Gavi Alliance Board Meeting

29-30 September 2020
Virtual Meeting

Tuesday 29 September: 13.45-18.00 Geneva Time
Wednesday 30 September: 13.45-17.00 Geneva Time
Quorum: 14

Document list

No.	Document
00a	Document list
00b	Agenda
01a	Declarations of interest
02	Recalibrating Gavi 5.0 in the light of COVID-19 and successful replenishment
03	COVAX Facility operationalisation and vaccine programme
04	*Review of decisions – No paper*
05	*Closing remarks – No paper*

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Agenda

Next Board Meetings: 16-17 December 2020, Virtual
17-18 March 2021, TBD *(Board Retreat)*
23-24 June 2021, Geneva
1-2 December 2021, Geneva

Brenda Killen, Director, Governance and Secretary to the Board, +41 22 909 6680, bkillen@gavi.org
Joanne Goetz, Head, Governance, +41 22 909 6544, jgoetz@gavi.org

Please note that the Board meeting will be recorded. This recording will be used as an aid to minute the meeting. A transcription of the full proceedings will not normally be made. Should a transcription be made it will be used only as an aid to minute the meeting.

Board Meeting - DAY ONE – Tuesday, 29 September 2020

Item	Subject	Action	Schedule
	Board members dial into virtual meeting		***13.45-14.00***
	Closed session for Board members and Alternate Board members only		14.00-14.30
1	**Chair's report** • Declarations of interest Ngozi Okonjo-Iweala, Board Chair		14.30-14.45
2	**Recalibrating Gavi 5.0 in the light of COVID-19 and successful replenishment** Anuradha Gupta, Deputy CEO	**DECISION**	14.45-18.00

Board Meeting – DAY TWO – Wednesday, 30 September 2020

Item	Subject	Action	Schedule
	Board members dial into virtual meeting		***13.45-14.00***
3	**COVAX Facility operationalisation and vaccine programme** Seth Berkley, Chief Executive Officer *Includes covering the following:* • *Funding arrangements* • *Financial operating model and financial risk exposure* • *Governance* • *AMC* • *COVID-19 vaccine delivery in AMC countries*	**DECISION**	14.00-16.45
4	**Review of decisions** Brenda Killen, Director, Governance		16.45-16.55
5	**Closing remarks** Ngozi Okonjo-Iweala, Board Chair		16.55-17.00

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Declarations of Interest

Declarations

Section 5.5 of the Conflicts of Interest Policy for Governance Bodies states “Members involved in decision-making processes on behalf of Gavi must take appropriate action to ensure disclosure of Interests and Conflicts of Interest, and take the necessary action in respect thereof.”

Section 6.2 of the Conflicts of Interest Policy for Governance Bodies further states, “The duty to disclose [in 6.1 above] is a continuing obligation. This means that Members are obliged to disclose any Interests and/or Conflict of Interest, whenever the Member comes to know the relevant matter.”

The following declarations were made by members of the Board on their most recent annual statements:

Board members:

Member	Organisational Interests	Financial/Personal/Advisor Int/ Others
Ngozi Okonjo-Iweala, Chair	None	Board Member, Twitter; Board Member, Standard Chartered Bank; Board Chair, African Risk Capacity; Co-Chair, The Global Commission on the Economy and Climate; Co-Chair, Lumos; Fellow, Harvard; Non-resident Fellow, Brookings; Board Member, Carnegie Endowment for International Peace; 1 of the 4 Envoys, AU Special Envoy for COVID-19; Board Member, The B-Team; Board Member, Asia Infrastructure Investment Bank; Board Member, International Advisory Board – Japan International Cooperation Agency (JICA); Board Chair, African University of Science and Technology; Member, IMF External Advisory Group; Member, Economic Advisory Council for South African President Cyril Ramaphosa; WHO Special Envoy, Access to COVID-19 Tools (ACT) Accelerator; Gavi-appointed special adviser

Member	Organisational Interests	Financial/Personal/Advisor Int/ Others
William Roedy	None	US State Department, Foreign Affairs Policy Board (Member) with no engagement with USAID
Margaret (Peggy) Hamburg	Joint Coordinating Group for Coalition for Epidemic Preparedness Initiative (CEPI), Chair	CEPI Board (Observer); Sabin-Aspen Vaccine Science and Policy Group; Vaccine advisory group of the Wellcome Trust; Scientific Advisory Board on Global Health of the Bill & Melinda Gates Foundation
Helen Rees	Chair, South African Health Products Regulatory Authority (SAHPRA); Board Co-Chair, National Health Data Advisory and Coordinating Committee (HDACC); Member, South African National Advisory Group on Immunisation (NAGI) and focal point for HPV vaccines; Member, National Institute of Communicable Diseases Scientific Advisory Committee; Chair, WHO AFRO Regional Immunization Technical Advisory Group (RITAG); Member, IHR Emergency Committee on COVID 19; Chair, WHO International Health Regulations (IHR) Committee on Polio; Co-Chair, WHO SAGE Working Group on Ebola Vaccines; Chair, WHO STI Vaccine Roadmap; Expert, Advisory Committee and advisor to WHO on STI vaccine research; Chair, Coalition for Epidemic Preparedness Innovation (CEPI); Scientific Advisory Board; Non-Voting Board member, CEPI Member, Facilitation Committee COVID19 Clinical Research Coalition; Member, UNICEF and Bill and Melinda Gates Foundation Equity Reference Group for Immunization; Chair, Bill and Melinda Gates Foundation HPV Vaccine One Dose Advisory Group; Member, The Sabin-Aspen Vaccine Science and Policy Group	None

Member	Organisational Interests	Financial/Personal/Advisor Int/ Others
Teresa Ressel	ON Semiconductor (Board; Member of Audit and Nominations/Committee) Invesco Funds (Board Vice-Chair; Member of Audit Committee; Compliance Global Asset Manager)	None
David Sidwell	CHUBB LTD (Board; Member of Audit Committee)	None
Stephen Zinser	None	Roxbury Asset Management Limited Commercial London Regeneration Limited (CEO and Co-Chief Investment Officer)
Yibing Wu	Temasek (Joint Head, Enterprise Development Group; Head, China)	None
Afsaneh Beschloss	RockCreek (Founder and CEO)	None
Orin Levine	Bill & Melinda Gates Foundation (Director, Global Delivery Programs)	Stanford University (Spouse) and University of Maryland School of Medicine – International Immunisation field (Father)
Muhammad Pate	World Bank Group (Global Director, Health, Nutrition and Population HNP)	None
Omar Abdi	UNICEF (Deputy Executive Director for programmes)	None
Zsuzsanna Jakab	WHO (Deputy Director-General)	None
Lia Tadesse	Government of Ethiopia (AFRO Anglophone)	TBD
Myint Htwe	Government of Myanmar (SEARO/WPRO)	Gavi-appointed special adviser
Ahmad Jawad Osmani	Government of Afghanistan (EMRO)	TBD Gavi-appointed special adviser
Arsen Torosyan	Government of Armenia (AMRO/ EURO)	Gavi-appointed special adviser
Abdoulaye Sabre Fayoul	Government of Chad (AFRO Francophone)	TBD Gavi-appointed special adviser
Jan Paehler	European Commission, (DE/FR/LU/EC/IE)	None
Francesca Manno	Government of Italy (CA/IT/ES)	None
Harriet Pedersen	Government of Sweden (NO/NL/SE)	None
Beth Arthy	Government of the UK (UK/QA)	TBD
Sarah Goulding, Vice Chair	Government of Australia (US/AU/JP/KR)	None
Roger Connor	Int'l Federation of Pharmaceutical Manufacturers & Associations (GSK, Global Vaccines, President)	TBD

Member	Organisational Interests	Financial/Personal/Advisor Int/ Others
Mahima Datla	Developing Countries Vaccine Manufacturers Network (Biological E Ltd, Managing Director)	Biological E; ME; Vaccine Sales
Maty Dia	CSOs (Global Financing Facility, Partnership Manager)	Gavi-appointed special adviser
Marta Nunes	Research &Technical Health Institutes (RTHI) Vaccine Preventable Diseases Unit/Respiratory and Meningeal Pathogens Research Unit (RMPRU), Senior Researcher	None
Seth Berkley (non-voting)	None	Professor, University of Geneva; Policy Advisory Board, Gilead Sciences; Board Member, ID2020; Member, Polio Oversight Board; Agency Head, Global Action Plan for Healthy Lives and Wellbeing for All (GAP)

Alternate Board members:

Member	Organisational Interests	Financial/Personal/Advisor Int/ Others
Violaine Mitchell	Bill and Melinda Gates Foundation (Director, Health Funds and Partnerships, Global Delivery Program)	None
Michael Kent Ranson	The World Bank (Senior Economist, Health)	None
Etleva Kadilli	UNICEF (Director, Supply)	None
Kate O'Brien	WHO (Professor-Department of International Health & Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, United States of America)	None
Kwaku Agyeman-Manu	Government of Ghana (AFRO Anglophone)	Gavi-appointed special adviser
Bounkong Syhavong	Government of Lao PDR (SEARO/WPRO)	Gavi-appointed special adviser
Assad Hafeez	Government of Pakistan (EMRO)	Gavi-appointed special adviser
Edna Yolani Bátres	Government of Honduras (AMRO)	Gavi-appointed special adviser
Jacqueline Lydia Mikolo	Government of Congo (AFRO Francophone)	TBD Gavi-appointed special adviser
Joan Valadou	Government of France (DE/FR/LU/EC/IE)	None

Member	Organisational Interests	Financial/Personal/Advisor Int/ Others
Megan Cain	Government of Canada (CA/IT/ES)	None
Noor Khan	Government of Norway (NO/NL/SE)	None
Susan Elden	Government of the UK (UK/QA)	GVAP Technical Working Group for WHO/SAGE (Expert)
Carmen Coles Tull	Government of the USA (US/AU/JP/KR)	None
Keiichi Ono	Government of Japan (US/AU/JP/KR)	TBD
An Vermeersch	IFPMA (GSK, Vice President, Head of Vaccines Global Health)	None
Xiang Shu	Developing Countries Vaccine Manufacturers Network	TBD
Rafael Vilasanjuan	CSO constituency (ISGLOBAL, Director of Policy and Global Development)	Gavi-appointed special adviser
William Schluter	Research &Technical Health Institutes (RTHI) Centers for Disease Control and Prevention (CDC), Director of the Global Immunisation Division in the Center for Global Health	None

SUBJECT:	**RECALIBRATING GAVI 5.0 IN LIGHT OF COVID-19 AND SUCCESSFUL REPLENISHMENT**
Agenda item:	02
Category:	For Decision

Section A: Executive Summary

Context

The COVID-19 pandemic has triggered an unprecedented crisis, calling for an equally exceptional response. At the Global Vaccine Summit in June 2020, in a remarkable show of solidarity, global leaders came together to support the Alliance and its mission for 2021-2025. The successful replenishment provides Gavi with an opportunity to bolster support for its ambitious equity agenda, mitigate the impact of the COVID-19 pandemic on immunisation, sustain hard won gains and scale up smart investments in improving the quality, efficiency, effectiveness and sustainability of immunisation delivery systems. **Given the profound, multi-faceted impacts of COVID-19 and in light of the successful replenishment, it is opportune for the Alliance to take stock and re-examine the objectives for Gavi 5.0.**

Questions this paper addresses

- What **key shifts in Gavi 5.0 priorities** does the Alliance envisage in the context of COVID-19 and the successful replenishment?
- What are the implications for Gavi's **programmatic focus**?
- What are the **resource implications**?

Conclusions

While **leaving no one behind with immunisation and Gavi's strategic goals and objectives for 2021-2025 are more relevant than ever**, **the following recalibrated priorities will require urgent action:**

1. **Maintaining, restoring and strengthening immunisation services:** Given the COVID-19 pandemic has caused widespread disruption of immunisation services in Gavi supported countries, a key priority of the Alliance will now be to support countries in adapting services to operate safely in the context of the pandemic, restoring previous levels of immunisation coverage and catching up on children missed due to the breakdown of services. In doing so, there is an opportunity to 'build back better' with efficient, integrated and sustainable approaches.

2. **Reaching zero-dose children and missed communities**: Gavi's ambitious equity agenda has become even more urgent as COVID-19

thrusts millions of people into deeper poverty, exacerbating inequities and gender discrimination. An unambiguous and relentless focus with highly local approaches and partners is needed to reach zero-dose children and missed communities. In the absence of urgent attention, decisive action and increased investments, there is an imminent risk of increasing child deaths and disease outbreaks.

3. **Pacing the expansion of new vaccines:** As countries' immediate focus is towards containing the pandemic, keeping immunisation services running and trying to reduce the number of zero dose and under-immunised children, further vaccine introductions may happen at a pace that is slower than expected. New vaccines included in the Vaccine Investment Strategy (VIS) will have to be deferred until the acute phase of the pandemic is over.

4. **Delivering COVID-19 vaccines:** Timely delivery of COVID-19 vaccines in Gavi-supported countries will be critical to halting the pandemic. Given the different vaccine profiles and target populations, delivery will require novel approaches from those used for traditional vaccines. While countries are expected to leverage existing capacities, which have been strengthened with Alliance support, some additional support will be needed. More detail is provided in Doc 03.

5. **Safeguarding domestic financing for immunisation:** While domestic financing for immunisation remains a key priority for the Alliance, the significant economic impact of the pandemic may require a recalibration of expectations on countries' transition trajectories and ability to co-finance vaccine doses. The Alliance has been working to protect the significant gains in increasing country ownership and financial sustainability of immunisation programmes. As of August 2020, countries had already met 57% of their 2020 co-financing obligations. Given the continued low visibility on the pandemic's impact in 2021 and beyond, Gavi's response must remain flexible and agile.

Besides the above, this paper outlines additional areas for strategic investments that are critical to deliver on the objectives set out in Gavi 5.0. It also considers the need for **expanding partnerships and additional capacity for Alliance partners and the Secretariat**. With limited resources in comparison to the additional needs, Gavi's investments will be catalytic in nature. The high-level investment needs presented in this paper, which indicate the underlying relative prioritisation, will be refined and substantiated based on the Board's feedback, and brought to the Programme and Policy Committee (PPC), Audit and Finance Committee (AFC) and Board for further consideration.

Questions to the Board

- *Does the Board agree with the recalibrated programmatic priorities?*
- *Is the proposed indicative level of investment appropriate?*
- *Are any priorities missing and should be added?*
- *Does the Board agree with the proposal to provide additional HSS to countries dedicated to zero dose and missed communities?*

Section B: Recalibration of Programmatic Priorities in Gavi 5.0

1. Context

1.1 Gavi's successful replenishment in June 2020 reaffirms its mandate and strategic direction and provides an opportunity to strengthen support for the Alliance's ambitious equity agenda in the context of COVID-19. **An additional US$ 1,662 million of non-programmed financing [1] is estimated to be available to compliment planned expenditures to deliver on the Alliance's mission**.

1.2 At the same time, **the COVID-19 pandemic continues to evolve rapidly.** As of mid-September, almost 7.5 million cases of COVID-19 and over 130,000 COVID-19-related deaths have been reported in Gavi-eligible countries, accounting for 24% of total global cases. Recent International Monetary Fund (IMF) reports suggest the pandemic can undo a decade worth of gains in poverty reduction by pushing millions more into extreme poverty and hunger, exacerbating inequalities and deepening gender disparities and barriers in lower income countries. The economic squeeze caused by the pandemic is reducing the fiscal space of countries to invest in health and immunisation.

1.3 Disruptions in immunisation services due to lockdown measures, supply chain disruptions, fears and rumours **risk millions of children missing on-time immunisation services, with marginalised populations disproportionately affected.** The risk of diseases and child deaths among the poor who lack resources to access health care are spiralling, threatening hard won gains. Therefore, the direct and indirect impacts of the pandemic make Gavi's ambition to leave no-one behind with immunisation more challenging but more important than ever.

2. Maintaining, restoring and strengthening immunisation services

2.1 While the impact of COVID-19 has varied across Gavi-eligible countries, it is clear that **significant efforts will be required to adapt immunisation services to operate safely in the context of the pandemic, restore previous levels of immunisation coverage and catch-up children** who have missed their vaccinations. The pandemic has also exposed weaknesses in current immunisation programmes, highlighting **opportunities to build back better.** These include, for example, improving real-time data systems, addressing mistrust and hesitancy by strengthening community engagement, promoting delivery approaches that encourage greater integration of primary health care services and introducing digital training tools in place of traditional in-person training.

