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

27 January 2021
Virtual meeting

1. Welcome and Introduction

1.1 Finding a quorum of members present, the meeting commenced at 11.05 Geneva time on 27 January 2021. Dr Lia Tadesse, COVAX Advance Market Commitment (AMC) Engagement Group Co-Chair, opened this session.

1.2 Co-Chair Lia Tadesse, Minister of Health of Ethiopia, welcomed the AMC Engagement Group ("The AMC Group") for their first meeting.

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2. Governance

Priorities from the Co-Chairs

2.1 Co-Chair Karina Gould, Minister of International Development, Canada, emphasised that access to timely information will be key to the success of the COVAX facility ("the facility"). She noted her enthusiasm to work with the AMC Group to contribute to the success of COVAX.

2.2 Co-Chair Retno Marsudi, Minister of Foreign Affairs, Indonesia, underlined three priorities, namely: 1) transparency, inclusiveness and ensuring transparent processes within the AMC Group 2) certainty on key issues such as the number of vaccines available, timelines and regulatory issues, and, 3) solidarity and international cooperation to ensure a fair and equitable access to the COVID-19 vaccine for all.

2.3 Co-Chair Lia Tadesse underlined her priorities to ensure timely, fair, and equitable access to the COVID-19 vaccine to all, and having clarity on timelines, phasing of access to the vaccine, and types of antigens that

countries will be receiving. She recognised the tremendous progress reached so far by the facility.

Operating Procedures

2.4 Co-Chair Tadesse recalled that at the AMC Group meeting of 17 November 2020, the Terms of Reference (ToR) of the AMC Group were approved. The AMC Group had requested the Secretariat to develop Operating Procedures, which were being submitted for approval at this meeting.

2.5 The AMC Group approved the AMC Engagement Group Operating Procedures. Co-Chair Lia Tadesse encouraged participants to reach out to the Secretariat should there be any clarifications pending the distribution of the translated ToR.

2.6 Finally, she referred to frequency of meetings, informing the participants that the AMC Group should meet approximately 6 times per year, with the possibility to organise consultations in between should the necessity arise.

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3. COVAX Facility

Update on Deals, Financials, Allocation Rounds, First Wave

3.1 Seth Berkley, CEO, provided opening remarks and thanked the Co-Chairs for taking on their roles, noting the importance of a strong leadership in an independently organised group. He underlined the importance of engagement, transparency and ensuring rapid global access to the COVID-19 vaccine given the deepened global inequities. This will require ramping up of production, funding, and addressing country readiness. He noted the overwhelming health and economic benefits of ending the health crisis.

3.2 Dr Berkley noted that COVAX has attained its target of securing over 2 billion doses in 2021. Supply issues and changes in production will be carefully monitored and reported on in a timely manner. He further noted that for the first time in a pandemic context lower-income countries will be able to receive vaccines in a similar timeframe as higher-income countries and thanked the donors for their support and welcomed the United States of America (USA) as the newest member of the AMC Group.

3.3 Dr Berkley then presented updates from within the COVAX Facility since the last AMC Group meeting, including on: the number of eligible participants; launching the first wave of vaccines, announced deals including with Pfizer; indicative allocation of near-term COVAX supply; and progress on the COVAX exchange. In this regard he recognised Canada for their commitment to donate excess doses to the facility and for helping to organise a process for other countries. He made reference to vaccine trials, and initial data coming out from the COVID-19 vaccine roll-out on side-

effects and logistical requirements. He spoke briefly of the COVID-19 variants.

3.4 Concluding, Dr Berkley reiterated that COVAX is committed to continue working in collaboration with the Coalition for Epidemic Preparedness Innovations (CEPI) to take any necessary steps if there are changes in the strain requiring a change in vaccines or vaccine strategy.

3.5 Mr Jeremy Konyndyk, US Agency for International Development (USAID), reiterated the commitment of the US administration in combating the pandemic, and underlined their eagerness to contribute to the COVAX facility as fully engaged members.

3.6 Adam Hacker, Head of Global Regulatory Affairs, CEPI, provided an update on the new COVID-19 variants. He noted that the rapidly spreading variants are putting strain on health systems. The new variants have multiple mutations that could affect the effectiveness of vaccines, monoclonal antibodies and diagnostics. He mapped out the COVAX response to the new variants, on the short, medium and long terms.

3.7 Aurélia Nguyen, Managing Director, Office of the COVAX Facility provided an update on deals, timelines and forecasts. She outlined the COVID-19 vaccine landscape comprising 49 candidates in clinical evaluations. COVAX is engaging with most of the advanced candidates to assess whether they should be included in the COVAX portfolio.

