

SUBJECT: GAVI COVAX AMC

Agenda item: 04a

Category: For Decision

Section A: Context and summary

The COVID-19 pandemic is spreading rapidly in low income economies¹ (LIEs) and lower middle income economies (LMIEs), with South Asia so far most affected. The pandemic has put an immediate brake on progress towards the Sustainable Development Goals. For vaccine programmes in particular, the pandemic has meant that campaigns against highly infectious diseases like polio and measles have been paused – though are now slowly resuming – routine immunisation systems are running at far lower levels of capacity, and healthcare workers normally engaged in immunisation services have been diverted towards COVID-19 response. 45 out of 68 planned vaccine introductions have been impacted in Gavi-eligible countries. As a result, there is an increasing risk of other disease outbreaks particularly among children, further encumbering stretched health services.

Following a call by the G20 under the Saudi Presidency, at an event in April 2020 co-hosted by the President of France, the President of the European Commission, the Director General of the World Health Organization, and the Bill and Melinda Gates Foundation, the Access to COVID-19 Tools (ACT) Accelerator was launched. This initiative brings together a range of partners to achieve equitable access to COVID-19 therapeutics, diagnostics and vaccines.

Gavi and the Coalition for Epidemic Preparedness Innovations (CEPI) were charged to co-lead the Vaccines Pillar of the ACT-Accelerator. Within this Pillar, **CEPI**, as lead for the *Development and Manufacturing Workstream*, is making direct financial investments to support R&D and manufacturing expansion of promising COVID-19 candidates. **WHO**, as lead for the *Policy and Allocation Workstream*, is developing global policy recommendations and an Allocation Framework on use of vaccines, including via the Strategic Advisory Group of Experts (SAGE) on Immunization. **Gavi**, as lead for the *Vaccine Procurement and Delivery at Scale Workstream*, is with partners developing the COVAX Facility (the “**Facility**”), a global mechanism to pool resources and demand for COVID-19 vaccines with the goal of accelerating the availability of and access to safe and efficacious vaccines, and the COVAX AMC (the “**AMC**”), a financing mechanism to ensure that low income and lower middle-income economies, as well as other

¹ Terminology as per World Bank income groups:
<https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>.
Accessed 23 July 2020.

IDA-eligible economies have access to COVID-19 vaccines. The Facility aims to make available up to 2bn doses of COVID-19 vaccines by the end of 2021. Of these doses up to 1bn will be financed by the AMC for low income and lower middle-income economies, plus other IDA-eligible economies² and initially be secured through the Facility.

The AMC and the funding to support it are needed to signal urgently to manufacturers that they should scale up production and reserve capacity to achieve the objective of accelerating the uptake of new vaccines in AMC eligible economies.

Recognising that the Facility, as proposed, would require engaging with different stakeholders than Gavi's normal constituencies and presents different risks, the Facility and the AMC are presented in separate papers (see Doc 4b). If approved, it is envisioned that the procurement of vaccines for the set of economies eligible for the AMC – the 'COVAX AMC Group' – would be supported by the AMC.

Questions this paper addresses

The Board's approval is requested: (1) to establish the Gavi COVAX AMC recognising the need for the AMC to be operational quickly to realise the benefits, and (2) to define the scope of economies to be eligible for support through the AMC (the 'COVAX AMC Group').

An outline of the COVID-19 vaccine programme, including a decision on co-financing, will be brought to the Board in September 2020. Individual transactions will be brought to the Market Sensitive Decisions Committee.

B. The Gavi COVAX AMC

- 1.1 The objective of the AMC is to reduce the impact of COVID-19 in AMC eligible economies. While designed to meet the unique challenges related to COVID-19 vaccines, the AMC draws from the Alliance's previous market shaping and innovative finance tools for accelerating the availability of vaccines for Gavi-supported countries, in particular the pneumococcal AMC and the Ebola vaccine Advance Purchase Commitment. As with these previous market shaping instruments, long term binding commitments are needed to accelerate the development and availability of vaccines for LIEs and LMIEs. Conversely, without the COVAX AMC, analysis shows that these economies would be unlikely to have access to COVID-19 vaccines for 3-4 years.³
- 1.2 The AMC will be capitalised through Official Development Assistance (ODA) funds, and concessional, philanthropic, and private sector funds and use these to provide demand guarantees to incentivise timely investment in and expansion of manufacturing capacity. In particular, Gavi will enter into transactions with manufacturers in order to secure availability of vaccines

² Subject to Board decision on eligibility. Hereafter "LIEs and LMIEs".