2.2 In this context, supporting countries to **maintain, restore and strengthen immunisation services** will likely be the **immediate to medium term**

[1] As per the financial forecast presented to AFC in September 2020, subject to legal signature of funding pledges. This figure includes US$ 413 million of provision for strategic investments as well as anticipated savings of 72 million from pacing the introduction of new vaccines described below.

priority for many countries. As a result, **much of Gavi's Health Systems Strengthening (HSS) and Targeted Country Assistance (TCA) under the Partners' Engagement Framework (PEF) will be needed to support countries in this objective.** However, HSS for the 2021-2025 strategic period is currently forecast at US$ 1.2 billion, lower than Gavi 4.0, despite the Alliance's higher ambition. The same applies to the TCA forecast. As a result, little will be left for reaching zero-dose children at a time when the pandemic is pushing millions of people into extreme poverty, exacerbating further existing inequities, including gender inequity.

3. Reaching zero-dose children and missed communities

3.1 **The Alliance has made equity the defining feature of Gavi 5.0.** This builds on the coverage and equity agenda from Gavi 4.0, adding a more **acute and deliberate focus on reaching zero-dose children**[2] **and missed communities,** towards a vision of reaching every child with a full course of vaccines by 2030. Two thirds of zero-dose children live below the poverty line, in communities which face high child mortality rates and multiple deprivations including malnutrition, lack of education, open defecation, lack of drinking water and social stigma (see Figure 1 below). They are also often home to acute gender challenges such as lack of reproductive and sexual health, child marriages, teenage pregnancies, female illiteracy and gender-based violence. These communities are prone to recurrent outbreaks of vaccine preventable diseases, such as measles, which can spread rapidly necessitating reactive and repeated investments in immunisation campaigns and outbreak response.

3.2 **Reaching zero-dose children with immunisation services is getting ever more complex and expensive.** Half of all zero-dose children are in fragile countries, where conflict, weak infrastructure and poor governance can impede efforts to extend immunisation services and build strong community engagement. In other countries, these children are clustered in marginalised communities who are underserved because they live beyond the reach of existing health services or systematically excluded from government service provision (e.g. in urban slums or remote rural areas or active conflict zones). **Zero-dose children and missed communities can no longer be neglected and call for decisive action** and prioritised investments in line with the central goal of Gavi 5.0, the Immunisation Agenda 2030 and the SDG aspiration to leave no-one behind.

[2] **'Zero-dose children'** are those that have not received any routine vaccine. For operational purposes, Gavi defines zero-dose children based on lack of the first dose of diphtheria-tetanus-pertussis containing vaccine which in Gavi countries is Penta1.

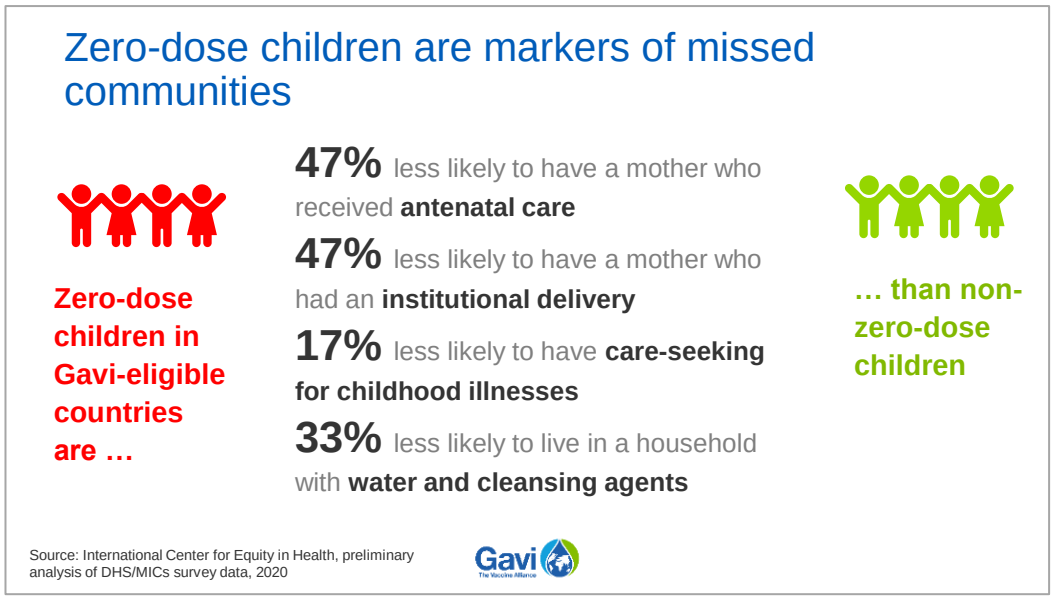

Figure 1

3.3 Gavi has made **positive strides and learnt important lessons in pursuing the goal of equity in Gavi 4.0**, reducing the number of zero-dose children by 14% between 2015 and 2019, after a period of near stagnation in Gavi 3.0. This is despite growing birth cohorts in Gavi countries and the fact that the number of zero-dose children in the rest of the world increased by nearly 30% over the same period. Progress has been faster in PEF Tier 1 countries[3], where the Alliance has had the greatest focus in terms of its political engagement, innovations, technical assistance and monitoring. These countries have reduced the number of zero-dose children by 22% between 2015 and 2019 (vs. 6% between 2010-2015), demonstrating the **progress that is possible with sufficient focus, support and engagement**.

[3] PEF Tier countries: Afghanistan, Chad, DRC, Ethiopia, India, Indonesia, Kenya, Nigeria, Pakistan, Uganda

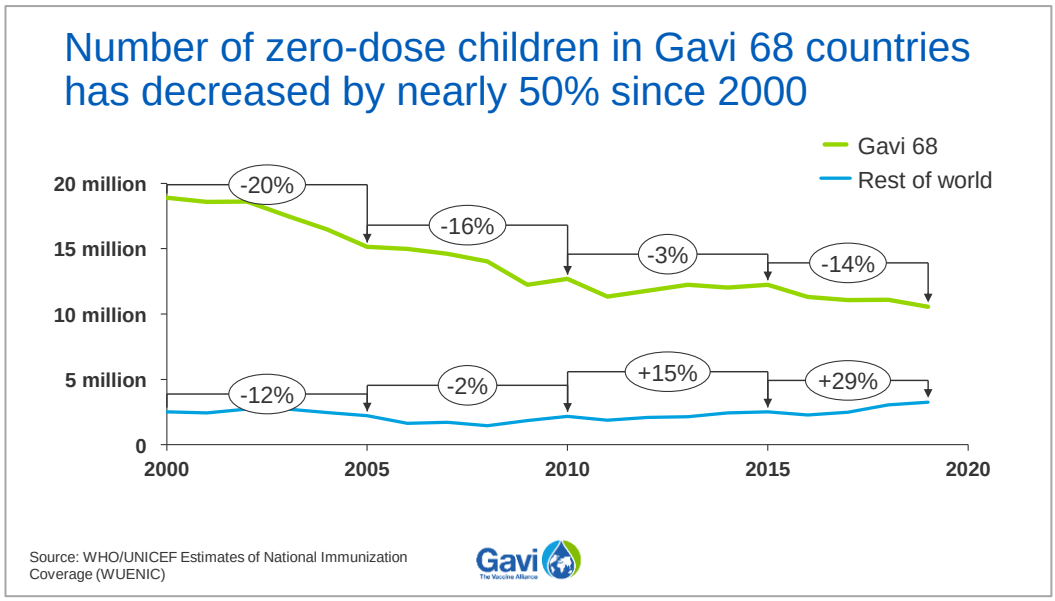

Figure 2

3.4 The Alliance will work with countries to shine a spotlight on these missed communities that are home to clusters of zero-dose children, design tailored strategies to reach them and provide the support required to deliver the full range of vaccines, paving the way for sustained and equitable primary health care. **Five steps have been identified to sustainably reach zero-dose children** as illustrated in Figure 3. This will form the basis of a deliberate and systematic approach in every Gavi-supported country.

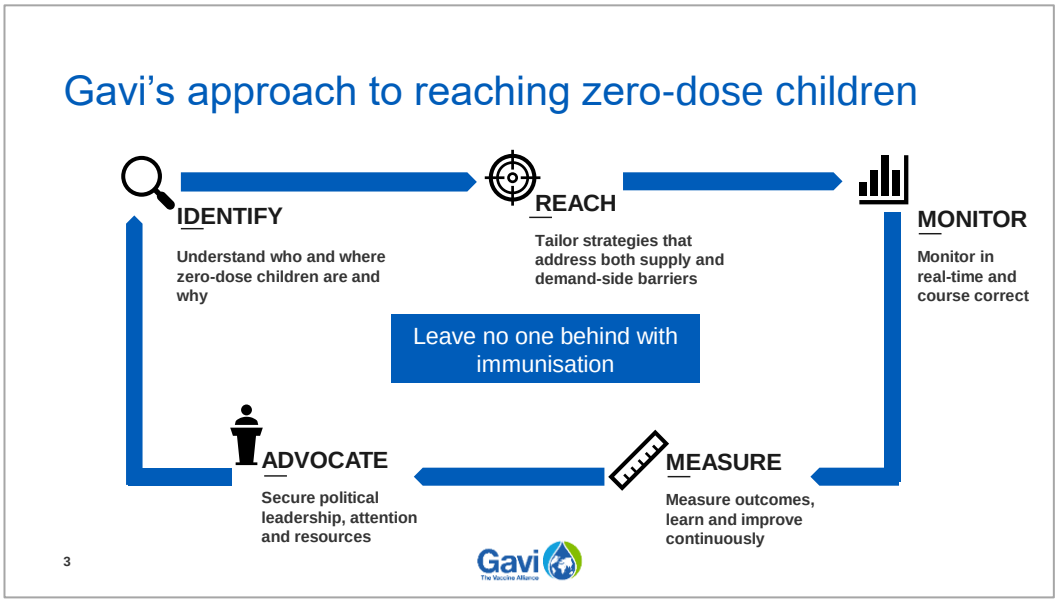

Figure 3

a) ***Advocate**:* Harnessing the full breadth of the Alliance (including Civil Society Organisations (CSOs)) to make zero-dose children and missed communities part of the political discourse, encourage governments to prioritise resources towards them and highlight immunisation as a pathfinder for universal primary healthcare. Gavi's experience from countries such as India, Pakistan and Democratic Republic of the Congo (DRC) have demonstrated that strong political leadership is one of the most important factors in catalysing rapid progress on immunisation equity.

b) ***Identify**:* A clear understanding of who, where, how many and why zero-dose children and missed communities have not been reached is a critical step in developing robust plans to reach them. These communities are often not visible through existing data systems and assessments. They face more profound barriers to vaccination including gender barriers, living in inaccessible or unrecognised settlements, migration, economic challenges and social or political stigma. Interventions including triangulation of existing subnational data, both within immunisation and other sectors (including nutrition and education), better enumeration of the distribution of zero-dose children, and geospatial mapping can better support countries to identify and develop improved plans for addressing both supply and demand-side barriers to immunisation. In Pakistan, triangulating data from the Electronic Immunisation registry with polio-line-listing data helped identify pockets of zero-dose children in large districts and urban areas. In Kenya, administrative data of coverage combined with geospatial estimates of coverage, socio-economic and gender variables from a population-based survey (i.e. Demographic and Health Survey (DHS)) and estimated denominators from WorldPop helped improve the understanding of who zero-dose children and missed communities are, and how to target them (see Figure 4 and Annex A).

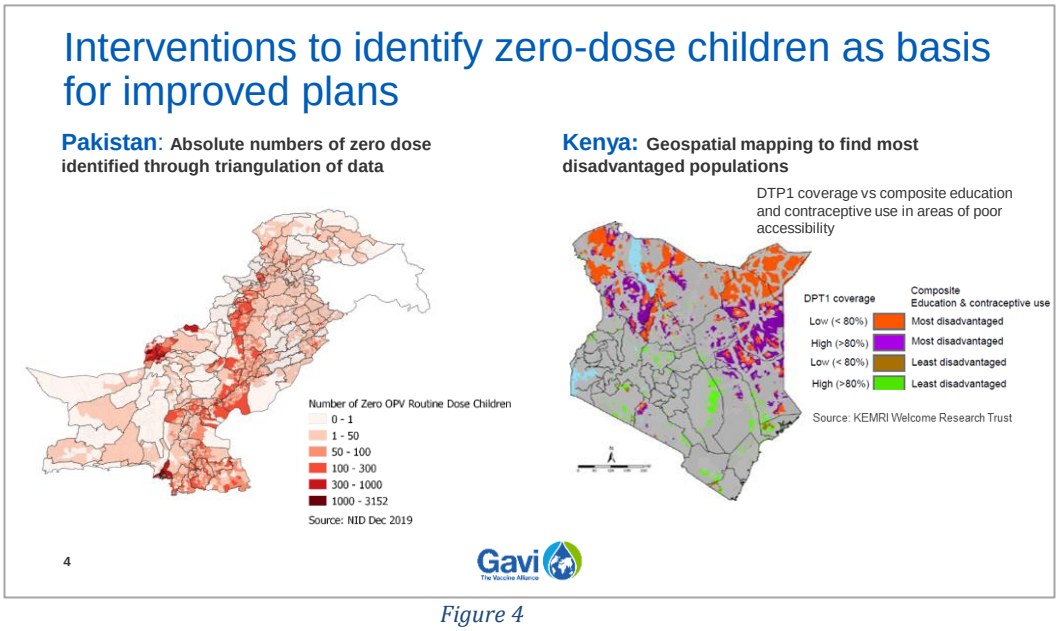

Figure 4

c) **Reach:** Zero-dose children and missed communities will be at the heart of Gavi's programmatic strategies. New partnerships, innovations and flexible approaches will be needed to overcome supply and demand side barriers. On the supply side, the Alliance will work with countries to be more deliberate in designing appropriate service delivery strategies for missed communities, grounded in strong routine immunisation and utilising the full spectrum of approaches from fixed post immunisation to outreach, mobile strategies, periodic intensification of immunisation, child health days and other supplementary activities. This will be done with a specific focus on gender-related barriers that prevent girls from accessing immunisation services (e.g. in Pakistan, fewer girls were reached with catch-up immunisation as services resumed after the COVID-19 lockdown) or mothers to bring their children for vaccination (e.g. due to unsuitable timing or inconvenient location of immunisation services, experience of poor service, stigmatisation).

   Gavi will also work with new partners based on their comparative advantage – such as strengthening engagement with humanitarian and emergency organisations in conflict settings, and collaborating more closely with other financing organisations to co-fund delivery of a broader package of Primary Health Care (PHC) services to these communities in addition to immunisation. On the demand side, it will take much more tailored strategies to engage communities, change behaviours and ensure services meet their needs. This will be even more important in countries where COVID-19 has generated new rumours and mistrust of immunisation, pushing up numbers of zero dose children.

d) ***Monitor & Measure***: Investments to improve measurement including targeted sub-national surveys and assessments, assistance to build capacity and tools for generating insights from monitoring dashboards and analytics, real-time monitoring and country-specific learning approaches will better enable the Alliance to monitor progress on a continuous basis and course correct when needed. In Rwanda, for example, Gavi supported the nationwide launch of an immunisation e-tracker that is linked with birth registry. This provides live data on vaccination coverage, which was particularly useful during the pandemic to monitor the impact on coverage.

3.5 **The Alliance will systematically learn across a subset of countries** through working with local partners to develop learning hubs. Routine monitoring will be supplemented by going deeper in measurement, analysis and understanding of factors influencing implementation and performance of approaches to reach zero-dose children. Learning hubs will support cross-country synthesis, inform key strategy and policy questions, and help identify best practices to be shared across countries.

3.6 **Additional resources are needed to support countries in reaching zero-dose children and missed communities.** Given the core focus on

equity in Gavi 5.0 and the fact that reaching zero-dose children and missed communities is much more complex and costly**,** the Secretariat proposes to **top up the HSS disbursement envelope by US$ 500 million to allow countries to access up to 50% additional HSS on top of their existing grant for dedicated activities to reach zero dose children and missed communities.** This builds on the HSS flexibilities approved by the Board midway through Gavi 4.0, which allowed countries to access an additional 25% above their existing HSS ceilings for targeted investments in coverage and equity. The new top-up would apply for the full strategic period and reflects the increased ambition and expected higher cost of reaching zero-dose children particularly in the challenging context of the current global emergency. The proposed additional funding amount is similar to additional HSS funds that application of the Fragility, Emergencies, Refugees (FER) policy would provide in recognition of the higher cost of operating in the face of an emergency.