3.8 On progress on agreements with suppliers, she noted that since the AMC Group last met, a Memorandum of Understanding (MoU) was signed with Jansen/Johnson & Johnson, in addition to the Pfizer/ BioNTech, AstraZ eneca (AZ) and Serum Institute of India (SII) agreements. In relation to the current portfolio of agreements with manufacturers, advanced purchase agreements have been signed for 1.3 billion doses, additional MoUs are being negotiated to secure the remaining doses to reach 2,3 billion for 2021 period. COVAX is in negotiations to secure additional 800 million doses.

3.9 Ms Nguyen provided an overview of the vaccine portfolio focusing on 2021. She presented an overview of the facility's global supply forecast and underlined a number of external factors which may contribute to supply delays such as: 1) deal terms of deals under negotiation 2) the manufacturing performance and yield 3) regulatory success and timelines and, 4) delivery timelines to, and within countries.

3.10 Further information on the facility's global supply forecast by region, and the split between the AMC eligible participants and the Self-Financing Participants (SFPs) were provided. Based on current forecasts, it is foreseen that 1.8 billion doses will be available for AMC countries. A fully funded AMC will support the procurement of 1.3 billion doses out of the 1.8 billion and thus additional finance may be required.

3.11 Marie-Ange Saraka Yao, Managing Director, Resource Mobilisation, Private Sector Partnerships & Innovative Finance, provided an update on the AMC funding outlook underpinned by the aim to accelerate equitable access to all participants. She noted a significant progress since the last AMC meeting in November 2020. She emphasised that the AMC is a ten-year instrument. While the current focus is on 2021, the outlook for securing funds for the next years remains a priority. She highlighted the funding target of at least US$ 7 billion to help secure 1.3 billion doses.

3.12 She acknowledged the strong donor support, with pledges reaching US$ 2.5 billion by end of 2020, and Euro 400 million guarantees from team Europe[1]. She referred to the ongoing discussions with the USA regarding a US$ 4 billion pledge, which will contribute to a very strong funding base. Ms Saraka-Yao noted the need for an additional US$ 2 billion for procurement of vaccines by June 2021, and US$ 1.5 billion for vaccine delivery. She then provided an outline on the COVAX AMC replenishment timeline, starting with an Investment Opportunity launch in the first quarter.

3.13 Ann Lindtstarnd, Unit Head, EPI-Essential Programme on Immunization Unit Head, WHO provided an update on the indicative allocations of first-wave vaccines. She noted that the first wave comprises a limited number of Pfizer doses to be delivered to countries in February 2021. She referred to the letter issued by the facility on 6 January and clarified that applications from 51 countries were received and reviewed. An announcement on allocations and the shortlisted countries that will be receiving first wave vaccines would be announced shortly after the meeting. In relation to the Pfizer vaccines, she underlined the importance of country readiness, signature of the Indemnification and Liability (I&L) agreements and regulatory approvals to receive the early doses during the in second half of February and early March 2021.

3.14 A further announcement on the indicative volumes of the AstraZeneca vaccine for allocation until June 2021, based on current supply estimates was expected on Friday 29 January 2021. She underlined that only countries that submitted their National Deployment and Vaccination Plan (NDVP), and were deemed ready for deployment, would be included in allocation rounds. The actual allocation would only be announced when the World Health Organization (WHO) has granted Emergency Use Listing Procedure (EUL) to AstraZeneca vaccines. She noted that indicative allocation can change due to manufacturing constraints, and emphasised country readiness as crucial. She urged countries to complete and upload their NDVPs on the Partners Platform.

Discussion

- The AMC Group members acknowledged the achievements of the facility and the huge progress made to date. One member highlighted the importance of timely and coordinated communication, noting that news on

[1] The European Commission and the European Investment Bank

vaccine deliveries to AMC countries must be shared widely to further support the COVAX facility and harvest more political commitment. Multilateral efforts in responding to the pandemic was underlined, and reference was made to the ongoing work by the Group of 20 (G20) on preparedness for pandemics.

- On preventing supply constraints and addressing bottlenecks, the Secretariat noted that where possible, manufacturers are producing at risk to secure volumes. Once manufacturers obtain regulatory approvals the facility will be able to deploy the vaccines. COVAX is actively reviewing supply chains with CEPI to ensure that candidates can increase their capacity, in addition to leveraging technology transfer to widen and diversify the supply base as much as possible.

- Regarding an inquiry on non-binding agreements with manufacturers, the Secretariat clarified that such agreements would eventually be converted into legally binding agreements.

