SUBJECT:	**COVAX AMC SUPPORT TO INDIA**
Agenda item:	07
Category:	For Decision

Section A: Executive Summary

Context

In September 2020, the Gavi Alliance Board requested that the Secretariat present the proposed approach for Gavi COVAX Advance Market Commitment (AMC) support to India for COVID-19 vaccines and delivery at its next meeting in December 2020. It recognised that India, given its large population size, second largest number of COVID-19 cases in the world, contracting economy and role as a global vaccine supplier, merits a tailored approach, recognising that the 92 economies included in the AMC (AMC92) include countries with Gross National Income (GNI) per capita (p.c.) of similar value or higher than India (*see Table 1*). Further, given that **India accounts for 17% of the world population (35% of the total COVAX AMC participants' population)**, continuing COVID-19 cases in India would pose a risk to global efforts to stop the pandemic.

Table 1

Country	GNI[1]	Population[2]
India	2,130	1,380,004,000
Indonesia	4,050	273,524,000
Nigeria	2,030	206,140,000

In October 2020, the Programme and Policy Committee (PPC) was requested to provide guidance on the level of appropriate support within the presented parameters and further conversations with the Government of India should take place to align on a proposed package of support to be presented at the December Board for approval.

Questions this paper addresses

- What is the appropriate level of support of COVAX AMC doses for India?
- What is the appropriate level of delivery support for India?

[1] 2019 GNI pc constant USD (WB Atlas)
[2] World Bank 2020 Population projections

Conclusions

Based on the principles of aspirational equity, feasibility, collaboration, and transparency, and recognising the constraints of AMC funding resources and doses, this paper provides the rationale for a proposed package of support to India of **20% of total AMC doses[3]** to cover ~7-9%[4] of India's population and **20% of the overall amount provided for TA (technical assistance) and delivery costs** (CCE – Cold Chain Equipment). Following several conversations with the Government of India and other key stakeholders and as requested by the PPC, this paper provides additional information on the following:

- India's domestic procurement strategy for non-COVAX doses and delivery needs for vaccine roll out
- How the allocation of 20% of COVAX AMC doses/funding will affect AMC91 participants in their efforts to reach their target population

Section B: Content

1. Background

1.1 **The September Board recognised the need for COVID-19 vaccine support when it approved India as part of the Gavi57 eligible group of countries and as part of the AMC92.** This need has become more apparent as the pandemic has progressed. India has reported over nine million COVID-19 cases confirmed (16% of total global cases reported and 10% of total deaths), making it the highest-burdened Gavi-supported country and currently the second most-affected in the world. Confirmed deaths have passed 135,000. **India is also one of the 20 most affected countries globally by COVID-19 mortality** (with 9.96/100,000 pop)[5]. If we compare it with next three largest AMC91 countries (Indonesia, Pakistan and Nigeria), their reported COVID-19 mortality remains relatively low with 6.02/100,000 3.68/100,000 and 0.60/100,000 respectively. India is clearly an outlier compared to the other AMC 91 economies. Routine immunisation significantly declined in the initial phase of the lockdown with administrative reports of over 25% decline in diphtheria-tetanus-pertussis (DTP3) coverage compared to the same period (Q1 2019) with a significant drop of over 50% during the month of April. Health management information systems (HMIS) recorded more than two million fewer children received oral polio vaccine (OPV3) and inactivated polio vaccine (IPV) in India during the first six months of 2020 and acute flaccid paralysis (AFP) surveillance sensitivity declined by >50%. Following what has been dubbed the world's biggest lockdown starting in March 2020, India's gross domestic product (GDP) shrank by 24% in Q2 2020[6]. The International Monetary Fund (IMF) is projecting India's economy to contract by 10.3% by the end of the fiscal

[3] Donor-funded doses. Excludes COVAX Buffer.
[4] Assumes 2 dose regimen. Based on base case and higher price scenarios described in Paper 8.
[5] Johns Hopkins (https://coronavirus.jhu.edu/data/mortality)
[6] Government of India, Ministry of Statistics and Programme Implementation (http://www.mospi.gov.in/press-release)

year (ending in March 2021)[7], making it the worst affected of the emerging economies and one of the worst affected AMC92 economies by far. With the informal sector and low-income populations being affected heavily, poverty reduction is forecast to stop if not regress, according to the latest World Bank (October 2020)[8] South-East Asia regional update. **India's economy is now seen as one of the hardest hit in the region.**