3.7 While access to funding would follow a similar process to core HSS, **the proposed extra funds would not be an entitlement but would be made available based on a clear commitment and robust plans from countries to identify, reach, monitor and measure zero dose children.** The proposed approach would generate political focus on zero-dose children, create an incentive for countries to invest in identifying them and ensure that incremental funding is targeted to successfully reaching them. By investing in primary prevention, countries would break a vicious cycle of outbreak response and antigen specific campaigns which are not only highly expensive but often fail to reach the consistently missed children.

3.8 This approach could also serve as a **catalyst for other donors and financiers to add complementary funding** to expand access to other essential PHC services e.g. skilled birth attendance, contraception, prevention of child marriages and teenage pregnancies, bed-nets, malaria and TB treatment, deworming, nutritional support and supplementation, early childhood development, school education.

3.9 **The risk of not allocating additional HSS funds for equity is that more than 50 million children could go unvaccinated over 2021-2025** (>10.5 million zero-dose children per year based on 2019 WUENIC estimates), in addition to a large but unknown number of additional zero-dose children resulting from the COVID-19 pandemic. This would lead to large numbers of unnecessary outbreaks and necessitate the Alliance to invest large sums of money in outbreak response and campaigns. A clear focus on reaching zero-dose children and missed communities with routine immunisation services is thus an efficient, cost effective investment in prevention.

3.10 Given that countries require urgent additional HSS support in light of the impact of COVID-19 pandemic and the FER policy is applicable in this case**, the Secretariat requests the Board to approve this additional HSS support**. This will enable the Alliance to proceed in operationalising the

approach as soon as possible. The Secretariat will continue to provide more details and regular updates at the upcoming PPC and Board meetings.

4. Pacing the Expansion of Breadth of Protection

4.1 **The Alliance has exceeded expectations on expanding the breadth of protection in Gavi 4.0.** Between 2016 to 2019, 259 million children were immunised with Alliance support, saving an estimated 5.4 million lives. Over the past four years, the average coverage of Gavi-supported vaccines that children receive through routine immunisation has nearly doubled (from 30% to 56%), meaning that more children are protected against more serious diseases than ever before. While the pandemic has led to the delay of at least 15 vaccine launches, these are expected to resume soon.

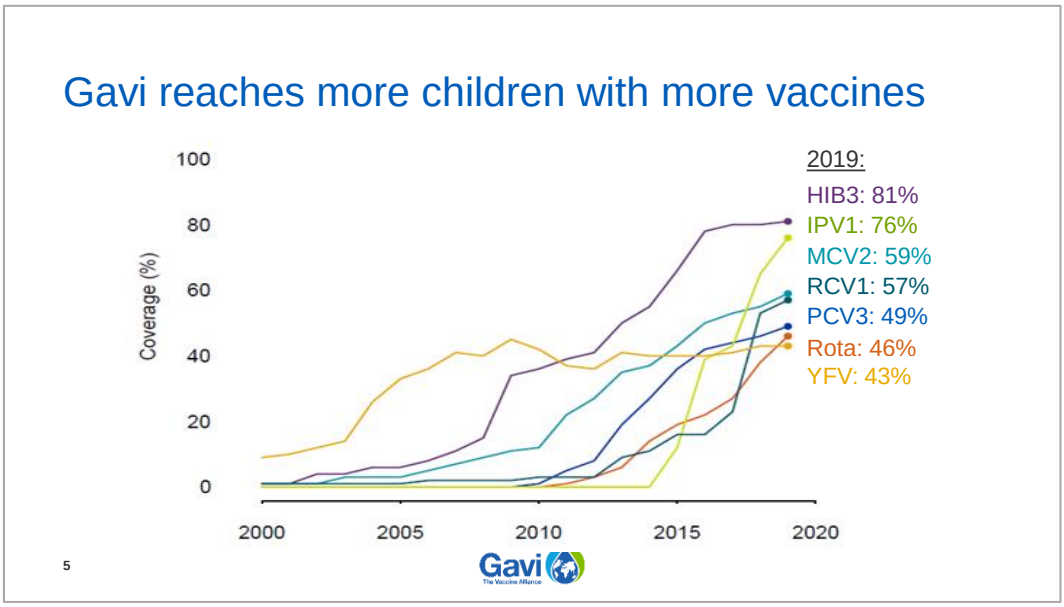

Figure 5

4.2 **In Gavi 5.0 the Alliance will prioritise the conclusion of long-standing introductions and scale-up programmes** including measles second dose, rubella, yellow fever, rotavirus and pneumococcal vaccines along with the continued scale-up of human papillomavirus (HPV) and Typhoid Conjugate Vaccine (TCV). **However, the pace of new vaccine introductions is likely to be impacted by the duration and intensity of the pandemic.**

4.3 **Coverage for Pneumococcal conjugate vaccine (PCV), Rota and Hib vaccines in Gavi-supported countries is now higher than the worldwide average**, reflecting decades of progress and hard work by countries and Alliance partners to support introductions and scale up coverage. The scale-up of PCV in Indonesia and India is expected to drive the largest vaccine uptake and the Alliance will also strengthen support to fragile countries with strong political will to introduce PCV. In addition, in the next strategic period Gavi expects increased HPV vaccine supply from both existing and new manufacturers. If these supply expectations materialise and the impact of COVID-19 on demand and country uptake is minimised,

Gavi's HPV programme may reach 75 million adolescent girls during the 5.0 period.

4.4 Gavi will **continue its investments in preventive programmes for diseases with outbreak potential as well as stockpile investments, including endemic cholera and multivalent meningitis** (approved through the Vaccine Investment Strategy (VIS)). Since the beginning of Gavi's support for Oral Cholera Vaccine (OCV) both available supply and country demand have rapidly increased. While supply capacity from existing and new manufacturers is expected to increase in 5.0, the short- to medium-term impact of COVID-19 is still to be fully understood, meaning supply planning will remain challenging. For multivalent meningococcal vaccines, suitable immunisation product(s) are set to be added later in the new strategic period.

4.5 **Support for other VIS vaccines including rabies, Hepatitis B birth dose and DTP boosters, would be paused during the acute phase of the pandemic**. The lead candidate for **respiratory syncytial virus (RSV)** did not meet its primary endpoint and therefore will not meet the timelines seen in the VIS**.** These **delays are forecasted to incur an estimated savings of US$ 72 million**[4] during Gavi 5.0. Gavi will reassess the decision to defer the addition of new vaccines to its portfolio on a periodic basis, taking into account the effect of the pandemic on introductions from ongoing vaccine programmes and country specific financial and programmatic capacity to add more vaccines to their schedules.

4.6 For the regular portfolio of vaccines, Gavi **currently forecasts about 160 routine introductions and campaigns (ex. IPV) across the Gavi 5.0 period**. Countries forecasted to conduct IPV catch-up campaigns could add 15 introductions to this total. Gavi will also support countries with incorporating a second dose of IPV into their routine immunisation schedules, in line with GPEI and SAGE recommendations. A further 50 launches could come from OCV and multivalent meningococcal vaccines. While the forecasted estimate factors in a **certain level of slowing down of introductions from the impact of the pandemic** during the acute phase, it does not reflect the required effort in introducing a potential COVID-19 vaccine from countries causing other vaccine launches to be potentially delayed.

4.7 The Secretariat requests the Board to **provide perspectives and guidance on the approach to vaccine introductions explained above.**

5. Delivering COVID-19 vaccines

5.1 **Significant efforts are underway to help countries prepare for COVID-19 vaccine delivery.** Based on current assumptions, the focus will initially be on immunising frontline workers in health and social care settings, and then on other high-risk groups including those over 65 years or those with co-morbidities. Targeting and delivery strategies are still being developed.

[4] Financial forecast is based on assumption that introductions will resume in 2023

Uncertainties related to vaccine profiles (e.g. dose schedule, cold chain requirements, efficacy/effectiveness and safety) require the Alliance and countries to plan for multiple delivery scenarios (for further detail see Doc 03).

5.2 **Despite these uncertainties, countries need to begin planning for vaccine introductions now.** Alliance support will be urgently needed in the coming weeks and months to meet the anticipated timelines for in-country delivery. This is particularly relevant for services that have long lead times, including the procurement of cold chain equipment (CCE), as well as technical assistance to support effective delivery planning and execution at country level.

5.3 **Given the urgency of preparing for the introduction, the Board is being requested to allocate US$ 150 million from core resources** for the operationalisation of COVID-19 vaccine programmes and vaccine deployment[5]. Further details, including on the decision point, can be seen in Doc 03.

6. Safeguarding domestic financing of immunisation

6.1 **The continued worldwide spread of COVID-19 has significant impact on macro-economic and fiscal stability**. To ensure immunisation services were not disrupted, the Board exceptionally approved flexibility by granting the CEO the authority to provide waivers of 2020 co-financing on a case-by-case basis and upon request by a country. This has been applied judiciously, with the Alliance's engagement geared towards finding possible alternative solutions and ensuring that waivers are granted only in exceptional circumstances. As such, the **Secretariat has been working closely with Alliance partners, in particular the World Bank, to protect the significant gains achieved in strengthening the financial sustainability of immunisation programmes.** As of August 2020, over US$ 85 million (57%) of 2020 co-financing obligations had already been transferred by countries. Furthermore, out of eleven countries that have requested co-financing waivers[6], four have now indicated that they expect to fulfil their obligations.

6.2 Nevertheless, given the continued low visibility on the pandemic's impact in 2021 and beyond, Gavi's response must remain flexible and agile. It is therefore **proposed to roll over the unused US$ 85 million of the US$ 150 million originally envisaged for co-financing waivers in 2020 into 2021**, which will only be used as a last resort.

6.3 **The macroeconomic impact of the pandemic is likely to affect countries' transition trajectories and their expected co-financing. The fiscal squeeze resulting from the pandemic may exacerbate the risk**

[5] Proposal is based on the precedent set by the 2016 approval for core resources to be used to jumpstart the Ebola program while external fundraising was ramped up.
[6] At its May 2020 meeting, the Board has granted the CEO the authority to provide select waivers for 2020 co-financing.

that countries are unable to co-finance vaccines. This could, in certain scenarios, result in a much larger share of countries remaining in the initial self-financing phase by 2025 compared to previous projections, thus decreasing the total amount of co-financing expected in the next strategic period.

6.4 Because of these multiple effects, total expected co-financing could thus be reduced substantially in 2021 to 2025. A reduction of **US$ 150-200 million in co-financing has been reflected in Gavi's financial forecast for 2021- 2025.**

7. Other priorities with potential future resourcing implications

7.1 **The Alliance is working through further programmatic priorities critical for delivering on Gavi 5.0.** These includes innovation, VPD (vaccine-preventable disease) disease surveillance, support to former and never Gavi-eligible countries, the strategic partnership with India as well as fiduciary risk assurance and financial management. These are briefly described in the following paragraphs. The Secretariat is **seeking guidance from the Board on the broad direction of the priorities** to be able to develop them further in the coming months and bring back to the PPC and the Board.

7.2 *Innovation:* **Achieving Gavi's strategic goals and objectives will require the Alliance to implement and scale-up innovative approaches based on country needs.** Over the last five years, the Alliance has invested in and learned from a range of experiments in accessing and promoting innovation. This experience suggests that building an innovation ecosystem that is firmly grounded in the needs of countries requires further efforts in market shaping, coordination and support across Alliance stakeholders. At the December Board meeting, the Alliance will present an innovation strategy which includes a revised process for governing, financing and coordinating investments in scaling up practices, services and products that would **catalyse Gavi's strategic objectives including the approach to identifying and reaching zero-dose children and missed communities, and to successfully deliver COVID-19 vaccine** (e.g. through leapfrogging digital systems).

7.3 A **cohesive, structured and systematic approach to innovative investments** will help the Alliance to *advocate* for missed communities more effectively, for example via digital engagement and behavioural interventions; *identify* missed and under-immunised communities, using techniques such as geospatial data analysis; *reach* children through new products such as micro-array patches, heat-stable vaccines, barcoding and other products that have the potential to transform immunisation delivery systems; *monitor* the implementation of programmes via live planning, real-time monitoring of campaigns, optimised vaccine supply chain management and e-LMIS-enabled logistics; and *measure* effectiveness and efficiency by empowering district health teams and alliance partners to visualise coverage, stock, surveillance and population data. In India for example,

Gavi supported the Rapid Immunization Skill Enhancement (RISE) training module to strengthen the ongoing training of frontline health workers engaged in routine immunisation using mobile learning solutions. This was particularly effective during the pandemic where lockdowns and physical distancing measures required new ways of preparing frontline health workers. Such interventions will be scaled up.

7.4 **As an early estimate, an additional US$ 150 to 200 million of dedicated innovation funding may provide the needed impetus to catalyse and accelerate innovation.**

7.5 *VPD surveillance:* **Vaccine-preventable disease (VPD) surveillance enables more effective, efficient, sustainable and equitable use of vaccines** by helping countries to identify children and communities missed by immunisation more quickly and supporting the targeted use of vaccines. However, significant barriers to scaling up and strengthening VPD surveillance remain in Gavi-eligible countries. The COVID-19 pandemic has underscored the importance of adequate surveillance data for all countries in order to guide decisions about disease prevention and control measures as a critical part of global health security.

7.6 **US$ 75 to 100 million is proposed as the Alliance investment in VPD surveillance** contingent on developing a concrete proposal in collaboration with Alliance partners for consideration by PPC and the Board. For example, Gavi's catalytic support on strengthening yellow fever diagnostics during the current strategic period appears to be successful. Similar efforts to strengthen laboratory testing for public health needs where there is an important gap could be considered for other vaccine preventable diseases. Without this investment, the ability of countries to detect an outbreak, and respond with speed is compromised. This is more critical now as polio investments in surveillance are winding down.

7.7 *Former and never Gavi-eligible countries:* In Gavi 4.0 the Alliance has been providing technical support through post-transition engagement for former Gavi-eligible countries. In light of COVID-19, the Board recently approved an initial allocation of US$ 20 million to provide targeted support to mitigate programmatic backsliding and help recover coverage levels in former Gavi-eligible countries highly affected by the pandemic. **As part of Gavi 5.0, the Board requested the Secretariat to develop an overarching approach for engagement with former and select never Gavi-eligible countries and allocated up to 3% of planned expenditure in Gavi 5.0 for this engagement.** This approach aimed to prevent backsliding in former Gavi-eligible countries and support the introduction of new vaccines in some never Gavi-eligible countries. This work was temporarily put on hold due to COVID-19 and the immediate focus of countries and partners on responding to it.

7.8 However, the originally envisaged objectives are more relevant than ever. Therefore, the **Secretariat will present a high-level view of a future strategy to the Board in December**, taking into account the heightened risks of backsliding due to COVID-19 and the additional need to support

countries to introduce a future COVID-19 vaccine. In the meantime, our active dialogue and work with these countries as part of the COVAX Facility will facilitate our engagement with them on this work. The Secretariat will continue to reflect and learn from the impact of the pandemic on both countries and the Alliance, ahead of bringing back the detailed approach to the Board later on.

7.9 *Strategic Partnership with India:* The Secretariat has initiated work on an investment case to continue the strategic partnership with **India, which does not receive formulaic support from Gavi given its large birth cohort and financing implications.** Instead a strategic partnership between Gavi and India was established in Gavi 4.0 to provide catalytic support of US$ 500 million for introduction of new vaccines and HSS.

7.10 **India used to have the highest number of under-immunised children in the world.** Due to the intense effort by the Indian government to reach them, they are now second in number. India is expected to transition out of Gavi support at the end of 2021 although the substantial financial effects of the COVID-19 pandemic may put this at risk. The country has the highest number of COVID-19 cases in all Gavi-supported countries, individually accounting for 70% of all cases. This has led to large scale disruption of services but more notably a massive fall in economic growth.

7.11 **Given India's large birth cohort, deep inequities, lack of introduction of key vaccines such as HPV and potential for public health impact, a new strategic partnership will be developed for Gavi 5.0.** As India is also a major vaccine producer with the world's largest birth cohort, the Alliance's work in market shaping is also critical. India has received a total of US$ 905 million in Gavi support to date, which in per child terms is the lowest among Gavi countries (except Ukraine). Countries with much smaller birth cohorts have received much higher Gavi support in absolute terms (Nigeria, with a birth cohort of 16.6 million less than India but GNI (gross national income) higher than India has received US$ 1,154 million; Pakistan, which has a birth cohort of 18 million less than India has to date received US$ 1,470 million).

