year instrument, and flexibility to meet needs beyond 2021 is critical.

2.23 Jeremy Konyndyk, US Agency for International Development (USAID) announced that the US government will be co-hosting the COVAX AMC investment opportunity event with Gavi, expected to be in mid-April. This is to demonstrate the US government's commitment to COVAX and its desire to see further expansion of COVAX support.

Discussion

- On queries related to products with WHO EUL or stringent regulatory authority authorisation, and products that are in the process of achieving such licenses, it was underlined that the Facility is committed to providing products that meet international standards for safety, efficacy and production quality. This is demonstrated by regulatory authorisation either through the WHO EUL, or by a stringent regulatory authority. A number of products are still in the process of WHO EUL; the process can only go as fast as manufacturers can provide and submit data. It was noted that WHO makes available on its website the products of manufacturers that are engaging with WHO. Manufacturers were urged to prioritise their work with the WHO EUL process to unlock these products.

- In relation to the expiration date of COVID-19 vaccines, it was noted that all products currently have a 6-month expiration time window. This is expected to increase as manufacturers obtain more information about the stability of their products. Particularly on AZ products, WHO recommends an interval of 8-12 weeks between the two doses, based on evidence that efficacy improves when doses are spread out. It was clarified that WHO recently issued operational guidance recommending to countries receiving AZ products but with supply shortages, that the first deliveries should be used for first doses across a wider population, instead of reserving stock for a second dose.

- The Secretariat noted the importance of having more predictable shipment timings beyond May 2021 and underlined the ongoing efforts to address each of the bottlenecks systematically, including import and export licenses. Countries will be updated with any new information. It was also noted that UNICEF provides a map showing the total number of doses delivered, doses ordered, and shipments due in the next 7 days. Providing longer-term visibility would be challenging, as the allocation model was based on the

best forecast from manufacturers, and this may change. This information can be tracked on the dashboard available on UNICEF website.

- In relation to bilaterally sourced products, the Secretariat clarified that the benefits of COVAX products and what the Facility has put in place vis-a-vis reviews from regulatory perspectives, I&L and the no-fault compensation scheme cannot be extended to products that have been sourced externally to the Facility.

- The Secretariat responded to a query on the possibility for countries to receive different vaccines, noting that as new vaccines are approved, there may be instances where other products are made available to countries, bearing in mind supply constraints in 2021. The Facility will strive to meet country needs and increase their coverage whether through one or several vaccines.

- In response to a query about cost-sharing and the ability of MDBs to meet these demands, the Secretariat reported a high level of interest from AMC participants in utilising domestic funding provided by MDBs to purchase additional doses. Discussions are ongoing with MDBs to define the structure of financing arrangements and no delays are foreseen.

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3. COVAX Facility Design

3.1 Santiago Cornejo, Director, Country Engagement, Office of the COVAX Facility, presented an outline on the cost-sharing process. He noted that AMC participants could purchase additional doses through COVAX via the cost-sharing mechanism, to supplement the doses that will be fully financed by the AMC. These doses will be fully financed by the participant, drawing on MDB financing, and will be in addition to, not replacing, each country's share of fully funded doses. By purchasing additional doses via the Facility, AMC participants will benefit from all the advantages of COVAX. AMC participants will also be able to align and streamline cost-sharing doses with the AMC-financed doses.

3.2 He noted that, according to the latest forecast for 2021, the Facility is expecting approximately 500 million additional doses beyond the 20% target. The timing of the supplies will be subject to supply constraints and the allocation mechanism. This pipeline now provides security to launch the cost-sharing process to all AMC participants.

3.3 In terms of process, countries will be requested to provide their demand, from which the Facility will calculate the aggregate demand and assess supply and fundraising requirements. The Facility will then inform the countries of the amount of doses that will be available in 2021-2022. He further noted that countries will be making legal and financial commitments to purchase these additional doses. The participants will be able to purchase doses once they are available, at the actual negotiated price by COVAX. Template letters will be communicated to countries after this meeting, with additional information.

3.4 Marie-Ange Saraka Yao, presented the Dose Sharing Mechanism. She recalled that the dose sharing principles were launched in December 2020 to encourage countries to share their excess doses with the Facility. Discussions with interested countries about operationalising the mechanism are ongoing. She noted that dose sharing is a means to accelerate coverage to high-risk populations or to extend recipient's coverage, building on the allocation mechanism. There are three approaches to dose sharing as follows: 1) Donation 2) Re-selling, and 3) Transfer of rights. She underlined the importance of the Facility taking title of the doses to facilitate the transfer from the manufacturers to the countries. To this effect, setting up a legal framework is ongoing, with a view to starting dose-sharing in early April.

3.5 Aurélia Nguyen presented the exchange mechanism. She noted that it could complement the COVAX allocation framework and the other tools such as the dose sharing mechanism, to optimise vaccine needs for participants, ensure efficient distribution of doses across countries and accelerate global access. COVAX participants will trade allocated doses with others, allowing each participant to optimise their individual needs. The priority is to work with countries to develop a model that will add value and not complexity.