1.2 **As has been the case in the past, India's situation warrants a tailored approach for Gavi support that takes into account its population size, the disease burden and related mortality, subnational inequities, economic crisis and its role as a global vaccine supplier.** While efforts have been made in the past strategic period to increase Gavi support through HSS (health system strengthening) grants and new vaccine introductions, a combination of limited resources as well as large population size, have always resulted in Gavi support being capped. India accounts for over 35% of the total AMC participants' population, so support to India requires tradeoffs in the level of support provided to the other 91 AMC economies. While considering these factors, there is wide recognition that continued or sustained high transmission in a country the size of India will disproportionately affect global efforts to stop the pandemic. India also has domestic manufacturing capacity for COVID-19 vaccines, potentially facilitating its access to COVID-19 vaccine doses and also making it a critical partner to the COVAX Facility and the world for the global public good. India has at least twenty-four vaccines in the pipeline with manufacturing capacity for either self-developed or in-licensed products by a non-Indian company. Eight of these vaccines are in clinical trials, of which four are in phase III and one is under regulatory review. The Prime Minister of India has gone on record to affirm the Indian Government's commitment to a global solution to the pandemic.

1.3 **The tailored approach to India should also consider the ability of the AMC91 countries to support COVID-19 vaccine procurement and delivery to reach their target population.** The World Bank has recently announced US$ 12 billion in COVID-19-related financing, which IDA- and IBRD- eligible economies can use to finance COVID-19 vaccine doses and delivery, including via the COVAX AMC cost-sharing approach, as described in Doc 08.[9] The cost-sharing approach, which enables economies to leverage World Bank and other multilateral development bank funding to purchase additional doses beyond those covered by AMC donors, can thus mitigate the impact that India's allocation would have on the other 91 AMC economies, and provide them with an avenue to reach or exceed 20% population coverage. Other initiatives in Africa and Latin America are also developing pooled financing to mitigate the lack of access to deals with manufacturers. Some lower and middle-income countries have

[7] IMF World Economic Outlook October 2020
[8] World Bank's report
[9] More information on the World Bank Covid-19 financing is available at https://www.worldbank.org/en/news/factsheet/2020/10/15/world-bank-group-vaccine-announcement---key-facts. A list of IDA- and IBRD-eligible economies is available at https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups.

been able to negotiate advanced purchase commitments, given their infrastructure for clinical trials or local manufacturing capacity.

1.4 **The Government of India has indicated their plans for the rollout of COVID-19 vaccines as soon as regulatory authorisation is received.** In recent discussions held between Gavi leadership and the Government, they confirmed plans for three initial waves of vaccination within the priority phase in 2021. These plans require >600 million doses to reach a target population of ~23%. Plans were developed by the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) and in line with the principles and values of the WHO Allocation Framework for COVID-19 vaccines.

- **1st wave -** targeting 10 million front line heath workers by February
- **2nd wave -** targeting 20 million frontline/essential workers by March
- **3rd wave -** targeting 270 million >50yr olds and co-morbidities by August

Based on the assumption that domestic regulatory authorisation will be given within the coming weeks (likely before the end of 2020), it is likely that India will be able to start vaccinating before other AMC91 countries, as they will need to wait for WHO approval to receive allocated COVAX-funded doses. While it is assumed India could vaccinate its first 2 waves of targetted population without COVAX AMC-funded doses, it is uncertain how far it could cover its 3rd wave and beyond without COVAX AMC support.

The Government also acknowledged the challenges of storing and distributing larger volumes of vaccines through its current available routine immunisation system. The Universal Immunisation Programme (UIP) targets (annually) approximately 17% of the currently planned COVID-19 target population prioritised in the first eight months of 2021. At least four of the largest private sector logistics companies will be competing to fill the gaps, given the limited capacity of the current system. Those gaps are estimated by one local logistics company as ~75% of the required cold chain needed for COVID-19 rollout.

As of the writing of this paper, the Government had not provided Gavi Secretariat with details of its National Deployment Vaccination Plan (NDVP) but these are under development in collaboration with Alliance partners. The Gavi Secretariat did receive its Technical Assistance (TA) and Cold Chain Equipment (CCE) urgent needs. Based on costing estimates developed through UNICEF's overall COVID-19 vaccine delivery estimates and an Alliance-supported modelling exercise[10], additional cold chain needs in India were broadly estimated between US$ 30 million - US$ 80 million.[11] The COVAX Facility recently received TA needs for planning, preparedness