7.12 **Support in India is envisaged to be highly catalytic in the next strategic period accounting for US$ 200 to 250 million** to address the large subnational inequities, gaps in breadth of coverage and country-specific challenges related to COVID-19.

7.13 *Fiduciary risk assurance and financial management:* **Investments** in fiduciary risk assurance and strong financial management in countries are **critical to ensure timely, efficient and equitable funding of immunisation activities while minimising the risk of misuse and increasing the share of funds flowing through governments**. Rapid funding for the immediate COVID-19 response may entail a higher risk of misuse and thus increase the needs for such investments. At the same time, the focus zero-dose children and missed communities increases the need for timely funding of activities at sub-national level and will require strong financial management capacity of involved actors.

7.14 Early **cost estimates for fiduciary risk assurance and financial management capacity building range from US$ 75 to 125 million**. The Secretariat will come back to the Board in December with a refined estimate.

8. Partners' Engagement Framework (PEF) for Gavi 5.0

8.1 **Partnerships are at the heart of the Gavi model.** The Partners' Engagement Framework (PEF) was introduced in 2016 to leverage the comparative advantage of WHO, UNICEF, World Bank, Centers for Disease Control and Prevention (CDC), Civil Society Organisations (CSOs) and other partners. Besides global and regional levels, partners are funded at country level to provide technical support.

8.2 The latest financial forecast presented to the Board in July 2020 had allocated an increased amount of US$ 1,365 million for PEF's programmatic activities in 2021-25, taking into account the surge needed for 2020-2021. Given increased demands on partner's capacity in light of COVID-19, and Gavi's ambition on zero-dose children and missed communities, **an additional US$ 148 to 157 million for 2021-2025 may be necessary** encompassing increase in funding to partners at global and regional levels under the Foundational Support (FS) and special investments in Strategic Focus Areas (SFAs) and at country level under TCA. TCA funding would be through a five-year envelope, approved as part of the financial forecast, which countries can access over the strategic period.

8.3 **At a global and regional level**, an increase of US$ 48 to 53 million in Foundational Support (FS) and Strategic Focus Areas (SFA) may be needed to accelerate normative guidance and transformative tools, particularly in reaching zero dose children and missed communities. Understanding and addressing **gender-related barriers** which are important to reaching zero-dose children would be an area of focus. There is a need to quickly design gender responsive and transformative interventions, undertake implementation research and rapidly document and disseminate what works. This will greatly assist in implementing Gavi's ambitious gender policy. In addition, to mitigate the risks of **vaccine hesitancy**, a more systematic approach to social listening and engagement needs to be rapidly developed. This will help develop a common taxonomy and approach for addressing misinformation, with critical new partnerships bringing new skills and expertise to the Alliance.

8.4 At a **country level**, increased technical assistance would be needed to support countries to maintain, restore and strengthen immunisation in the wake of COVID-19 and for the equity agenda. There is broad recognition that successfully identifying and reaching zero dose children will require working with local partners such as CSOs, faith-based organisations and humanitarian actors that work at grassroots level and are trusted by communities. **An increase of US$ 80 to 84 million is proposed for PEF TCA**, bringing the total amount for Gavi 5.0 to US$ 500 million. Around 30% of this total would be focused on local partnerships for zero-dose children and missed communities.

8.5 Finally, **US$ 20 million would advance the zero-dose learning agenda** at a country and global level (reflected under PEF Targeted Assessments).

8.6 **Without dedicated additional funding for Alliance partners and community organisations, Gavi's investments are unlikely to yield the required results.** Partner support is necessary given countries require technical knowledge as well as hands-on, operational support in difficult and underserved settings to maintain, restore and strengthen immunisation services and define appropriate strategies for identifying missed communities and zero dose children. In addition, funds allocated as part of Gavi 5.0 are at the same level as Gavi 4.0- despite additional needs.

9. Secretariat capacity and resourcing

9.1 The Secretariat has been highly stretched owing to growing complexity, volume and breadth of work. **Additional capacity is needed to equip it to exercise effective stewardship of resources and priorities. Resources** for 2021-2025 for the Secretariat might be required to be increased by 15 to 20%, corresponding to US$ 84-112 million, which would be substantiated and confirmed as part of the ongoing organisational review of the Secretariat. The Secretariat will bring back the approach for adjusting Partner and Secretariat resourcing to the next meetings of the AFC and Board.

10. Summary of priorities and indicative investment amounts

10.1 Table 1 gives an **overview of the recalibrated programmatic priorities and indicative amounts for the associated investments**. These are based on initial high-level assumptions and indicate the underlying relative prioritisation of the various programmatic areas.

Table 1: Programmatic priorities and indicative investments

Programmatic priority	**Approved investments (US$ million)**	**Indicative additional investments (US$ million)** *Lower range* *Higher range*
Available funds for current investments as per financial forecast presented to AFC in Sept. 2020		*1,662*[7]
Recalibrated priorities *(requiring urgent action)*:		
Maintaining, restoring and strengthening immunisation services	1,200	0
Reaching zero-dose children and missed communities	0	500
Pacing the expansion of new vaccines	-	N/A[8]
Delivering COVID-19 vaccines	-	150
Impact on co-financing	-	150 - 200[9]
Further priorities *(to note and to be brought back to the Board at a later stage)*		
- Innovation	-	150 - 200
- VPD surveillance	-	75 - 100
- Former and never Gavi-eligible countries	281[10]	TBD[11]
- Strategic partnership with India	-	200 - 250
- Fiduciary risk assurance and financial management	-	75 - 125
Alliance partner and Secretariat resources *(to note and to be brought back to the Board at a later stage)*		
- Partnership Engagement Framework (PEF)	1,365	148 - 157
- Gavi Secretariat	557	84 - 112
Total of indicative additional investments		**1532 - 1794**

10.2 Funds raised through the June 2020 replenishment included US$ 413 million for Strategic Investments[12], enabling Gavi to allocate funds to emerging priorities. If all of the above priorities were adopted at their lower

[7] Includes US$ 413 million of Provision for Strategic Investments allocated to Available Resources
[8] Savings of US$ 72 million have been included in the financial forecast presented to AFC in September 2020.
[9] Corresponds to anticipated reduction in co-financing amounts, not additional investment.
[10] In June 2019 the Board approved an envelope of up to 3% of then projected Gavi 5.0 expenditure for the MICs Approach, equal to approximately US$ 281 million
[11] Financial implications of new approach on former and never Gavi-eligible countries to be presented at later stage.
[12] This amount is included in the total available funds of US$ 1,662 million

range, US$ 130 million[13] would remain as strategic reserve. Given the uncertainties on the impact of the COVID-19 pandemic, **Gavi will retain its ability to reallocate funds accordingly and guided by the Board.** The experience from previous strategic periods shows that reallocations remain possible as not all funding will be firmly committed until later in the strategic period and not all of the above priorities would be adopted at their maximum range.

Section C: Actions requested of the Board:

The Gavi Alliance Board is requested to:

a) **Provide guidance** on the recalibration of programmatic priorities and how they reflect appropriate trade-offs in light of COVID-19 and the successful replenishment;

b) **Approve** an additional US$ 500 million to the HSS allocation of US$ 1.2 billion for the strategic period 2021-2025 as dedicated funding for zero-dose children and missed communities. This amount is in addition to the funding amounts included in the forecast presented and previously approved by the Board at its July 2020 meeting;

c) **Approve** the carry-forward of an amount of US$ 85 million in co-financing waivers and **extend** to 2021 the authority granted by the Board in May 2020 to waive 2020 co-financing obligations on a case-by-case basis upon request from a country;

d) **Note** that US$ 500 to 675 million may be required in 2021-2025 for innovation, vaccine-preventable disease (VPD) surveillance, the strategic partnership with India, and fiduciary risk assurance and financial management capacity, and will be brought back to the Board for decision in due course per guidance provided at the September 2020 Board meeting;

e) **Note** that to deliver on the recalibrated priorities an increase in PEF spending in the order of US$ 148 to 157 million may be required, and that the details of this request will be brought to the upcoming meetings; and

f) **Note** that additional Secretariat resources of approximately US$ 84 to 112 million may be required in 2021-2025, to be confirmed by the ongoing Organisational Review, and would be brought back to the October 2020 AFC and December 2020 Board meetings respectively.

Annexes

Annex A: Zero-dose and equity approach to immunisation: best practices

[13] Based on lower range estimates for additional investments.

Annex A: Zero-dose & equity approach to immunisation: best practices

Pakistan: *Precise identification of zero-dose children supported by data integration and triangulation*

- Pakistan has the 4th highest number of zero-dose children (0.8m) in Gavi supported countries after Nigeria, India and Indonesia[1]. **Identifying** where the highest number of these missed children are located and knowing why they have been missed is a key step in **reaching** these children through Primary Health Care (PHC) services. Sub-national data analyses including triangulation of data to support identification of areas with higher immunity gap and/or with immunisation services gap. In some specific context like in pivotal countries or during preparation of Full Portfolio Planning, identification steps could be more granular. **Triangulation of population data** from polio line listing has started to bear fruit. Most of the electronic immunization registries (EIR) are not suited to identify zero-dose children as only children who have been at least once in contact with immunisation services are registered. To address this issue, Pakistan used Alliance support during polio campaigns in 2019 to identify children who have never being vaccinated in routine immunisation, to line-list them and integrate them into Zindagi Mehfooz (ZM), the EIR solution used in Sindh province. This was designed to solve two problems: (1) identifying zero-dose children missed by routine immunisation; and (2) understanding which children are missed by polio campaign efforts. For the first use case, analyses showed not only pockets of zero-dose children but also the underlying reasons for non-vaccination (e.g. ZM captures data relating to vaccinator compliance which is critical to **identifying** supply-related issues in the Pakistan context).
- To demonstrate the second use case, in 2019, the line list of children lost to follow-up for polio was compared to the registry of surviving infants captured by ZM. As this analysis is quite complex and requires advanced data integration skills (which are costly), a proof of concept focused on a single Union Council was generated. Results showed that 11% of children lost to the polio programme, had in fact been **reached** through routine immunization activities. While these approaches require significant investment, they demonstrate how innovation can help identify children who are otherwise missed by traditional data systems.

South Sudan: *partnership with International Organisation for Migration (IOM) and Health Pool Fund (HPF) to accelerate vaccination coverage and reach missed communities*

- Gavi entered a partnership with IOM South Sudan in October 2019, with an aim to support RI through, (1) 20 high priority health facilities in and around Protection of Civilian (POC) sites and (2) provision of immunisation services at a few specific nutrition treatment centres where mothers regularly access supplementary nutrition or therapeutic food. A pilot conducted in 5 counties of former Unity state (Rubkhona, Mayom, Leer, Mayendit & Panyijar) between 2016 and 2018 showed that almost **50%** of children vaccinated with Penta3 received their vaccination from Outpatient Therapeutic Programme (OTP)

[1] WUENIC (2020)

centers. Persistent droughts and related community mobilisation strategies have led to a higher demand for nutrition services. Therefore, the identified OTP centers have specific guidelines that ensured all children were screened for basic health parameters and vaccinated before receiving their scheduled nutrition service. In addition, IOM is conducting village level assessments and mapping of population movements through digital tools to ensure that all children, including those who are mobile, hard-to-reach within communities on the borders with neighboring countries, cattle camps, settlements, and military barracks are **identified** and **reached**.

- In October 2019, Gavi joined the Government's Health Pool Fund, partnering with Canada, UK Aid, Sweden and USAID in supporting 8 of the 10 states in South Sudan. Through this arrangement RI is now integrated within PHC services and intensified in almost half of the health facilities in priority counties managed by the HPF. These specific health facilities were selected based on criteria including number of unvaccinated children and the number of visits by mothers accessing reproductive and maternal health services. An Advisory Steering Committee of HPF donors including Gavi, was established to regularly engage with the MOH leadership on a monthly basis to discuss programme priorities, implementation challenges, **monitor** progress and help take corrective measures. The HPF also helps ensure donor alignment on the importance of equity in immunisation, providing a platform for **advocacy** to ensure these remain high priorities for the Ministry of Health and other donor funded programmes.

India: *Increasing male engagement in Safal Shuruaat project through concurrent monitoring and evaluation*

- India has the 2nd highest number of zero-dose children (1.4 million) in Gavi supported countries[2]. While the Government of India has been continuously scaling up service provision and availability to optimise vaccination coverage, demand side challenges remain a significant barrier to reaching every child. In 2017, Gavi, the Vaccine Alliance and Lifebuoy (Unilever's leading health soap brand) came together for an innovative public private partnership called '*Safal Shuruaat',* to co-promote immunisation and handwashing with soap, to **reach** out to zero-dose communities. Translated as '*Successful Beginning'*, the programme harnesses parents' aspirations for their child's success to help mobilise parents to wash hands with soap at key occasions, immunise their children and other key parenting behaviors. The project was concurrently **monitored** to track changes in Key Performance Indicators (KPIs) on handwashing and immunization across the first 300 days of intervention, followed by a 100-day test to understand the sustainability of KPIs after the program was completed.
- The 300 days monitoring showed that compliance for three priority vaccines – Rotavirus, Measles-Rubella (MR) and Pentavalent -- relevant for children under the age of 2, grew by 45%, 35% and 20% respectively. The 100-day sustainability test showed that the possession of Mother and Child Health cards with parents increased by 10%. In addition, age relevant compliance of Pentavalent, Rotavirus and MR vaccines saw significant increase, during this

[2] WUENIC (2020)

period. Also, positive attitudes among parents, towards necessity of immunization and its benefits increased by 25%. The proportion of zero-dose children (no pentavalent vaccine) fell from 25% at baseline to under 1%. This approach and the findings can be used to tailor demand interventions to effectively **reach** zero dose communities.

Afghanistan: *broadening of partnerships to enhance services to reach marginalised communities*

- Afghanistan has a substantial number of zero-dose children (310,000)[3]. Some of these children are clustered in conflict affected and insecure areas where access to public health programmes is limited. **Humanitarian actors** often have better access to **reach** these communities. In Afghanistan, the Ministry of Public Health has used Gavi support to partner with the International Federation of Red Cross (IFRC)/Afghan Red Crescent Society (ARCS) to provide routine immunisation in conflict-affected areas. Vaccines are delivered as part of a integrated basic primary health care services to 15,000 children in 30 targeted districts. COVID-19 information and trainings have been added to the package of services during the recent months of the pandemic.
- With support from Gavi and UNICEF, the Afghan government is also co-delivering a Periodic Intensification of Routine Immunisation (PIRI) along with nutritional support through existing health infrastructure targeted in 100 districts (out of 421) that had a less than 80% coverage in the previous Measles SIA campaign. In addition, a partnership with Acasus is building programme management capacity and accountability through digital technology in hard to reach areas. This is to ensure that missed communities and under- immunized children are **monitored** for receiving regular Routine Immunisation (RI) in 17 targeted provinces (out of 34 in Afghanistan) including polio endemic provinces.

Mali: *district level micro-plans to reach missed children*

- Immunisation in Mali has been facing serious challenges in the last 10 years with high political instability, and insecurity in the north and centre of the country, and weak capacity and increasing fragmentation within the Ministry of Health. As a result immunisation DTP3 coverage slowly decreased from 75% in 2010 to 66% in 2017 as per WUENIC estimates.
- Following a high quality Coverage and Equity (C&E) analysis, a strategy was designed to **reach** the un/under immunised children. District-level micro plans were developed tailored to the local situation and barriers to reach missed children. An urban immunisation strategy was developed to reach the significant numbers of under-immunised and zero-dose children who resided in major cities. Among the different approaches put in place, the setting up of strong local accountability framework involving a wide range of stakeholders (religious and community leaders, CSOs, Provincial and District Health offices, etc.) allowed for a clarity in roles and responsibilities amongst different actors and an agreed process to **monitor** progress collectively. In urban areas 300 female leaders played a crucial role in mobilising communities to demand RI through an active WhatsApp group and home visits. This approach was implemented in phases starting with 11 districts in 2018 to which 12 priority

[3] WUENIC (2020)

districts were added in 2019. The Alliance played a critical role in providing financial support through Gavi HSS and a strong Technical Assistance sub/nationally throughout this period.

- The approach has yielded positive results with DTP3 coverage increasing to 77% in 2019 and particularly rapid progress in targeted districts.