3.6 She noted that the Facility intends to complete a feasibility study and proof of concept by the end of the second quarter of 2021, with the aim to launch the mechanism in the third quarter of the year. She noted the following important questions that need to be resolved: 1) The relative value of the exchange for different types of participants 2) The right timing to introduce the Exchange, so that participants benefit and COVAX can realise its objectives 3) The safeguards needed to mitigate the risk that the value of the COVAX portfolio might appear to be undermined 4) Any alternatives to a separate exchange to address evolving preferences. She concluded by noting that, overall, the aim is to have a mechanism that is simple and impactful.

3.7 Alya Dabbagh, Project Manager, WHO, provided a brief introduction to the No-Fault Compensation Programme. The Programme provides a rapid and fair no-fault lump-sum compensation in full and final settlement of any claims by individuals who suffer a serious adverse event resulting in permanent impairment or death associated with COVID-19 vaccine.

3.8 She noted that the key goal is to reduce the claims in courts and the need for AMC participants to indemnify manufacturers of COVID-19 vaccines which were procured or distributed through COVAX. The programme is being managed by an independent claims administrator, ESIS Inc. a subsidiary of Chubb, one of the largest global insurers, which operates in accordance with a publicly available protocol. The mechanism will be operational by 31 March 2021 and will have a fully operational web portal in English, French and Spanish. ESIS Inc is contacting the Expanded Programme on Immunisation (EPI) managers in countries to provide information and highlight the need to raise awareness.

3.9 Sanne Wendes, Lead, Design and Operationalisation, Office of the COVAX Facility, presented the COVAX Buffer. Pending approval of the Gavi Board of this mechanism, the Buffer aims to make available 5% of COVAX doses and AMC funding to ensure access to COVID-19 vaccine for high-risk populations in humanitarian settings that are not covered by national vaccination programs. The Buffer will also provide a contingency provision to enable an emergency release of doses to meet public health needs where normal allocation timelines may not be sufficient. The latest assessment is that the contingency provision will be rolled out once basic coverage is achieved across all COVAX participants.

3.10 Ms Wendes underlined that the first resort for providing doses to cover all high-risk groups, irrespective of legal status, as per the SAGE guidelines, is their inclusion in national vaccination plans. If unavoidable gaps in vaccination plans occur, the Buffer may be used as a last resort. All COVAX participants, both AMC economies and Self-financing participants (SFPs), will be eligible to apply for the Buffer. Countries will be requested to demonstrate clearly why the target population is not covered by the national vaccination plan, and what other attempts have been made to cover the gap. For AMC-eligible economies, doses granted through the Buffer will be both additional and AMC-funded, on top of their standard AMC allocated doses. Countries will be requested to demonstrate that the target population is 'new' or 'uncounted' in population statistics, such as irregular, undocumented, stateless populations. Humanitarian agencies will also be able to apply for the Buffer, contingent on a demonstrated gap in population coverage, the capacity to deliver, and the agency's experience with vaccination campaigns.

Discussion

- In relation to a query about the funds needed to increase coverage to 30% for AMC countries and funding from MDBs, the Secretariat clarified that, collectively, donor funds and domestic funding supported by MDBs could accelerate the access to 500 million doses with an estimate of US$ 3 billion. The proposal aims to obtain US$ 2 billion by donor funding and US$ 1 billion through MDB funding, including the World Bank. Discussions with MDBs and the World Bank are ongoing to fine-tune this arrangement. Discussions between the World Bank, Gavi and partners are ongoing to ensure that the World Bank funding is aligned to support delivery to countries. Challenges include having visibility on what MDB funding will cover in practice and when funds would become available.

- The Secretariat clarified that the allocation of doses for the second wave, including cost-sharing doses, will be through the allocation mechanism, to ensure a fair and equitable allocation and to ensure alignment with the AMC doses.

- On countries' participation in developing the design of the cost-sharing scheme, the Secretariat welcomed and encouraged interested parties to participate in the co-creation of the scheme.

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4. Summary and key take-aways and Closing Remarks

4.1 Aurélia Nguyen, Managing Director, Office of the COVAX Facility, presented the summary and key take-aways.

4.2 In his closing remarks, Dr Seth Berkley, Gavi CEO, emphasised the need to address the challenges at hand and highlighted the absolute necessity to sustain routine immunisations to continue preventing diseases. He noted that the Facility will keep the information flowing, and he looked forward to continuing working with COVAX participants on the largest multilateral mechanism since the Paris Climate Accord and the largest vaccine roll-out in history.

4.3 Co-Chair Retno Marsudi thanked the participants for their contributions and announced that the next AMC Group meeting would take place on 17 May 2021.

4.4 After determining that there was no further business, the meeting was brought to a close.