³ Internal BMGF (Bill & Melinda Gates Foundation) analysis

that meet the agreed WHO Target Product Profile (TPP). These transactions will reduce uncertainty and lack of predictability of demand and financing as barriers to capacity expansion for manufacturers and in doing so, will enable Gavi to secure supply rapidly on behalf of LIEs and LMIEs.

- 1.3 Following the success of the pneumococcal AMC in driving lower prices and ensuring sustainable availability of supply (see Annex C), it is expected that over time the COVAX AMC will also succeed in securing lower prices and availability than otherwise would have been possible without certainty of financing, demand prospects, and pooling of demand.
- 1.4 It is envisioned that the procurement of vaccines by the Facility (see Doc 04b) with respect to AMC eligible economies would be funded by the AMC. The AMC benefits from working through the Facility for the duration of the Facility, as it provides:
 - a) Access to an actively managed broad portfolio of vaccine candidates including through Gavi's partnership with CEPI but also will be able to purchase vaccines not being managed through CEPI.
 - b) Independent review of vaccine candidates by an expert panel.
 - c) Additional economies of scale through the participation of additional economies in the Facility.
 - d) Investments in scale up of manufacturing at risk and at scale to assure early access to doses in adequate quantities to help control the pandemic.
- 1.5 The Secretariat has led the creation of the AMC and the Secretariat will administer it. While the need to move quickly has prevented the usual consultation processes, the Gavi Board held initial discussions on the AMC in May and June, and members of the Alliance have been engaged during the design process on the Facility and the AMC, including through the Gavi CSO Constituency Steering Committee, immunisation and advocacy partners, donor meetings, discussions with countries including at country consultations on 21 and 22 July 2020, and wider discussions with more than 170 experts.

C. Eligibility

- 1.6 The objective of Gavi's engagement in COVID-19 vaccines is to ensure that no economy is left without access to a future COVID-19 vaccine because of a lack of available vaccines, procurement capacity, or buying power. This objective is in line with the broader goals of the Facility and the ACT Accelerator. **A key tool for achieving this objective is the Gavi COVAX AMC and the scope of economies eligible for support through the AMC should reflect this objective.**

- 1.7 Gavi defines its scope of supported countries as the 'Gavi 73'⁴. However, this list of countries is based on a historical assessment of eligibility that used GNI per capita (p.c.) data from more than 10 years ago. As such, the 'Gavi 73' now includes some upper middle-income countries that are significantly wealthier than other countries that have never been eligible for Gavi support. This is because the GNI p.c. in some low income countries has risen much more rapidly than in some never Gavi-eligible economies. There is therefore a concern that using the standard Gavi scope of supported countries for the AMC may not be the optimal way of achieving the AMC's objective to ensure equitable access to a future COVID-19 vaccine to bring the pandemic under control as quickly as possible.
- 1.8 In addition, the work done to date on the development of a forthcoming middle-income country (MIC) approach has provided valuable learning that is relevant here. Through that work it was recognised that some middle income economies (MIEs), especially LMIEs, are often those that lag behind in immunisation, specifically in the introduction of key vaccines such as PCV, Rotavirus and HPV. This inter-country equity challenge was considered difficult to disregard in light of Gavi's ambitious goal of 'leaving no-one behind with immunisation'. The COVID-19 pandemic has created further barriers to new vaccine introductions for MIEs. Without support to overcome these barriers, these economies may not be able to introduce a future COVID-19 vaccine, with serious potential consequences for both the health of their own populations and for global health security.
- 1.9 Four options for the scope of the AMC were considered:
- a) **Gavi eligible countries:** All Gavi eligible countries, i.e. pre-transition (the 'Gavi 57').
 - b) **Gavi supported countries:** All Gavi supported countries, i.e. pre- and post- transition (the 'Gavi 73' plus Syria).
 - c) **Low income and lower middle-income economies**, i.e. economies with a GNI per capita under ~US\$ 4,000. This would include 78 economies⁵.
 - d) **Low income and lower middle-income economies, plus the other World Bank IDA-eligible economies**, i.e. economies with a GNI per capita under ~US\$ 4,000 plus other IDA-eligible economies. This would include 90 economies⁶.