- In relation to delivery timelines of first-wave vaccines, the Secretariat noted that communication to countries, in the form of letters, will be shared on 29 January with a view of the first wave of Pfizer vaccines, and indicative allocation of AstraZeneca and AZ/SII. The principle of fair and equitable access to vaccines was reiterated, and countries that benefited from bilateral deals and began vaccination at the national level were encouraged to voluntarily step back to allow other countries to benefit from first-wave vaccines. It was also clarified that the 51 applicants for early vaccines include AMC economies and SFPs, representing 6 different geographical regions.

- In relation to country readiness and receiving vaccines from multiple manufacturers, the Secretariat noted that from a programmatic perspective the number of manufacturers providing vaccines to one country will be as limited as possible to facilitate deployment. Discussions on readiness in fragile settings will address countries' ability to deploy the vaccine safely and effectively.

- The Secretariat clarified that the advance purchase agreement with AstraZeneca was limited to 170 million doses only strictly due to production capability in the first half of 2021, with the possibility to procure more in the future.

- Concerning WHO EUL, it was noted that the COVAX facility is committed to provide participants with safe and efficacious vaccines, therefore only vaccines that are pre-qualified by WHO, or by another stringent authority, would be included in the facility's portfolio. Dossiers submitted by manufacturers to WHO are processed in a timely manner, however having full clinical data remains an absolute necessity to assess the safety and efficaciousness of the vaccines.

- It was noted that WHO will provide guidelines to support countries complete their readiness assessment with the support of WHO regulatory teams.

- In response to questions on AMC funding, the Secretariat noted that the AMC mechanism plans to support countries over the next ten-year period. Funds raised to present constitute a strong base of resources which enables COVAX to make deals with manufacturers. An AMC specific replenishment will be launched, with more details to come on the campaign.

Readiness Regulatory indemnity and Reliability

3.15 Ann Moen, Chief, Preparedness and Response, WHO, outlined the process for country readiness starting with submitting NDVPs to the Partners Platform, which is followed by regional committees' review. Countries that meet the minimum criteria will be included in the allocation round. Further confirmations on I&L, regulatory approvals and import licences will be necessary before purchase orders are confirmed, and doses are shipped.

3.16 Countries were encouraged to coordinate with their regional task force for COVID-19 vaccination to organise WHO pre-assessment checks to improve NDVPs. She highlighted the four minimum criteria for allocation as follows: 1) target populations and how to reach these populations 2) supply chain management and logistics 3) costing and funding and, 4) vaccine safety. Countries were strongly encouraged to submit their NDVP online by 9 February at the latest.

3.17 Pascal Bijleveld, Director, Country Support, provided a brief summary on the support provided to countries to prepare for country readiness, noting that two support windows were made available for Technical Assistance (TA) and for Cold Chain Equipment (CCE). The bulk of technical assistance has been directed to countries in particular Gavi 56 countries plus India. Support was also extended to non-Gavi eligible AMC participants, at smaller scales, with the aim to accelerate country readiness.

3.18 He updated participants on cold chain support available to all AMC participants to cover CCE, bundle distribution, installation and training services as well as passive devices & remote monitoring solutions. He gave an overview of applications received to date, noting that Gavi is targeting first orders for March 2021 to see first round of equipment deployed in-country in the second half of 2021. He urged countries to submit applications for any additional CCE support needed so that bulk orders can be placed, and encouraged countries to make use of TA support provided to countries to this end as well as for submitting NDVPs.

3.19 Deus Mubangizi, Essential Medicines and Health Products, WHO, provided an update on regulatory issues. He noted that Pfizer vaccines are the first to be granted WHO EUL and several other vaccines are expected to follow in the first quarter of 2021. WHO is in the process of assessing the various versions of the AstraZeneca vaccine that are manufactured in Europe,

South Korea and India, a decision on these versions is expected in the coming weeks.

3.20 Regarding the Janssen vaccine, currently WHO is accepting information in rolling submission, noting that critical data will be available in April 2021. Potential authorization is expected in May, depending on availability of data.

3.21 Dr Mubangizi emphasised that WHO assesses information on a rolling basis and highlighted that quality and safety cannot be compromised. To facilitate robustness, WHO invited regulatory authorities from across WHO regions, to ensure sufficient expertise as well as to have buy-ins from countries. WHO requested manufacturers to authorise sharing WHO assessment reports. A link was provided to participants to direct them on vaccines authorisations status which is updated on weekly basis.