SUBJECT:	**COVAX FACILITY OPERATIONALISATION AND VACCINE PROGRAMME**
Agenda item:	03
Category:	For Decision

Section A: Summary

Context

In July 2020, the Gavi Board approved Gavi as the legal entity to administer 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 equitable access to safe and efficacious vaccines. The Board also approved the establishment of the Gavi COVAX AMC (the "COVAX AMC"), a financing mechanism to accelerate and reserve COVID-19 vaccines to ensure that low income and lower middle-income economies, as well as other IDA-eligible economies, have access to COVID-19 vaccines at the same time as wealthier economies.

The COVAX Facility will have global participation of over 170 economies representing over 70% of the world's population. As this paper is being written, self-financing economies have begun to provide their legally binding agreements which include upfront funding to reserve doses with manufacturers now. This will allow the Facility to build an actively managed portfolio of 10-15 vaccine candidates based upon diverse technologies and geographies to maximise the chance of a successful outcome and accelerate access with up to two billion doses by end of 2021. The COVAX Facility will shape the vaccine market to expand supply and achieve economies of scale through aggregating demand and increasing availability simultaneously in developed and developing countries.

Without a successful COVAX Facility there is a very real risk that lower income countries will be left behind, and the majority of people in the world will go unprotected. This would allow the virus and the pandemic to continue unabated and continue to disrupt the global economy as well as Gavi's core mission. The Gavi Secretariat, including the Office of the COVAX Facility, under the guidance of the Board, must find the right balance to safeguard the reputation and finances of the Alliance and successfully deliver on the promise of the Facility. To this end, the COVAX Facility is designed to ensure the procurement and governance needs of both Self-Financing Participants ("SFP") and 92 COVAX AMC-eligible economies ("AMC92") are adequately addressed whilst minimising risks to Gavi core resources and programmes.

Questions this paper addresses

- What are the design, funding and financing arrangements for the COVAX Facility to be able to deliver on the commitment of procuring up to 2 billion doses of COVID-19 vaccines, while effectively managing financial risks and liabilities within the Board's risk appetite?
- What Facility governance arrangements have been made to ensure appropriate oversight of the Facility?
- What progress has been made in engaging manufacturers and economies?
- How is the Alliance planning to support eligible economies with COVID-19 vaccine delivery, including the potential need for ultra-cold chain?

Conclusions

We have set out in this paper: (1) Preliminary Facility funding arrangements; (2) the financial operating model of the Facility; (3) proposed Facility governance structure; (4) a vaccine pipeline and manufacturer engagement update; (5) an update on country engagement in the Facility; (6) the establishment of the Office of the COVAX Facility; (7) cost-sharing with AMC-eligible economies; (8) vaccine delivery and technical assistance support required to deliver COVID-19 vaccines, and; (9) proposed support for India. Related risks and mitigating measures have been highlighted throughout the paper, based on a detailed risk assessment being carried out and to be shared in further detail with the Audit and Finance Committee (AFC) and at the December Board meeting as part of regular risk reporting in the Risk & Assurance Report.

The Board is requested to approve the proposed COVAX Facility governance structure, the proposal for cost-sharing with AMC-eligible economies and a request to allocate US$ 150 million of core Gavi resources towards the preparation required to deliver COVID-19 vaccines, focusing on urgent technical assistance and cold chain needs. The Secretariat is also seeking guidance on the scope of countries that should be eligible for the US$ 150 million of support.

Section B: Update on COVAX Facility Model

1. Design and funding arrangements

1.1 The Facility accelerates the usual process and timelines for bringing vaccines to market at-scale by enabling investments in a diverse and actively managed portfolio of candidates to maximise the probability of success, facilitates manufacturing capacity expansion, technology transfer and vaccine production in advance of licensure. The Facility is a pass-through mechanism matching limited supply in 2021 with expressed demand. By aggregating global demand, and providing upfront reservations, and commitments to manufacturers through advance purchase agreements and options, the Facility allows economies to have a more diverse portfolio and manufacturers to serve a broad array of economies. In combination, this accelerates the speed and scale of

available vaccines once approved, and the portfolio effect maximises the probability of success.

1.2 The Facility's planning assumptions are that by 2021, the maximum availability of doses for the Facility would be around 2 billion; this informed the ambition to attempt to procure that number of doses to end the acute stage of the pandemic. Once the final commitments from SFPs are submitted, and the Facility has visibility to what funds are likely to be available for the AMC, the procurement amount will be adjusted to the demand. In the meantime, the Office of the COVAX Facility is actively negotiating memoranda of understanding with individual manufacturers (see section 4 below) to be able to enter into upfront reservations, advance purchase agreements and future options. To minimise financial liabilities and risk, the Office of the COVAX Facility will only enter into binding agreements with manufacturers once these are backed by legally binding financial commitments [1] with appropriate financial backing for such commitments (in accordance with the July Board decision[2]). Subject to this, to protect against anticipated vaccine candidate failure, the Facility will enter into agreements with manufacturers for additional doses beyond the 2 billion target[3]. Entering into agreements rapidly is critical to the success of the Facility through ensuring sufficient volumes are reserved for Facility Participants to vaccinate the highest priority populations.

1.3 Manufacturer agreements will consist of two components: commitments for the purchase of a pre-defined number of doses of COVID-19 vaccine once the vaccine has been approved[4] and the option to purchase a pre-defined number of additional doses. These agreements will require some payments to manufacturers in advance of vaccine approval – to cover scale-out to further increase manufacturing capacity and enable production of vaccine prior to licensure – with these upfront costs converting into initial payment for doses if vaccine candidates are successful. The Facility will also incur costs associated with financing (e.g. insurance, interest costs) – and operating costs. The Participants' arrangements are structured to cover these upfront costs.

1.4 There will be two separate and independent sources of funding to cover these costs: COVAX AMC and SFPs. SFPs will have the opportunity to choose between two models: the "Committed Purchase" arrangement or the "Optional Purchase" arrangement (see Appendix 1 for further details).

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[1] Legally binding commitments from SFPs to procure such doses to serve SFPs and from AMC funding to serve the AMC92.

[2] The July Board agreed that "Gavi would not enter into agreements with manufacturers which result in SFPs being distributed doses without having provided a legally binding financial commitment to procure such doses, with appropriate financial backing for such commitment."

[3] Initial planning suggested an average failure assumption of 50% across candidates in the portfolio. Optionality in manufacturing agreements will be structured to mitigate the risk of overshooting the number of procured doses, should the rate of failure (attrition) ultimately be below the current assumption.

[4] An 'approved' vaccine is one that receives WHO prequalification or on an exceptional basis, at minimum, licensure/authorisation from a stringent regulatory authority.

a) **"Committed Purchase" arrangement**

The "Committed Purchase" arrangement commits Participants to purchase allocations of approved vaccines from the Facility. Participants make an upfront payment of US$ 1.60 per dose (in order to cover a proportion of the pre-approval costs to manufacturers and Facility financing and operating costs) and provide a financial commitment of US$ 8.95 per dose for the remainder owed, via a guarantee from the Participant's Ministry of Finance or Central Bank if a country's long-term credit rating is equal to or greater than B2/B/B from at least one of the indicated rating agencies (Moody's, Fitch, S&P). If a country does not meet either condition, Gavi will accept a financial guarantee from a multilateral development bank or from a financial institution with a credit rating of Baa2/BBB/BBB (Moody's, Fitch, S&P).

b) **"Optional Purchase" arrangement**

The "Optional Purchase" arrangement allows Participants to decide whether to purchase any approved vaccine candidate allocated to them. Participants make a higher upfront payment of US$ 3.10 per dose to reserve options to purchase vaccine doses through the Facility. This amount will cover the full amount of estimated pre-approval costs to manufacturers and Facility financing and operating costs.

Under this arrangement Participants are additionally asked to provide a risk-sharing guarantee of US$ 0.40[5] per dose to help protect Gavi against the **risk of opt-outs** and any liabilities resulting from Participants deciding not to purchase a particular vaccine candidate after the Facility has already entered into a contract with the manufacturer. Modelling residual liability shows that US$ 0.40 per dose is sufficient to reasonably cover most scenarios of extent of Participant opt-outs (although the Facility can only enter into supply agreements to the extent that fully committed resources are available). If a Participant opts out of purchasing a vaccine, the Facility could draw from that Participant's risk-sharing guarantee amount (US$ 0.40 per dose multiplied by the number of doses the Participant has requested to access through the Facility) to cover any residual liabilities associated with that vaccine.

Participants will also be given the opportunity to opt-out prior to manufacturer deal-signature. This allows the Facility to factor this into the manufacturer agreement and reduces the instances of SFPs under the Optional Purchase arrangement opting out of purchasing doses of approved vaccine allocated to them.

1.5 Under both arrangements, Participants will pay the procurement cost that the Facility has negotiated through bilateral agreements with

[5] Based on financial liability modelling of different scenarios covering level of optionality in manufacturer deals, opt-out behaviour by economies and level of absorption by other Participants. This model ran a range of scenarios of percentages of economies who would opt for the optional purchase arrangement. Once the true percentage is determined, the model will be rerun to inform the deals with the manufacturers.

manufacturers. This allows the Facility to provide the benefits of economies of scale to Participants while allowing some tailoring to the circumstances of each Participant.

1.6 The COVAX AMC will be funded by Overseas Development Assistance (ODA) (including through contributions through IFFIm (International Finance Facility for Immunisaton)) as well as through support from foundations, private donors and concessional funds from multilateral development banks. The AMC will initially reserve doses of vaccines for eligible economies and with respect to upfront payments and procurement it is analogous to the Committed Purchase model.

1.7 The Facility's operational planning up to now has assumed a specific proportion of SFPs selecting the Committed Purchase vs Optional Purchase arrangement. The actual data coming in through the signed Commitment Agreements shows a more significant proportion selecting the Optional Purchase arrangement than anticipated. This has implications for the amount of upfront funds the Facility is likely to receive – more than anticipated – as well as the quantity of fully committed doses – less than anticipated. This information will shape the types of deals the Facility intends to negotiate with manufacturers. The Facility will work with industry to match demand with supply in such a way to minimise risk.

2. Financial Operating Model and financial risk exposure of the Facility

2.1 A full operations plan is under development and we are seeking risk and financial advice from a number of investment banks and financial experts to feed into the development of a detailed and risk-adjusted operations plan.

2.2 The partners of the ACT-Accelerator vaccine (COVAX) pillar (Coalition for Epidemic Preparedness Innovations (CEPI), Gavi, and WHO) have estimated the cost of securing and delivering 2 billion doses of successful COVID-19 vaccines through the Facility by the end of 2021 for AMC and SFP economies based upon a model portfolio of known vaccines. The Facility is being structured as a pass-through mechanism where Participants will pay the actual price manufacturers will be charging (which, manufacturer dependent, may be either a tiered price or a single price for all countries) plus a speed premium for pre-approval payments (for scale up, tech transfer and reservation fees) and a small charge to support the operation of the Facility[6].

2.3 While the Facility will seek to balance the timing of cash outflows with cash inflows, Gavi may seek a debt facility secured against committed resources to ensure that the Facility has access to the necessary liquidity to make upfront cash payments to manufacturers in excess of upfront payments received for SFPs. External legal counsel has confirmed that Gavi can borrow funds should this be deemed necessary and desirable to ensure

[6] The share of total cost is estimated to be 15-20% for the speed/access premium, 80-85% for ex-factory costs (covering variable costs of manufacturers to produced doses) and <3% for financing and operating costs.

appropriate timing and the overall success of the Facility. This would be presented to and approved by the AFC.

2.4 Gavi is seeking to appoint an external Treasury Manager to ensure segregation of, and manage, the SFP funds and expects to issue a Request for Proposals (RFP). The costs related to the Treasury Manager will be covered by upfront payments made by economies, and the oversight of the Treasury will be performed by the AFC. Until the Treasury Manager is in place, funds related to the Facility will be ringfenced in separate Gavi bank accounts.

2.5 As per the Gavi Board decision at its meeting in July 2020, Gavi is the legal entity administering the Facility, although Participants will take title to the vaccines and any associated risks. This means that the Alliance will ultimately be assuming the financial risk exposure of the Facility. As described above, in order to protect Gavi's Balance Sheet, Gavi will not enter into any advance purchase agreements with manufacturers until it has legally binding financial commitments for secure funding to procure such doses. This operating principle will considerably limit **financial risk exposure and liabilities** for Gavi, however there is a risk that this results in **delays for deal-making**[7] (due to financial backing being insufficient at the time deals need to be signed), which may pose a risk to the success of the Facility. As set out above, the Facility is therefore looking into additional bridge financing or insurance solutions that can be used to secure these contracts and support deal making and procurement.

2.6 To mitigate the **risk of Participants defaulting**, SFPs are asked to provide a guarantee from creditworthy financial institutions (see section 1.4a). Gavi is engaging investment banks and multilateral development banks with relevant financial expertise on sovereign risk to assess robustness of guarantees and guarantors, and limit downside risk.

2.7 The Facility will seek to mitigate residual risks of overcommitment due to **higher than anticipated opt-outs** (after deal signature) from SFPs selecting the "Optional Purchase" arrangement or having **more successful vaccine candidates** (lower attrition) than anticipated (and excess doses cannot be reallocated to or absorbed by other Participants), through optionality in manufacturer agreements (whereby Gavi has the option, rather than an obligation to purchase doses), and risk sharing guarantees, as described above.

2.8 The AFC, at its meeting on 15 September 2020, discussed the financing operating model and financial risk mitigation steps in place for the Facility, and suggested to explore further steps to better understand and quantify any residual risks and explore innovative ways to further minimise credit and liquidity risk. The Gavi Secretariat is exploring additional insurance products and financial instruments to cover vaccine candidate portfolio

[7] Delays could be caused by being unable to obtain credible guarantees from SFPs in time, actual prices turning out higher than the estimated weighted average price used for Participant cost calculations, or by a potential AMC funding shortfall.

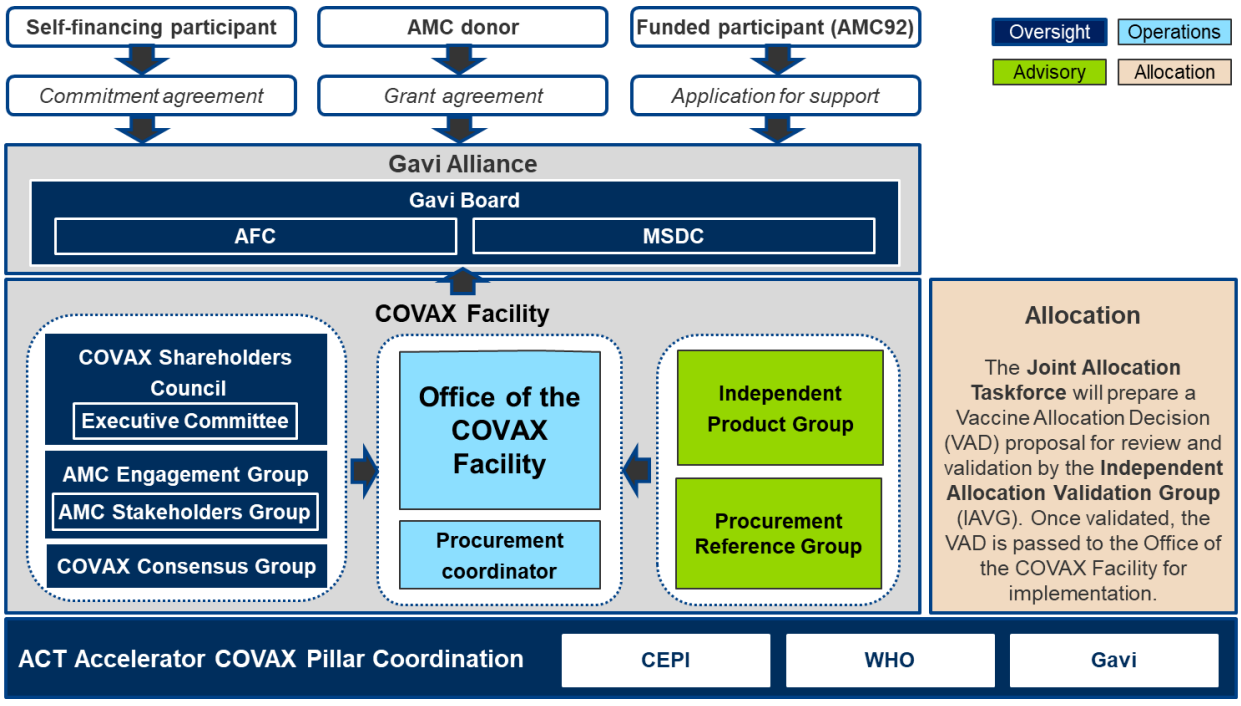
uncertainty, opt-out risks, risk of countries defaulting and other risks of having purchase commitments on vaccine doses in excess of the Facility's committed resources and guarantees. Gavi is in initial discussions with major insurers who have expressed interest in structuring this instrument for the Facility.