⁴ Gavi 73 includes both Gavi-eligible and post-transition countries. Syria is additionally eligible for Gavi support.

⁵ Based on 2018 World Bank GNI data

⁶ Based on 2018 World Bank GNI data

| Option | # economies ⁷ | % Global pop ⁿ | Pop ⁿ covered by the Facility (20%) | Considerations |
|--|--------------------------|---------------------------|--|---|
| (a) Gavi eligible countries | 57 | ~40% | 619 Mn | Pros: Aligned to current Gavi criteria Cons: Criteria is unique to Gavi; may be insufficient to have a meaningful impact on the pandemic as omits many economies likely to be unable to introduce the vaccine without support; perpetuates the inter-country inequities faced by MIEs. |
| (b) Gavi supported countries | 74 | ~47% | 725 Mn | Pros: Based on the list of countries that Gavi has substantively engaged with Cons: Criteria is unique to Gavi; may be insufficient to have a meaningful impact on the pandemic as omits many economies (e.g. LMIEs) likely to be unable to introduce the vaccine without support; does not only cover the poorest economies but also some UMIEs with comparatively high GNI; maintains the inter-country inequities faced by MIEs highlighted in the MICs work. |
| (c) Low income & lower middle-income economies | 78 | ~50% | 770 Mn | Pros: Focuses support on the poorest economies; uses recognised definitions; is transparent; covers 50% of the global population to make a meaningful impact on the pandemic; addresses the barriers previously identified for MIEs. Cons: Would entail Gavi creating new relationships with 10 economies not previously substantively engaged with ⁸ |
| (d) Low income & lower middle-income economies, plus other IDA-eligible economies | 90 | ~50% | 771 Mn | As per option (c) plus: Pros: Acknowledges the recognised vulnerabilities of IDA-eligible economies and their relatively high levels of exposure to shocks ⁹ . Cons: Would entail Gavi creating new relationships with 21 economies not previously substantively engaged with ¹⁰ |

1.10 In respect to **Secretariat resourcing**, there is no significant difference between the four options for the set up of the AMC, although they have implications for resourcing the COVID-19 vaccines programme. A proposal

⁷ The number of economies for each option is based on 2018 World Bank GNI data. All options include India.

⁸ These 10 are: Cape Verde, Egypt, El Salvador, Eswatini, Micronesia, Morocco, Philippines, Tunisia, Vanuatu, and West Bank and Gaza

⁹ More information about World Bank IDA eligibility can be found here: <https://ida.worldbank.org/about/what-is-ida>. Accessed 11 July, 2020

¹⁰ The additional 11 compared to option (c) are: Dominica, Fiji, Grenada, Kosovo, Maldives, Marshall Islands, Samoa, St. Lucia, St. Vincent and the Grenadines, Tonga, and Tuvalu

on the Secretariat resourcing necessary to finalise the design and set up of the AMC, including structuring financing solutions, supporting fundraising of seed capital and developing relationships with new partners, will be brought to the Board at a later date.

- 1.11 Considering the four options against the objectives of the AMC and the broader ACT Accelerator, it is recommended that the scope of eligibility for support through the AMC include **all low income and lower middle-income economies, plus other World Bank IDA-eligible economies (option (d))**.
- 1.12 Using option (d) as the definition of scope **focuses Gavi support on the poorest economies in the world today, uses recognised definitions** (the World Bank's low income and lower middle-income categories and IDA-eligibility) instead of a Gavi-specific threshold, and is **transparent**. This definition also speaks to the Board's acknowledgement, through the prior work on the MICs approach¹¹, of the challenges faced by lower middle income economies in introducing new vaccines, as well as the World Bank's recognition of the vulnerabilities and relatively high levels of exposure to shocks face by IDA-eligible economies¹². It should also be noted that the additional 12 IDA-eligible economies represent a very small fraction (0.13%) of the population proposed to be covered by the AMC.
- 1.13 In May 2020, the Gavi Board decided to 'freeze' eligibility and co-financing for 2021 at 2020 levels, which were defined using the 2018 World Bank GNI data¹³. This was in response to the inherent multi-year time lag in GNI data that, in the context of rapid deterioration in GNI per capita, can result in inaccurate categorisation of economies. There was concern that without this 'freeze', Gavi would be using data from before the onset of the pandemic to determine future eligibility, possibly disadvantaging economies who are now facing a very different reality than that which had been expected.
- 1.14 Using the 2018 World Bank GNI data to determine AMC eligibility would be consistent with this approach. Based on this 2018 World Bank GNI data, this definition of eligibility for the AMC would result in a total of 90 economies: the **'COVAX AMC Group'**. This comprises **78 low income and lower middle-income economies plus the 12 other World Bank IDA-eligible economies**¹⁴. The list of the 90 economies included in the proposed COVAX AMC Group is provided in Annex B.
- 1.15 It should be noted that since the May 2020 Board meeting, the World Bank in July 2020 released the 2019 GNI data. The new data includes income categorisation changes for a small number of economies, notably moving Indonesia from a lower middle-income country to an upper middle-income