[10] Modelling was conducted by PATH in close coordination with UNICEF, WHO and Gavi.
[11] US$ 30 million figure is derived from PATH model, and assumes equipping national, regional and all districts with incremental capacity. US$ 80 million figure is based on UNICEF modelling derived from aggregated cost/dose estimates.

and delivery for COVID-19 vaccines totaling US$ 27 million[12]. TA activities included, but were not limited to the following categories: Demand Generation and Communication, Monitoring and Evaluation, Training and Supervision, Safety Surveillance, Service Delivery and Vaccine Cold Chain & Logistics (including an upgrade to the successful eVIN platform for tracking COVID-19 vaccines down to beneficiary level). While it was acknowledged the needs are higher and the Government is in the process of negotiating with private sector entities its urgent needs for CCE were quantified at US$ 8.7 million.

1.5 **Given the limited data in the public domain and different assumptions and analyses, this paper is not able to provide conclusive evidence of implications to India getting a particular range of support.** According to one of these analyses, India has many manufacturers producing doses and a large indigenous development of potential candidates but outcomes are not yet known and would likely not affect the initial efforts of the first two waves of vaccinations in 2021. While some forecasts highlight a potential large number of doses, they do not count for attrition and focus mostly on confirmed purchase of potential doses through Advanced Market Commitments. These comparisons classify countries in macro-economic status (high, middle or low-income) yet do not factor economic downturn and burden of COVID-19 on countries' affordability. While this paper is not able to provide conclusive evidence, it is able to establish the appropriateness of the range of support originally proposed and discussed at the PPC meeting.

1.6 **India needs ~550M COVID-19 vaccine doses to reach the aspirational equitable goal of the COVAX Facility – targeting 20% of their population.** If India receives the high range allocation of COVAX AMC-funded doses ~190-250M (see Table 1 in Annex A), the gap remaining to be filed from domestic manufacturing and financing would be ~300-360M doses. To fill this gap, the Government would need up to ~US$ 1.4 billion just on vaccine procurement (using publicly estimated prices from Serum Institute of India)[13]. If India receives the low range allocation ~95-125M doses (see Table 1 in Annex A), the gap remaining to be filled from domestic manufacturing and financing would be ~425-455M doses which would cost up to ~US$ 1.8 billion in Government financing for vaccine procurement alone. Given the disproportionate burden of the pandemic on India's economy, if compared to other AMC91 countries, providing a low range of support would exacerbate the country's ability to allocate enough resources to mitigate the risks of continued transmission of COVID-19.

1.7 **Five Indian manufacturers have claimed they will be able to supply billions of doses of COVID-19 vaccines:** Serum Institute of India, Biological E, Bharat Biotech International Limited, Zydus Cadila, and Dr Reddy's laboratories. While these developments are encouraging, further analysis is needed to provide a clearer picture of the probability and timing

[12] Draft COVAX India TA & CCE plan request
[13] Source: The Indian Express

of these potential doses to come to market. Some of these doses will be confirmed doses for domestic use in India, while others will be allocated through COVAX AMC and a few side deals with specific low and lower middle-income countries under licensing agreements with vaccine developers and manufacturers.

1.8 **In parallel, the Alliance is developing a comprehensive case for investment in India with a new partnership strategy for Gavi 5.0 focused on equity and will ensure that both process and content are consistent with the proposed COVID-19 vaccine support.** Catalytic support provided through the current partnership strategy approved by the Board in 2015 has helped India reduce the number of zero-dose children by 40% in the last four years. However, India still has the second highest number of zero-dose children among Gavi-supported countries (1.4 million), many of whom are clustered in the poorest and most deprived areas of the country. India also has a significant burden of cervical cancer and typhoid but has not yet introduced the corresponding vaccines. As the current strategic partnership with India ends in 2021, the Alliance is envisaging highly catalytic support during the next strategic period to address important subnational inequities, gaps in breadth of protection and current challenges related to COVID-19. It is striking to consider that Uttar Pradesh, one of India's most populous states, which has been heavily burdened by COVID-19 cases, has a level of poverty more pronounced than many of the most populous Gavi-eligible countries, and a birth cohort that would place it amongst the top three Gavi countries for potential support. Gavi aims to bring a comprehensive strategy to the PPC and Board in 2021.