3. Proposed Facility governance structure

3.1 The COVAX Facility is being established within the COVAX Pillar of the ACT-Accelerator. As Gavi is the legal entity administering the COVAX Facility, the governance arrangements for the Facility build on the Gavi Board and its Committees, with new bodies established to ensure appropriate oversight and agility to support the functioning of the Facility. The following proposals reflect:

- The Board's decision that Gavi should host the Facility, therefore giving the Board ultimate responsibility for decisions.
- The need to represent and give a voice to new parties, including new implementing economies and Facility Participants.

Schematic of the Proposed Governance Structure



Existing Governance Bodies

3.2 The **Gavi Board** will be responsible for overseeing the role of the Gavi Secretariat and the Alliance in the Facility and will have ultimate responsibility for decisions and effective implementation of the COVAX Facility. In this role it will:

a) Take responsibility to ensure that the Gavi Secretariat operates within the mandate granted to it;

b) Provide strategic direction and policy-making;

c) Receive regular reports from the Office of the COVAX Facility on operational progress and performance;

d) Receive updates from relevant Board Committees (e.g. AFC) on COVAX Facility matters; and

e) Provide strategic oversight of the COVID-19 programme and effective implementation including country engagement.

3.3 In light of the Board's decision about eligibility for funding through the AMC, the Gavi COVID-19 vaccine programme (see section 8) is available for implementing economies that are not currently represented on the Gavi Board. These economies will need to have a voice when the vaccine programme is considered. It is proposed that:

a) In order to maintain balance with the existing representation of implementing economies, implementing economies not currently represented on the Board should form new constituencies, and;

b) These new constituencies should be invited to attend Board meetings as observers where the COVID-19 vaccine programme is considered.

3.4 As agreed by the Board at its meeting on 30 July 2020, Gavi's **Market-Sensitive Decisions Committee (MSDC)** will be responsible for reviewing business terms of proposed agreements with manufacturers to ensure: (i) reasonableness of terms and acceptable level of reputational risks; and (ii) availability of resources to back proposed agreements. For the review of COVAX-related agreements with manufacturers, membership of this body has been expanded to include an additional three representatives nominated by the COVAX Shareholders Council (see section 3.7a).

3.5 Gavi's **Audit and Finance Committee (AFC)** will be responsible for: (i) ensuring funding availability for COVAX Facility operations, including review of the financial implications of Facility-related transactions; (ii) ensuring the COVAX Facility is properly represented in Gavi's Annual Financial Report; and (iii) monitoring risk to Gavi, the Alliance, and the COVAX Facility.

3.6 Other Gavi governance bodies may request updates from the Office of the COVAX Facility on aspects of COVAX implementation of relevance to the delivery of their mandates. These bodies may also be called upon by the Office of the COVAX Facility to advise on specific issues within their areas of responsibility, as appropriate.

New governance and technical advisory bodies

3.7 Whilst the principle of the ACT Accelerator is to not create new governance bodies, effective governance of the COVAX Facility, hosted by Gavi, will

require the establishment of new governance and technical bodies to account for stakeholders that would otherwise be unrepresented. The new bodies are described below:

a) The **COVAX Shareholders Council** ("the Council") will represent SFPs in the governance of the COVAX Facility. Membership of the Council will be open to all SFPs in the COVAX Facility. The Council will convene SFPs with the aim of supporting real-time information exchange and providing strategic guidance and advice to the Office of the COVAX Facility on the operational aspects of the COVAX Facility. Proposed Terms of Reference are attached as Annex B.

   As a self-organising body, the Council will determine its own operating procedures and take decisions at its first meeting regarding inviting observers. Draft Operating Procedures, for consideration by the Council are attached as Annex C.

b) Given the large number of SFPs, it is expected that the Council will decide to establish a smaller **Executive Committee** ("the ExCom") to prepare and guide its discussions. The ExCom will provide a clear link between the Council and other governance structures to ensure the consolidated advice/view of the Council is considered in relevant deliberations and that the Council is well prepared/briefed to provide advice as issues arise.

   Members of the ExCom will be chosen to represent constituencies as determined by the Council. ExCom will take decisions regarding inviting observers, such as representatives of the AMC92 economies, at its first meeting. Draft Terms of Reference for the ExCom, for consideration by the Council, are attached as Annex D.

c) The **AMC Engagement Group** will be open to representatives from implementing economies, donors and other parties engaged in the financing and operation of the AMC portion of the Facility. This body will represent the AMC in the governance of the Facility. The Group will convene with the aim of supporting real-time information exchange and providing strategic guidance and advice to the Office of the COVAX Facility on the operational aspects of the COVAX Facility. Proposed Terms or Reference are attached as Annex E.

   Within this body, an **AMC Stakeholders Group** will convene representatives from AMC donors, procurement organisations such as UNICEF and PAHO and, the representatives of multilateral development banks or regional banks involved in the financing of the AMC. It will discuss its investments in the AMC, options for additional financing and receive specific reporting on progress achieved against the objectives of the AMC. Proposed Terms or Reference are attached as Annex F.

d) A **COVAX Consensus Group** will be established to support effective operation of the COVAX Facility through consensus-based decision-making. It will be responsible for ensuring that any disputes or

challenges arising in the governance bodies of the Facility, where all other possible avenues to resolve the matters have been exhausted, can be addressed swiftly and in the best interests of the aims of the Facility. Comprising the Chair and Vice Chair of the Gavi Board; the Co-Chairs of the COVAX Shareholders Council; co-Chairs of the AMC Engagement group ; and – in an ex-officio, non-voting, capacity – the three leads of the ACT-Accelerator COVAX Pillar; the COVAX Consensus Group will be chaired by the Gavi Board Chair. Proposed Terms of Reference are attached as Annex G.

Technical bodies

3.8 Technical bodies of the Facility will make recommendations to the Office of the COVAX Facility on candidate selection and procurement.

a) **Independent Product Group** (IPG) will provide independent technical advice to the Facility on the prioritisation and inclusion of suitable vaccines and the status of the COVAX portfolio of vaccine candidates, based on information related to clinical development, manufacturing and supply. The IPG will assess all vaccine candidates against a uniform and systematic set of criteria. It will regularly consider the implications of timing/ availability of vaccine on the broader portfolio and review the portfolio for balance. Proposed Terms of Reference are attached as Annex H.

b) Once vaccine candidates have been selected to be funded by the Facility, informed by recommendations of the IPG, the **Procurement Reference Group** (PRG) will then be responsible for providing independent advice to the Facility on its procurement strategy and key business terms of proposed advance purchase commitments with the manufacturers of these vaccine candidates. Based on recommendation from the PRG, the Office of the COVAX Facility will advance negotiations with manufacturers and bring recommendations to the MSDC on final deal terms for approval.

Allocation Mechanism governance

3.9 The Facility will apply the WHO Allocation Framework as the basis for vaccine allocation decisions for Facility Participants, operationalised through the Allocation Mechanism. The Allocation Mechanism will comprise the Joint Allocation Taskforce and the Independent Allocation Validation Group:

a) The **Joint Allocation Taskforce** (JAT), comprised of WHO and the Gavi Secretariat, will prepare a Vaccine Allocation Decision (VAD) proposal for review and validation by the Independent Allocation Validation Group (IAVG). The VAD proposal will be based on a data-driven allocation model. The JAT will review all the data inputs needed for the allocation model and verify its output. Some flexibility to enable adjustments for clearly defined reasons, such as operational considerations, will be accommodated and fully documented. The JAT will respond to any

requests for clarification from the IAVG, re-running the model if necessary. The JAT will be convened by the Office of the COVAX Facility and WHO, with ToRs jointly defined by WHO, the Gavi Secretariat and CEPI in the coming weeks, aiming for finalisation by end October.

b) The **Independent Allocation Validation Group** (IAVG) will be established as an independent body to validate the VAD proposal put forward by JAT. Composed of technical experts, the IAVG will validate that the proposed VADs are technically informed, transparent and free from conflicts of interest. They may also request clarifications from the JAT, and for the model to be rerun if needed, before making their final determination. The VAD is characterised as a strong recommendation with any adjustments being made on an exceptional basis for clearly pre-defined reasons, such as specific operational considerations. The VAD, once validated by the IAVG, will be passed to the Office of the COVAX Facility for implementation with support from procuring agencies like UNICEF and the PAHO Revolving Fund.

   It is envisaged that the IAVG will be comprised of independent experts jointly nominated by the core COVAX partners (WHO, Gavi Secretariat and CEPI) and other relevant partners and stakeholders, with observers from CSOs and representatives of economies participating in the COVAX Facility. The ToRs for the IAVG will be defined jointly by the core COVAX partners in the coming weeks, according to established existing processes for constituting expert bodies, aiming for finalisation by end October 2020. A nomination process for the membership of the IAVG will be triggered upon finalisation of the ToRs, also in line with existing processes. Areas of expertise for the IAVG will be established based on the final ToRs but will likely include areas such as expertise in immunisation programmes and service delivery; vaccine safety evaluation and monitoring; access to medicines and health products; emergency public health response amongst others.

3.10 In addition, work is underway by Gavi and WHO, in consultation with partners, to jointly define the governance and use of the emergency buffer.

Civil Society Organisation engagement

3.11 CSOs have expressed a clear recommendation that participation in the COVAX effort through existing governance mechanisms (per ACT-A guidance to limit the creation of new governance bodies) is not sufficient. In support of this view and wanting to be more inclusive of civil society across the broad spectrum of work undertaken by the COVAX Pillar, 10 new CSO representatives are being added, including one each to the Central Coordinating Mechanism (CCM); CEPI's Technical Review, Enabling Science, Manufacturing and Clinical Development and Operations groups; WHO's Vaccine Strategy and Access and Allocation sub-groups, and; the Procurement and Delivery Workstream's country readiness and delivery coordination group and sub-groups.

3.12 CSOs were invited to nominate representatives for these positions until 14 September. More than 150 submissions were received. To ensure the best mix of skills and experience on each of the groups, a CCM and CSO co-created nomination process has been agreed. COVAX Pillar leads will shortlist CSOs from the submissions and CSOs will select representatives from that list to join the 10 groups listed above. CSOs are also already engaged in COVAX Pillar decision making bodies such as the Gavi Board, the Strategic Advisory Group of Experts on Immunization (SAGE), the HSS Connector Working Group, and the Gavi MSDC. COVAX Pillar organisations have held a number of CSO updates so far and plan to offer monthly briefings in the future.

Section C: COVAX Facility Progress

4. Vaccine pipeline and manufacturer engagement update

4.1 As of 21 September 2020 across a variety of technology platforms, WHO reports 38 candidates in clinical evaluation and 149 in preclinical development/ discovery. Of the candidates in clinical evaluation, 9 are in Phase III trials of which 3 have been granted 'Limited Use' status by national regulatory authorities. Of the CEPI portfolio, 8 of the 9 initial candidates are in clinical trials and there is an ongoing CEPI/ COVAX call for further candidates.

4.2 The Bill & Melinda Gates Foundation (BMGF) has also funded a portfolio of potential second-generation vaccine candidates for the medium-to-long term based on the potential for combining attractive attributes relative to leading COVID-19 vaccine candidates (such as higher potency, existing manufacturing capacity, lower cost of goods, and novel approaches). Except for two candidates which are in Phase I, the majority of these are at discovery/late discovery stages. The Foundation is also supporting technology transfer for selected candidates. It is understood that BMGF funding is conditional on manufacturers' making doses available to the Facility.

4.3 Gavi, CEPI and WHO are actively engaging industry as key partners in the success of the COVAX Pillar and the Facility. Representatives of the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) and DCVMN (Developing Country Vaccine Manufacturers Network) have been an integral part of the planning processes including serving on the CCM. Gavi worked with UNICEF on their Expression of Interest in June 2020 which drew submissions from 28 manufacturers. Gavi organised information sessions with partners, UNICEF and WHO about the Facility for the IFPMA, DCVMN and biotech members in June and August which attracted over 100 participants from the three industry associations, to explain the Facility design and benefits of supplying the participating economies through the Facility.

4.4 To date, Gavi, on behalf of the Facility, has approved a legally binding agreement with Serum Institute of India and a non-binding MOU with

AstraZeneca for the supply of up to 850 million total doses in 2021, subject to successful development, manufacturing scale up and licensure of the vaccines. There are ongoing discussions with several manufacturers to potentially provide up to an additional 1.6 billion doses in 2021. If successful, these agreements will contribute towards an estimated target of 10-15 agreements by end of 2020 for doses above this number given attrition to obtain up to 2 billion usable doses by end of 2021 for participating economies.

4.5 To accelerate the commitments by manufacturers to the Facility, Gavi is:

a) prioritising promising CEPI and BMGF candidates which already have the commitment to supply the Facility as condition of the R&D and/or manufacturing funding provided by these organisations;

b) prioritising vaccine candidates which are relatively advanced in development;

c) obtaining support from industry to use streamlined MOUs to gain commitment on key terms, then entering into legal agreements at the next stage.

4.6 Although the CEPI deals are attractive as they represent a well planned and diversified portfolio with access provisions, the Facility is open to procuring doses from any manufacturer. Manufacturer commitments will be entered into based on the technical advice of the IPG and PRG and approval of deal terms by the MSDC, as described in section 3.

5. Update on funding committed to the Facility and the AMC

5.1 To date, US$ 700 million has been pledged to the COVAX AMC, of which US$ 0.3 billion has been converted into legal agreements. The European Commission has also recently announced EUR 400 million in guarantees from the European Investment Bank for “low and middle income countries”. The Gavi COVAX AMC is on track to convert 50% of pledges by end of September and the remainder by the end of November. Discussions with donors are intensifying now that the AMC has been legally set up with a view to raise an initial US$ 2 billion by December 2020. Contributions to IFFIm are encouraged to help frontload much needed resources with ca. 70% of the value of the pledge immediately accessible in cash at signature. A further round of funding is anticipated based on current estimates for an additional sum of at least US$ 5 billion by end 2021. The rationale for this approach is a) to ensure doses can be accelerated and reserved for lower income economies in the first phase of fundraising; and b) establish better estimates of procurement costs and attrition rates. 28 public and private donors have confirmed intent to pledge to the AMC to date.

5.2 Additionally, while we did not initially request AMC-eligible economies to submit an Expression of Interest (EOI), we received voluntary EOIs from 35 economies.

5.3 Since the July Board meeting, the Secretariat has held five consultations with SFP and AMC Participants – three with SFPs and two with AMC-eligible Participants – in addition to numerous individual consultations with at least 37 different economies. Regular updates on the Facility have been provided at weekly WHO member state briefings to ensure maximal provision of information. Given the critical role of continental bodies such as the African Union (COVID-19 Special Envoys, Africa CDC), The Association of Southeast Asian Nations (AESAN), PAHO and the Friends of the COVAX Facility, African Export-Import Bank (Afreximbank), Inter-American Development Bank and the World Bank, the Secretariat has proactively engaged with these groups to provide regular and consistent communication on COVAX Facility and AMC process and progress, leveraging these bodies to support engagement with their economies/participants. We systematically tracked all questions and issued an updated Question & Answer document and other communications to ensure that all Participants received timely access to all information.

6. Establishing the Office of the COVAX Facility

6.1 The Office of the COVAX Facility is currently being established within the Gavi Secretariat to ensure a dedicated team to support the Facility operations and to mitigate disruption to Gavi's core work. Aurélia Nguyen has been appointed as Managing Director of the Office of the COVAX Facility and will move full time to the Facility for a one-year period starting 1 October 2020. Her previous duties at Gavi are temporarily being taken up by other members of the Senior Management Team. The Office will comprise several new, dedicated teams: e.g. design and operations; deal making and vaccine portfolio management; country engagement; and finance. The Office will also leverage dedicated, incremental resources within existing Gavi Secretariat teams (e.g. Resource Mobilisation, Legal, Public Policy Engagement, Governance and other teams) funded in the first instance out of pre-financing approved by the Board.

6.2 Recruitment of individuals both for the dedicated Office of the COVAX Facility teams as well as incremental resources in existing Gavi Secretariat teams is ongoing. In the meantime, surge capacity has been provided through the use of consultants. Gavi anticipates that surge resourcing is required through Q1 2021 to fully setup the Facility, with subsequent reduction to a level of resources for steady state operations beyond that. The Gavi Secretariat is also seeking secondments to ensure that it is fully leveraging the expertise from across Alliance partners and stakeholders.