¹¹ See Doc 10 to December 2019 Board meeting

¹² More information about World Bank IDA eligibility can be found here: <https://ida.worldbank.org/about/what-is-ida>. Accessed 11 July, 2020

¹³ The annual World Bank GNI data release in July provides the GNI data for the previous year, i.e. 2018 World Bank GNI data was released in July 2019

¹⁴ To note that this list does not include five upper middle-income countries currently included in the 'Gavi 73': Armenia, Azerbaijan, Cuba, Georgia, and Sri Lanka

country, and moving Sri Lanka and Algeria from upper middle-income economies to lower middle-income economies. Using the 2018 GNI data, in line with the Board decision, leaves Indonesia in scope of the AMC, and Sri Lanka and Algeria out of scope.

- 1.16 **The Secretariat is seeking a decision from the Board on the scope of economies eligible for support through the AMC, whilst the precise level and modality of that support is still being refined.** It is however envisaged that for eligible economies, Gavi would provide financial support for vaccine procurement through the COVAX AMC. The same scope of economies may also receive technical assistance and delivery support, although this would not be financed through the AMC but rather through alternative means. These channels are yet to be fully explored but are likely to draw upon some of the standard Gavi mechanisms already in place for Gavi-supported countries. The level and extent of support (e.g. the level of vaccine co-financing; the amount of operational support for vaccination; and the support for cold chain capacity), which may be differentiated within the COVAX AMC Group, will be further developed in the coming months and will be consulted on with partners, and will require additional fund-raising.
- 1.17 In particular, India may require a tailored approach, following the precedent set by Gavi's existing India-specific strategy and because India is the largest manufacturer of vaccines by volume, has more than 10 indigenous vaccines under development, and has numerous technology transfer efforts underway. As a result, it is a critical manufacturing and strategic partner to Gavi. Any tailored approach would be based on the principle that Gavi's support to India must be catalytic, balancing India's national needs and Gavi's comparative advantage, and ensuring alignment to national, sub-national, and state level strategies and initiatives as well as India's Covid Vaccine Task Force's strategies.
- 1.18 All options explored will aim to ensure that economies do not face any significant barriers to accessing a COVID-19 vaccine. As per the decision of the Gavi Board in June 2020, the scope of economies approved by the Board for the COVAX AMC group would also be eligible for cold chain support as part of the delivery of COVID-19 vaccines. **A proposal regarding the levels of support for the COVAX AMC Group will be brought to the Board for consideration in September.**

D. Governance of the AMC

- 1.19 The AMC will be based upon a Stakeholder Agreement with Gavi. The terms will establish an AMC Stakeholders Group, with rights and obligations in relation to the AMC funds. The Stakeholders Group will have representatives from AMC donors, procurement organisations such as UNICEF and PAHO, the representatives of countries and multilateral development banks or regional banks involved in the financing of the AMC. It will include private sector and philanthropic donors that have provided at least US\$ 10 million in funding to the AMC.