2. Proposed package of support

2.1 At the October PPC 2020 meeting, members of the Committee were presented with two ranges (10%-20% of donor-funded doses) of COVAX AMC support for India. The PPC was also presented with ranges of support (US$ 15 million-US$ 30 million) for TA and delivery (CCE) requirements for the rollout of COVID-19 vaccines. Members of the PPC recognised the importance of a successful Gavi-India partnership and acknowledged India's high burden of disease, demographic weight and importance in manufacturing. However, there was general consensus among PPC members that before being able to opine on the upper ceiling of support to India, more information was needed to understand how the other AMC 91 countries would be affected, given the level of support to India. Additionally, PPC members indicated it would be useful to have more transparency from all AMC 92 countries on the degree to which they have other sources of vaccines from domestic manufacturing or through bilateral agreements. The PPC was presented with two ranges as noted in Annex A.

2.2 **It is proposed that India receive 20% of AMC donor-funded doses[14]** to cover ~7-9% of country's population though the rest of AMC 91 would receive AMC doses to cover ~15-20% of their population subject to vaccine

[14] Excluding COVAX Buffer.

prices and fundraising (see Doc 08).[15] The proposed level of support **tries to strike a balance to provide to India as close as possible to an equitable allocation**. This takes into consideration India's population size, high COVID-19 disease burden, and particularly hard-hit economy. At the same time, it protects sufficient doses and funding for the rest of the AMC91. The lower, 10% of AMC level of support would mean that India would receive AMC doses equivalent to the next most populous AMC economy (Indonesia) despite having a fivefold higher population. This level of support would cover only ~3-5% of their population, creating high disparity with other AMC countries that would receive doses to cover ~17-22% of population.[16]

2.3 Under current assumptions, with the proposed level of support to India, AMC91 participants may be able to reach the aim of 20% population coverage with COVID-19 vaccines in the "base case" resource mobilisation scenario.[17] AMC91 participants will also have an opportunity to use **cost-sharing, drawing upon multilateral development bank financing, to achieve greater population coverage**, including to cover any gap between what donor resources are ultimately able to cover and the aim of 20% coverage. Under current assumptions and resource mobilization scenarios, the cost-sharing amount required to close this potential gap would not exceed the range of up to US$ 1.60-US$ 2/dose approved by the Board in September, when calculated on a per dose basis.[18] Allocating this proposed level of total AMC doses to India is thus **feasible under current resource mobilisation scenarios,** as the **AMC91 can still reach 20% coverage** via donor-funded doses and the previously approved cost-sharing approach.

2.4 As a COVAX AMC eligible economy, India will also get a tailored package of support for urgent TA for planning, preparedness and urgent CCE needs. Since the PPC guidance, the Gavi Secretariat received the draft TA plan request and provided seed funding for accelerating urgent planning and preparedness. Since the range available for India (for TA + CCE) was agreed to be feasible[19] between US$ 15 million-US$ 30 million, Gavi has received quantified needs for TA alone >US$ 27 million for critical preparations and >US$ 8.7 million needed for urgent CCE. These include an expansion of the successful eVIN platform to track COVID-19 vaccines down to beneficiaries, establishing improved AEFI (adverse events following immunisation) surveillance systems and other activities to name a few. While the Government has already initiated efforts to mobilise bilateral donors and the private sector to increment its CCE capacity, there are urgent needs for CCE which will not be possible to fill if the lower range allocation is used. For this reason, it is **proposed that India receives the**

[15] Based on base case and higher price resource mobilization scenarios, as presented in Paper 8. Assumes 2 dose regimen.
[16] Based on base case and higher price resource mobilization scenarios, as presented in Paper 8. Assumes 2 dose regimen.
[17] See Paper 8, base case scenario.
[18] Cost-sharing per dose calculated as total cost-share funding required to get to AMC91 20% coverage divided by total doses (donor funded doses + cost shared doses) received by AMC91 participants. This amount will not exceed $1.60-$2/dose in any of the resource mobilization scenarios presented in Paper 8.
[19] Funding available from the Board approved $150M for urgent TA and CCE to India without constraining the AMC 91 participants.

US$ 30 million (20% of overall funds) allocation for TA and CCE (delivery) support as part of their tailored package.

Section C: Actions requested of the Board

The Gavi Alliance Board is requested to:

Approve the proposed (high range) package of support for India - **20% of total AMC doses**[20] to cover ~7-9%[21] of India's population and **20% of the overall amount provided for urgent TA and delivery costs** (CCE).

Annexes

Annex A: Scenarios & implications for range of potential AMC support to India (estimated) and Allocation of US$ 150 million in delivery support (CCE and TA) to AMC91

[20] Donor-funded doses. Excludes COVAX Buffer.
[21] Assumes 2 dose regimen. Based on base case and higher price scenarios described in Doc 08.