3.22 He referred to three approaches to in-country approval of the COVID-19 vaccine, namely: 1) country granting Emergency Use Authorisation (EUA) or marketing authorisation using reliance on WHO EUL 2) special authorisation or other authorisation for use under exceptional circumstances, and 3) country granting EUA of marketing authorisation directly.

3.23 Countries that may be directly approached by manufacturers that are neither assessed by WHO nor by a stringent regulatory authority were encouraged to ensure that the products they are being offered are safe, efficacious and of good quality.

3.24 Anthony Brown, Senior Legal Counsel, provided a brief update on Indemnity & Liability (I&L). He provided some contextual background noting the importance of I&L in such unprecedented operating environment for manufacturers to be able to provide deals in the absence of traditional insurances. COVAX negotiated one model agreement that can be used across all manufacturers for AMC countries. He urged AMC participants to refer to the model agreement and make an assessment as to whether implementing legislation needs to be passed in order for countries to be able to sign the indemnity agreement. In addition, the COVAX partners are in the final stages of setting up a no-fault compensation programme for AMC participants which goes in tandem with the I&L. The no fault-compensation programme must also be assessed together with the I&L for any necessary implementing legislation. COVAX can provide AMC participants with support to draft such language.

3.25 Anne Mazur, Principal Legal Officer, WHO, presented a number of aspects of the COVAX no-fault compensation mechanism for AMC participants. The purpose of this programme is to provide access to fair compensation for individuals suffering serious adverse effects to the COVID-19 vaccine. In the absence of such a programme, individuals will need to go through lengthy and costly civil actions in courts to seek compensations. This programme aims to limit civil actions against manufacturers, and in turn this will limit the need for AMC participants to indemnify the manufacturers for any awards against them.

3.26 While the programme is expected to become operational in the first quarter of 2021, individuals will be able to apply for compensation in the event of adverse events of vaccines administered before the programme is operational. An extended reporting period will allow individuals ample time to submit applications. The compensation will be a no-fault lump-sum in full and final settlement of any claims. This is to ensure that individuals who accept compensation from the programme will not seek further compensations from national courts. In the event that individuals will seek further compensation in addition to the lump-sum provided by the programme, the AMC participant will need to indemnify the manufacturers concerned for any resulting court rewards. She urged the AMC participants to complete their assessment on whether implementing legislation is required, so that compensation will be accepted in full and final settlement. If such legislation is needed, AMC participants are requested to take the necessary steps and draft a legislation before the vaccine supply begins.

3.27 Once the compensation programme has been established, instructions must be made available to vaccine recipients and healthcare professionals. AMC participants were requested to work with the independent claims administrator to facilitate the submission of applications and exchange of info.

3.28 Aurélia Nguyen presented five key actions for countries to start preparation for vaccine delivery. She noted that further guidance on vaccine demand would be published soon after the meeting to build on demand and communication plans.

Discussion

- Regarding in-country approval of the COVID-19 vaccine, the Secretariat clarified that manufacturers have the responsibility to submit applications to local licensure. Countries are encouraged to use WHO reliance mechanisms. It is not recommended for applicants to submit their dossiers for licensures in-countries, as it can be a lengthy process for manufacturers to seek licensure in AMC countries simultaneously. The option of Special Authorization or other authorization for use under exceptional circumstances (within 5-15 days) was noted as one option to gain efficiencies.

- In relation to agreements with manufacturers, the Secretariat noted that agreement documents are subjects to confidentiality, however the office of the facility will provide AMC participants with summaries and outlines of such agreements.

- The Secretariat responded to inquiries on country approach regarding populations living within their territories, particularly refugees, Internally Displaced Persons (IDPs) and populations operating under countries with UN Peace Keeping forces, noting that COVAX is sending a strong message

to countries to ensure that all populations are included in COVID-19 vaccine roll-out plans.

- On the issue of Halal certification, WHO noted that vaccines listed from Pfizer do not contain products from animals' origin. In the event that future vaccines candidates would include such products, WHO will inform countries in advance. It was noted that WHO does not issue Halal certificates.

- The Secretariat clarified that the draft indemnity and liability agreement that was shared with countries can be used with all near-term vaccine manufacturers. Some manufacturers may require additional due diligence however the body and substance of the agreement remains the same.

- One participant highlighted the importance of pharmacovigilance and encouraged the Secretariat to address this issue in future meetings.

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4. Summary and Takeaways from AMC Group for further Deliberations

4.1 Co-Chair Lia Tadesse provided a summary and key takeaway from the AMC Group for further deliberations.

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5. Closing remarks

5.1 Co-Chair Lia Tadesse thanked the AMC Group members for their participation and active contributions.

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