- 1.20 AMC stakeholders will receive additional and specific reporting relating to progress achieved against the objectives of the AMC, the number of MoUs and legally binding agreements entered into with manufacturers of COVID-19 vaccines or candidate vaccines, aggregated data on results achieved by the AMC and, where possible, deal specific terms, cost estimates for the supply of COVID-19 vaccines to eligible economies and plans to introduce COVID-19 vaccines in eligible economies.
- 1.21 **As donors to Gavi, AMC donors will participate in the Gavi Board through existing donor representation and funding to the AMC is equivalent to other funding to Gavi for the purposes of calculating burden sharing among donors. The AMC Stakeholders Group will be represented on the COVAX Facility Shareholders Council.**
- 1.22 The AMC will be limited to ten years (i.e. for two Gavi strategic periods). AMC donors will have an opportunity to review its operation at the end of 2025.
- 1.23 Gavi's Board will make decisions on the opening of a funding "window" for COVID-19, including whether to consider support for vaccines provided under a WHO Emergency Use Authorisation, approval of the associated financial implications and financial forecast, and potential waivers to or changes in Gavi policies in relation to the implementation of the COVID-19 programme.
- 1.24 The Market Sensitive Decisions Committee (MSDC) will approve individual transactions (see Doc 4b for proposed changes to the Committee). AMC donors will be represented on the MSDC through donor members of the MSDC.

E. Funding requirement

- 1.25 The AMC requires seed funding of US\$ 2 billion, and for this to be most effective, pledges need to be made by Q4 2020. This is needed to signal and guarantee the market for LIEs and LMIEs. An additional US\$ 3.4 billion is estimated to be required to procure 1bn doses by the end of 2021 at benchmarked costs.¹⁵
- 1.26 As the ultimate vaccine technology, the manufacturing yield, amount of antigen, number of doses, raw material and manufacturing costs of successful vaccines are still unknown, any estimate of price is challenging. The cost estimates are based upon tiered pricing, which is expected to be offered by several manufacturers. The Facility, and therefore the AMC, promotes visibility into cost and fees. Manufacturers will be expected to disclose to the Facility push funding provided for development and manufacturing and Participants will be invited to disclose public funding and deals with manufacturers.

¹⁵ These costs assume a benchmark price of US\$ 5 per dose.

- 1.27 1bn doses will provide eligible economies with capacity to immunise health care workers, as well as high-risk individuals, and create a flexible buffer to be deployed where it is needed most and for use by humanitarian actors..

Section F: Financial, legal and other risks and mitigants

- 1.28 The main legal and financial risks identified as a result of Gavi administering the AMC are set out below. As the AMC will initially achieve its objectives through the Facility, some risks associated with the Facility are also relevant to the AMC (see the risks section of Doc 04b):
- a) **Risk that insufficient AMC funds are raised.** Donor ODA budgets are limited and will be affected by the economic conditions created by the pandemic. If insufficient funds are raised for the AMC, LIEs and LMIEs will not receive vaccines that protect against COVID-19 for several years, the economic impact of the pandemic in these economies will be severe, and the virus will continue to circulate worldwide. Gavi is mitigating this risk by developing a fundraising strategy involving several financing options including innovative finance and working with MDBs and regional development banks.
 - b) **Risk that the proposed scope of eligibility for the AMC creates a precedent for Gavi core business,** increasing current Gavi eligibility or reducing the potential eligibility of the MICs Approach. The AMC is an exceptional tool built to address the exceptional circumstances of COVID-19. The scope of eligibility for the AMC is defined to meet the specific objectives of the AMC and is therefore specific to this tool. If applicable, the Board could mitigate this risk by noting that any decision on AMC eligibility is exceptional and does not imply any change in eligibility for other Gavi work.

Section G: Actions requested of the Board

The Gavi Alliance Board is requested to:

- a) **Approve** the establishment of the Gavi COVAX AMC as a financing mechanism for the procurement of COVID-19 vaccines for eligible economies as set out in Doc 04b as read with b) below;
- b) **Approve** the recommended eligibility for the Gavi COVAX AMC as comprising all low income and lower middle-income economies, plus the other World Bank IDA-eligible economies, i.e. economies with a GNI per capita under ~US\$ 4,000, plus other IDA-eligible economies. Having regard to the 2018 World Bank GNI data, this comprises 90 economies.
- c) **Note** that this decision does not amend previous decisions on Gavi's eligibility for core financing and relates only to the Gavi COVAX AMC.



Annexes

Annex A: Terms of the COVAX AMC

Annex B: The COVAX AMC Group: proposed eligible economies

Annex C: Lessons from Gavi's Advance Market Commitment for Pneumococcal Conjugate Vaccines