Section D: Gavi COVID-19 vaccine programme

7. Cost-sharing with AMC92 economies

7.1 The COVAX AMC exists to ensure that all economies, regardless of income level, can participate in the COVAX Facility and have timely, equitable access to COVID-19 vaccines. The Facility and all its Participants represent

an unprecedented show of global solidarity in the fight against COVID-19, and a recognition of the equal role that all economies have in the success of this global effort. Indeed, many AMC economies have indicated their strong commitment to being equal partners in the COVAX Facility, including through contributions to vaccine financing. Contributions to AMC vaccine financing can also help to set a precedent for domestic resource mobilisation for COVID-19 vaccines in the future.

7.2 In the medium-to-long term (if long term vaccination programmes will be required), as with all Gavi routine vaccine programmes and in line with Gavi's strong and principled commitment to equity, AMC-eligible economies will be expected to co-finance COVID-19 vaccines with tiered contributions that reflect economies' ability to pay. The unknowns of vaccine efficacy, duration of protection and evolving disease epidemiology have implications on planning for optimal vaccine use, including cadence of vaccination, setting and population. These will be worked out over time and will inform an eventual co-financing approach. The goal of this longer-term co-financing will be to promote financial sustainability.

7.3 However, in the acute phase of the pandemic, given the urgency of bringing it under control, the primary objectives of a short-term, exceptional 'cost sharing' model should rather be to promote solidarity and country ownership and to mobilise additional resources for COVID-19 vaccines. In addition, in accordance with the overall principles underpinning the AMC, this cost-sharing approach will ensure that financing is not a bottleneck to any economy's access to, or delivery of, vaccines, thereby promoting equity across economies.

7.4 Country cost-sharing contributions may consist of both funding for the purchase of vaccine doses and funding for vaccine delivery (see section 8 below).

7.5 For the purchase of vaccine doses, the objective will be to mobilise up to US$ 1.5 - 2 billion in AMC92 country cost-sharing contributions for the acute phase of the response[8], equivalent to ~US$ 1.60-2 per dose[9]. This contribution would be a strong demonstration of global solidarity, mirroring the minimum US$ 1.60 per dose upfront payment made by fully SFPs, and representing all Participants' equal commitment to and ownership of the Facility, as well as recognition of the Facility's role in ending the acute phase of the pandemic. These AMC92 cost-sharing contributions will be used to fund critical investments such as reservation fees or vaccine procurement, but they will not be used for at risk investments.

7.6 Acknowledging the economic situation of many countries that have been heavily impacted by the pandemic, and true to the principle of ensuring that

[8] Until the end of 2021. Implementation of this cost-sharing approach may be extended if original targets for AMC doses are not fulfilled during this period.

[9] Assumes 2-dose regimen COVID-19 vaccine. Cost-sharing contribution will be adjusted, depending on the number of doses ultimately required for successful vaccines, so that economies pay equally on a per-person basis.

cost does not present a barrier to all economies participating in the Facility, Gavi is actively working to identify ways to support economies to meet their cost-sharing contributions for vaccines**.** To this end, Gavi is currently in conversation with multilateral development banks to identify resources and structure instruments (including grants, loans, and concessional loans) that could play this vital role. Depending on the modality of funding through this approach, economies that do leverage external financing to meet their cost-sharing contributions would still retain control and ownership of the process, actively choosing to commit funds made available to them either through grants or loans for COVID-19 vaccines over other needs. Leveraging multilateral development bank financing also supports the AMC principle of ensuring equitable access to vaccines, as this financing is structured to reflect an economy's ability to pay, with lower-income economies receiving more grants and more concessional lending terms. The US$ 1.5-2 billion total in cost-sharing for vaccine doses is a critical investment in both public health and economic security, and amounts to a very small share of total country annual allocations from multilateral development banks.

7.7 Should multilateral development bank financing not be available, and should economies express that they are unable to meet the expected cost-sharing contributions for vaccines, it is proposed that Gavi exercise flexibility with economy vaccine dose cost-sharing contributions during this initial acute phase[10], recognising the fiscal pressures economies are facing and the difficulty of mobilising and budgeting funds in such a compressed timeline. Gavi will work with economies on a case-by-case basis to adjust vaccine dose cost-sharing contributions as needed (i.e. partial or no cost-sharing). This flexibility will help to ensure that cost-sharing for vaccines does not prevent or delay the introduction of the vaccine in any economy, and that economies do not reallocate existing budgets for other routine vaccines towards COVAX cost-sharing, which would undermine both Gavi core programming and broader objectives.

7.8 This effort to mobilise additional financing from economies via multilateral development banks does not obviate the urgent need to fundraise additional ODA for the AMC before the end of this year to meet the total cost of vaccine doses. There continues to be a pressing need to accelerate and reserve doses for economies which would otherwise not receive them for several years. Furthermore, while country cost-sharing contributions will help to increase the total resources available for the AMC, these contributions may take some time to structure and process.

7.9 All economies will also be expected to contribute to the costs of COVID-19 vaccine delivery: costs will vary by candidate and by economy, and Participants will take heterogenous approaches based on their contexts. Therefore, rather than defining a specific delivery cost-sharing contribution by country at this time, it is proposed that the Gavi Secretariat allocates targeted funds to initially support technical assistance and urgent cold chain

[10] Until the end of 2021. Implementation of this cost-sharing approach may be extended if original targets for AMC doses are not fulfilled during this period.

gaps, with potential additional support contingent on resource mobilisation efforts (see section 8 below).

8. Vaccine delivery and technical assistance support

8.1 Across the ACT-A COVAX Pillar, significant efforts are underway to help economies prepare for COVID-19 vaccine delivery, including the development of policy and operational guidance. Based on the current vaccine scenarios, the assumption is that the first batch of vaccines, to cover 3% of their population, will be delivered through facility-based strategies to reach frontline workers in health and social care settings. Subsequent dose volumes are expected to be prioritised for other high-risk groups including >65 year olds or those with co-morbidities but targeting and delivery strategies are still being developed as we better understand the epidemiology of the infection in different settings.

8.2 Uncertainties related to the vaccine profiles make it necessary to plan for multiple delivery scenarios to mitigate **equity and delivery risks**. These include, but are not limited to, the recommended dose schedule (1 vs. 2 doses), cold chain requirements (2°C to 8°C, -20°C or -80°C), efficacy/effectiveness, and safety among different populations (e.g. pregnant women, the elderly). The evolution of the epidemic profile may also guide how sub-groups are prioritised (potentially geographically based). Finally, the rate at which doses are made available will also impact delivery strategies and health system capacity needs.

8.3 Despite these uncertainties, the Secretariat and Alliance partners will start working with AMC economies to develop end-to-end vaccine delivery plans using available assumptions. To ensure timely distribution of vaccines to those at highest risk, several elements will be critical. These include: the mapping and resolution of regulatory, liability and legal requirements; preparation of supply chains to store, transport and track COVID-19 vaccines (especially given different product profile and risk of diversion); identification and microplanning to reach target populations, which will include sub-populations not traditionally served by immunisation programmes (e.g. healthcare workers (HCWs), and at risk populations including older adults, individuals with underlying co-morbidities); collaboration with other health programmes, across other sectors and ministries, and non-traditional partners; enhanced data systems to track who among the target population has been immunised, and; strengthened surveillance for monitoring vaccine safety and effectiveness of the vaccines. Given increased risks of vaccine hesitancy fuelled by unprecedented rumours around COVID-19 vaccines in some countries, comprehensive demand side interventions will be critical to facilitate trust and acceptance among community members, including social listening and engagement, behavioural interventions, health worker confidence building and interpersonal communication. Open and transparent public communication will be vital at all stages in the process, including communicating the rationale for prioritising high-risk groups including health workers, not least to avoid creating expectations that cannot be met.

8.4 As raised to the Board at its June 2020 meeting, one particularly important consideration is **the potential need for a significant and urgent ramp-up of cold chain capacity.** Due to the uncertainties detailed above, additional CCE (cold chain equipment) needs could range from marginal increases to very significant additional investments.

8.5 The potential need for ultra-cold chain (-80°C, UCC) storage poses a particular challenge. At present, three of the initial vaccine candidates require UCC for long-term stability, though most manufacturers are indicating their products can be managed with traditional +2°C to 8°C/-20°C storage for up to 4-6 months. However, this could change as more data becomes available or the pipeline evolves. In addition, at least one candidate vaccine is currently expected to have only 24-48 hours of stability, requiring UCC storage nearly to the point of care[11]. If deployed to AMC92 economies, UCC vaccines would impose significant CCE, training and operational requirements. For CCE alone, deploying UCC in a given economy can cost between ~6–15x more than equivalent 2°C to 8°C/-20°C scenarios, which better leverage existing infrastructure.[12] In the medium term, the expectation is that nearly all vaccines will be manageable within a standard cold chain, so any need for UCC infrastructure if provided would be time-limited.

8.6 Given the significant cost required, time-limited need, and current indications that nearly all vaccines could be delivered without UCC, Gavi is **not recommending at-scale investment in UCC equipment at this time**, though we will continue to monitor and reassess this position as needed. If several of the first wave of vaccines do turn out to require UCC, this approach **could delay country readiness for vaccine introduction**, given the estimated 4-6 month lead time to procure, install and train HCWs on UCC. To mitigate this risk, Gavi is assessing strategies that would target UCC deployment to a subset of economies and exploring options such as (i) advance procurement of UCC equipment, (ii) contracting third-party logistics provider to provide surge or specialised capacity and (iii) leveraging UCC capacity in other sectors. The Secretariat would welcome Board guidance on whether the proposed approach to UCC appropriately balances cost and access considerations.

8.7 If economies can utilise existing 2°C to 8°C cold chain, initial modelling suggests existing facility-level capacity in most economies would be sufficient given Gavi's previous investments through the Cold Chain Equipment Optimisation Platform (CCEOP). Higher-level stores (national, regional) have not historically been targeted by CCEOP and will require meaningful expansion, particularly if economies receive large shipments of vaccine at one time.[13] Significant expansion may also be needed at district

[11] At least until further stability data becomes available in the period after licensure.
[12] This figure compares national/regional storage models for both UCC and 2-8/-20 strategies, at 20% targets; Range accounts for whether UCC-rated transport devices are needed for distribution.
[13] There have been signals from private sector partners and press that air freight for COVID vaccines will be a major constraint. This may lead delivery volumes to be consolidated into larger shipments.

level if economies opt to store significant volume of COVID-19 vaccines at this level to simplify distribution and access to service delivery points.

8.8 Across the AMC92 economies, the cost of the cold chain expansion required to reach the first 20% of the population is expected to range between US$ 35-125 million, of which US$ 25-80 million is for the 56 currently-eligible Gavi countries.[14] The major swing factor in this range is whether economies decide to store significant vaccine volume at district level. If UCC is required in a subset of AMC economies (working assumption is that this would be deployed in ~15% of economies), it would add an additional US$ 20-75 million in cost to reach the initial 3% of the population, which is when UCC is most likely to be required.[15]

8.9 The Alliance has coordinated with the Therapeutic and Diagnostic pillars of the ACT Accelerator to understand if any CCE needs exist. At present, there is no indication of significant needs from the Therapeutic pillar. Some rapid diagnostic tests are likely to require temperature control in select settings, but the needs are modest and not expected to intersect with EPI (Expanded Programme on Immunization) supply chains. As such, no needs are being flagged for Gavi support at this time, though this will continue to be assessed.

8.10 While economies will be expected to contribute to financing of COVID-19 vaccine delivery (see section 7 above), they will require technical and financial support from the Alliance given the unprecedented scale, pace and complexity of COVID-19 vaccine roll-out. The ACT-A investment case includes a preliminary estimate of US$ 1.5 billion to deliver the first ~1 billion doses to AMC92 economies in 2021 based on an initial costing exercise carried out by Alliance partners. This amount is subject to further refinement (it did not include technical assistance costs, for example) and will depend on the final characteristics and availability of vaccines (e.g. UCC costs are not included).

8.11 Funding for delivery is not secured as fundraising has just begun. While ACT-A resource mobilisation efforts are ongoing, initial funding and support will be needed in the coming months to meet the anticipated timelines for in-country delivery (as early as Q2 2021). This is particularly relevant for procurement of CCE, which has long and relatively inflexible lead times, and strategy-oriented/preparatory technical assistance. **The Secretariat recommends Gavi allocate US$ 150 million from core resources[16]** as initial funding to help economies prepare to deliver COVID-19 vaccine. This funding would be targeted towards TA for economies' planning and addressing urgent cold chain gaps. This level of support can be re-evaluated in the coming months when: (i) bottom up costing is available to

[14] India is excepted from these figures; they are expected to be supported via a dedicated modality.
[15] Figures are sensitive to whether UCC transport devices are needed for distribution. Estimate does not include India, and assumes UCC-receiving economies switch to 2-8 to for remainder of vaccine.
[16] Proposal is based on the precedent set by the 2016 approval for core resources to be used to jumpstart the Ebola program while external fundraising was ramped up.

better determine service delivery needs and; (ii) the availability of resources is better understood. Since this funding would be allocated from core resources, the Secretariat is asking the Board for guidance on which countries should be in scope for this funding. In line with previous Board guidance on the use of core Gavi resources, the Secretariat would plan to restrict the use of these funds to the 56 countries which are Gavi-eligible or in accelerated transition. However, this will create a risk to delivery preparation in some of the remaining 36 economies, some of whom may also have significant needs. Broadening the scope of economies also carries risk by stretching Gavi and the Alliance's limited resources.

8.12 Taking these factors into consideration, the Secretariat **is asking the Board for guidance on the scope of economies that should be eligible to receive the allocation of US$ 150 million** from core resources to prepare to deliver COVID-19 vaccines.

8.13 Additional resources will need to be mobilised to cover the remaining delivery costs for all AMC92 economies beyond this initial US$ 150 million. This will likely be funded through both additional donor resources and domestic funding from implementing governments. Multilateral development banks have already expressed interest in supporting countries with COVID-19 vaccine service delivery, and the Secretariat will help to facilitate conversations between countries and multilateral development banks on the nature of this support, which will vary by country based on their allocations.

9. Proposed support for India

9.1 India is Gavi's largest eligible country and in Gavi's accelerated transition phase. Collaboration with India is important to ensure adequate support for vaccine delivery in the country as the country with the second largest number of cases, and because of the highly important role India plays as a global vaccine supplier. India represents 35% of the total AMC92 population and has at least 24 vaccines in the pipeline/ potential to manufacture, either self-developed or in-licensed by a non-Indian company. Six of these vaccines are in clinical trials, of which two are in phase III.

9.2 Given Gavi's existing tailored approach to India and proposed continuing strategic partnership (detailed in *Doc 02 – Recalibrating Gavi 5.0 in light of COVID-19 and successful replenishment),* and India's set transition from Gavi support at the end of 2021, the AMC approach for India will be different than other economies. It will seek to balance equity with constraints on overall doses and AMC funding, while recognising that India is particularly hard hit and is feeling the dramatic economic effects of the pandemic.

9.3 The approach to India support will include decisions on the allocation of AMC funding, AMC doses, and vaccine delivery support to the country. AMC funding to India for vaccine doses will likely be capped at a fixed percentage of the overall AMC funds, with additional costs expected to be financed by the country. AMC doses allocated to India will be calibrated to balance the overall availability of doses, the ability to equitably distribute

across the other 91 AMC economies, and India's domestic manufacturing capacity. Vaccine delivery support to India will take into account the country's strong existing capacity for delivery. Conversations with the Government of India and AMC donors on potential packages of support across these three areas are ongoing.

Section E: Actions requested of the Board

The Gavi Alliance Board is requested to:

a) **Approve** the Terms of Reference of the COVAX Shareholders Council attached as Annex B;

b) **Approve** the Terms of Reference of the COVAX AMC Engagement Group attached as Annex E;

c) **Approve** the Terms of Reference of the COVAX AMC Stakeholders Group attached as Annex F;

d) **Approve** the Terms of Reference of the COVAX Consensus Group attached as Annex G;

e) **Approve** the proposal for AMC92 economies to cost-share vaccines up to US$ 1.60- US$ 2 per dose, assuming a 2-dose regimen, towards the full cost of purchasing a dose of vaccine [bearing in mind that Gavi will exercise flexibility and work with economies on a case-by-case basis to adjust vaccine cost-sharing contributions as needed until end 2021, and with the expectation of additional cost-sharing on vaccine delivery, with targeted Gavi support (see decision point f) to supplement additional resources to be mobilised];

   With reference to the discussion on Doc 02 *Recalibrating programmatic priorities for Gavi 5.0 in light of COVID-19 and the successful replenishment: Financial implications*, at the Gavi Alliance Audit and Finance Committee meeting of 15 September 2020:

f) **Approve** the allocation of US$ 150 million from core resources [for initial funding] to prepare [*eligible economies subject to Board guidance*] to deliver COVID-19 vaccines, focusing on urgent technical assistance and cold chain needs;

g) **Request** the Gavi Secretariat to present to the Board in December 2020 the proposed approach for Gavi COVAX AMC support for India for COVID-19 vaccines and delivery;

h) **Note** the proposed approach to not invest in UCC at this time, and the associated risks regarding access to COVID-19 vaccines; and

i) **Note** the risks and mitigation measures outlined related to the COVAX Facility.

Annexes

Annex A: Implications/Anticipated impact

Annex B: Terms of Reference of the COVAX Shareholders Council

Annex C: COVAX Shareholders Council Operating Procedures

Annex D: Terms of Reference of the Executive Committee of the COVAX Shareholders Council

Annex E: Terms of Reference of the COVAX AMC Engagement Group

Annex F: Terms of Reference of the COVAX AMC Stakeholders Group

Annex G: Terms of Reference of the COVAX Consensus Group

Annex H: Terms of Reference of the Independent Product Group

Additional information available on BoardEffect

Appendix 1: COVAX Facility Explainer- Participation Arrangements for Self-Financing economies

Appendix 2: Governance mapping

Appendix 3: 15 September 2020 AFC COVAX Paper

Appendix 4: 15 September 2020 AFC 5.0 Paper

Appendix 5: 30 July 2020 Board Paper - Gavi COVAX AMC

Appendix 6: 30 July 2020 Board Paper - COVAX Facility Structure and Governance

Annex A: Implications/Anticipated impact

Risk implication and mitigation, including information on the risks of inaction

- Risks associated with the Facility are set out in the paper.

Impact on countries

- The failure of the Facility to provide up to 2 billion doses of COVID-19 vaccines by the end to 2021 will impact equitable access to COVID-19 vaccines, in particular for low-income economies.

Impact on Alliance

- The full Alliance is invested in the success of the COVAX Facility and COVAX AMC, with Gavi also seeking secondments to ensure that it is fully leveraging the expertise from across Alliance partners and stakeholders.

Legal and governance implications

- Gavi, as the legal entity of the Facility, will enter into the commitments with Participants of the Facility and manufacturers and will ultimately bear any exposure whether financial, programmatic or reputational.
- In addition, Gavi must ensure that the administration of the Facility is in accordance with the decision of the July meeting of the Board to that Gavi would leverage current governance bodies as well as develop new decision-making bodies to provide inclusive, transparent leadership of the COVAX Facility and COVAX AMC, and prohibiting Gavi from entering into commitments with manufacturers relating to SFPs which are not fully secured by committed resources from the Participants, with appropriate financial backing for such commitment, as assessed by the MSDC.

September 2020

COVAX FACILITY SHAREHOLDERS COUNCIL TERMS OF REFERENCE

1. Purpose

The COVAX Facility Shareholders Council ("the Council") is established by the Board ("Board") of the Gavi Alliance ("Gavi") to convene Self-Financing Participants of the COVAX Facility with the aim of providing strategic guidance and advice to the Office of the COVAX Facility ("the Office") on the operational aspects of the COVAX Facility.

The Council is not deemed to be a committee of the Board in that its primary role is essentially an advisory function as contemplated under Article 20 of the Statues. It is empowered by the Board to undertake the responsibilities outlined in these terms of reference.

2. Membership

Membership of the COVAX Shareholders Council is open to all Self-Financing Participants of the COVAX Facility.

A. Composition and size

Each Self-Financing Participant may appoint one formal representative to the Council. All members are treated equally in terms of membership, rights and privileges.

B. Competencies and skills

Council representatives should be empowered to represent their government's policies and priorities, and reach agreements on their behalf. Members are expected to be willing and able to dedicate sufficient time to fulfil Council roles and responsibilities. All members are expected to act in a manner consistent with the Facility's goals.

The criteria for Council membership shall be consistent with Gavi's guiding principles on gender for Board and Board Committee nominations and Gavi's Conflicts of Interest Policy for Governance Bodies.

COVAX Facility Co-Chairs shall be selected from among Council members. The Co-Chairs should normally comprise one Co-Chair from a high-income economy and one from an upper-middle income economy.

The Co-Chairs of the Council shall:

- Plan, lead and facilitate the conduct of Council meetings;
- Facilitate and summarise discussions objectively and with clarity seeking to gain consensus and exert authority when necessary;
- Ensure all Council members appropriately contribute to deliberations and regularly participate in meetings;
- Collaborate with the Office of the COVAX Facility as appropriate;
- Collaborate with relevant bodies engaged in providing independent technical advice or governance of the ACT-Accelerator
- Report to the Board on relevant matters as appropriate.

C. Appointment and term

Membership in the Council lasts for the duration of an economy's participation in the Facility (i.e. membership ceases if an economy withdraws).

The work of the Council will be supported by a Secretary from the Office of the COVAX Facility. The Secretary shall:

- Provide the link between the Council, the Board and the Office of the COVAX Facility;
- Assist the Council in developing good governance practices; and
- Ensure that the agenda, meeting papers and minutes and other materials to support the Council are provided in a timely manner.

3. Authority

The Shareholders Council represents the interests of Self-Financing Participants in the governance of the COVAX Facility, and serves as a platform for engagement with other COVAX governance bodies.

The Council will have reasonable access to information, Gavi personnel and relevant other Gavi parties, and external expertise, particularly relating to parties engaged in/other governance bodies of the ACT-Accelerator as appropriate.

The Council may delegate its power and authority to its Co-Chairs and/or a Shareholders Council Executive Committee ("ExCom") as deemed appropriate.

The mandate of the Council is established in these terms of reference.

4. Responsibilities

The Council will:

- Provide strategic guidance and advice to the Office of the COVAX Facility (facilitated as appropriate through the Shareholders Council Executive Committee) on:

  - all non-technical elements of COVAX Facility strategy, policy and performance for all self-financing countries; and
  - issues relevant for management and oversight of activities, including tools necessary for monitoring progress and achievements.

- Receive regular updates from the Office of the COVAX Facility, including reports on allocation decisions and overall activities, and receive reports on all decisions or recommendations made by technical bodies (including the Market-Sensitive Decisions Committee, Independent Product Group, Procurement Reference Group and Independent Allocation Validation Group) and the Gavi Board.
- Receive regular updates from the Office of the COVAX Facility on expenditures, in particular spending of Participant down-payments/upfront payments.
- Share information with the COVAX Facility and other Shareholders.
- Select members to serve on the Executive Committee.
- Select members to serve on the Market-Sensitive Decisions Committee.
- Be open to all self-financing participants in the COVAX Facility, to whom allocation decisions and overall activities should be reported.

5. Mode of Operation

The Shareholders Council is a self-organising body and as such will determine its own Operating Procedures.

6. Conflicts of Interest

All Council members shall adhere to Gavi's Conflicts of Interest Policy for Governance Bodies and Ethics Policy and shall annually complete an Annual Declaration Form in accordance with these policies. The Declaration shall be updated by Council members when required.

At the commencement of each meeting, each Council member shall declare any actual or perceived conflict of interest arising in the matters before the Council. The relevant provisions in the Gavi Conflicts of Interest Policy for Governance Bodies shall regulate participation.

September 2020

COVAX FACILITY SHAREHOLDERS COUNCIL OPERATING PROCEDURES

Purpose

These Operating Procedures apply to the COVAX Facility Shareholders Council ("the Council") and should be ready with the Council's Terms of Reference which define Council membership, authority and responsibilities.

Council

1 Appointment Process – Council and Executive Committee

1.1 *To be discussed at the Inaugural meeting of the Council*

2 Co-Chairs

2.1 *To be discussed at the Inaugural meeting of the Council*

3 Resignation, replacement and vacancies

2.1 *To be discussed at the Inaugural meeting of the Council*

Council Meetings

3 Meetings of the Council

3.1 The Council shall meet as often as necessary, and at least four times per year. Council Members are expected to participate fully in all meetings of the Council unless extraordinary circumstances prevent attendance.

3.2 A meeting of the Council can be called by either of the Co-Chairs, or by the Secretary[1] at the direction of either of the Co-Chairs, or at the request of at least ten Council Members. Notice of any meeting shall be given in accordance with Section 4.

[1] From the Office of the COVAX Facility

4 Notices

4.1 Notice of each meeting confirming the date, time and agenda shall be forwarded to each member of the Council not less than five business days prior to the dates of such meeting and sent by email.

4.2 The notice will normally include relevant supporting papers for the agenda items to be discussed.

4.3 Either of the Co-Chairs may call a meeting on less than five business days' notice if in their reasonable opinion there exist exceptional circumstances require a Council meeting to be held on short notice; provided that the minimum notice that must be provided to Council Members is two business days.

5 Quorum

5.1 A quorum shall be a majority of Council Members.

5.2 The Council may only carry out its business while the quorum requirement is met. In the event that a meeting of the Council ceases to be quorate, at the option of the Co-Chairs, discussions may continue, but no decisions may be made. The Co-Chairs may choose to end the meeting upon it becoming inquorate.

6 Agenda and papers

6.1 The Secretary, in collaboration with the Co-Chairs, shall prepare the agenda for the meetings of the Council.

6.2 Background documentation for each agenda item should be circulated to the Council at least five business days in advance of meetings of the Council, with certain exceptions permitted by the Co-Chairs.

7 Minutes

7.1 The Council shall keep minutes of its meetings.

7.2 The Council may approve the minutes of its meetings on a no-objection basis. The minutes shall be deemed approved if the following conditions are met: (i) draft minutes are circulated to the Council for review and comment; (ii) a period of no less than five business days is given for Council Members to provide comments to the initial draft minutes ("Review Period"); (iii) notice of a request to approve the minutes is made after the conclusion of the Review Period; (iv) a period of no less than five business days is given for Council members to signal an objection in writing ("Objection Period"); (v) no objections to the motion are received by the Secretary by the conclusion of the Objection Period.

8 Decisions

8.1 The Co-Chairs should aim for consensus on all decisions. If consensus cannot be reached, decisions shall be taken by vote and considered approved if a majority of those present in the meeting, and entitled to vote, vote in favour of the decision.

9 Closed sessions

9.1 From time to time, at the discretion of the Co-Chairs, the Council may hold closed sessions with such parties as it deems appropriate, together or separately without members of the Office of the COVAX Facility present.

9.2 An official record of closed sessions shall be maintained by the Co-Chairs with the support of the Secretary.

10 Observers, guests and presenters

10.1 Except for closed sessions, Council Members may at any meetings of the Council be accompanied by their delegations comprising no more than five persons, including the Council Member.

10.2 The Co-Chairs may invite guests and presenters to Board meetings at such time and for such purposes, as they deem appropriate.

11 Conflicts of interest declarations

11.1 As defined in Section 6 of the Council's Terms or Reference, all Council members shall adhere to Gavi's Conflicts of Interest Policy for Governance Bodies shall annually complete an Annual Declaration Form, which shall be updated when required.

12 Amendments

12.1 These Operating Procedures may only be amended by the Council.

13 Entry into force

13.1 These Operating Procedures shall enter into force upon their approval by the Council.

September 2020

COVAX FACILITY SHAREHOLDERS COUNCIL EXECUTIVE COMMITTEE TERMS OF REFERENCE

1. Purpose

The COVAX Facility Shareholders Council Executive Committee ("ExCom") is established by the Shareholders Council ("the Council") to prepare and guide its discussions. It is empowered by the Council to undertake the responsibilities outlined in these terms of reference.

2. Membership

Members will be appointed to the ExCom on a constituency basis, through a nomination and selection process overseen by the Council.

A. Composition and size

ExCom will comprise 12 members plus two Co-Chairs.

Only Council Members may be ExCom Members.

Members will be chosen to represent constituencies as determined by the Council[1].

B. Competencies and skills

ExCom Members must be able to represent their constituency's priorities and reach agreements with other ExCom Members on their behalf. Members are expected to be willing and able to dedicate sufficient time to engage their constituency and reach positions ahead of ExCom meetings. All members are expected to act in a manner consistent with the Facility's goals.

The criteria for ExCom Membership shall be consistent with Gavi's guiding principles on gender for Board and Board Committee nominations and Gavi's Conflicts of Interest Policy for Governance Bodies.

The ExCom will be Co-Chaired by the Council Co-Chairs.

[1] For example, should Shareholders agree to be organised according to WHO constituencies, each constituency might nominate two members to the Executive Committee.

The Co-Chairs of the ExCom shall:

- Plan, lead and facilitate the conduct of ExCom meetings;
- Facilitate and summarise discussions objectively and with clarity seeking to gain consensus and exert authority when necessary;
- Ensure all ExCom Members appropriately contribute to deliberations and regularly participate in meetings;
- Collaborate with the Office of the COVAX Facility as appropriate;
- Collaborate with relevant bodies engaged in providing independent technical advice or governance of the ACT-Accelerator; and
- Report to the Council and the Board on relevant matters as appropriate.

C. Appointment and term

ExCom Members shall be appointed by the Council once every 12 months, at which point a constituency may choose to nominate a new member or members for appointment.

The work of the ExCom will be supported by a Secretary from the Office of the COVAX Facility. The Secretary shall:

- Provide the link between ExCom, the Council, the Board and the COVAX Facility;
- Assist ExCom in developing good governance practices; and
- Ensure that the agenda, meeting papers and minutes and other materials to support ExCom are provided in a timely manner.

3. Authority

The Executive Committee represents the interests of the Council Members in the governance of the COVAX Facility, and serves as a platform for engagement with other COVAX governance bodies.

The ExCom will have reasonable access to information, Gavi personnel and relevant other Gavi parties, and external expertise, particularly relating to parties engaged in/ other governance bodies of the ACT-Accelerator as appropriate.

The ExCom may delegate its power and authority to its Co-Chairs as deemed appropriate.

The mandate of the ExCom is established in these terms of reference.

4. Responsibilities

The ExCom will:

- Convene between meetings of the Council.
- Receive regular reports from the Office of the COVAX Facility on technical decisions, operational progress and financial updates.
- Provide a clear link between the Council and other governance structures to ensure the consolidated advice/view of the Council is considered in relevant deliberations and that the Council is well prepared/briefed to provide advice as issues arise.

- Conduct more detailed discussions on forthcoming issues, help set agendas, draft papers, and ensure a longer-term view is taken in order to be an appropriate bridge between the Gavi Board and other bodies.
- Facilitate effective coordination with the Office of the COVAX Facility and other Facility stakeholders on the operation of the proposed COVAX Exchange.
- Identify emerging challenges within the Self-Financing Participants and seek to find consensus on these. Where consensus is not possible, request that the COVAX Consensus Group be convened.

5. Mode of Operation

A. Meeting attendance

All COVAX Shareholders Council members, who are not serving on the ExCom, have the right to attend meetings of the ExCom as observers but may not speak or participate in the proceedings except at the invitation of one of the ExCom Co-Chairs.

Members of the Office of the COVAX Facility shall make themselves available to attend meetings of the ExCom as appropriate.

Other observers may attend meetings contingent upon approval of the ExCom Co-Chairs.

ExCom members shall prepare for and actively participate in ExCom meetings.

B. Frequency of meetings

The ExCom shall normally meet once a month, or more frequently as the Co-Chairs deem necessary.

ExCom meetings shall normally take place virtually

C. Notice of meetings

Notice of each meeting confirming the date, time and agenda shall be forwarded to each member of the ExCom not less than five business days prior to the dates of such meeting and sent by email.

The notice will normally include relevant supporting papers for the agenda items to be discussed.

D. Quorum

The quorum for the ExCom shall be a majority of members.

E. Conflict(s) of interest and declarations of interest

All ExCom Members shall adhere to Gavi's Conflicts of Interest Policy for Governance Bodies and Ethics Policy and shall annually complete an Annual Declaration form in accordance with these policies. The Declaration shall be updated by ExCom Members when required.

At the commencement of each meeting, each ExCom member shall declare any actual or perceived conflict of intreat arising in the matters before the Group and the relevant

provisions in the Conflicts of Interest Policy for Governance Bodies shall regulate participation.

F. Voting

The Co-Chairs should aim for consensus on all decisions. If consensus cannot be reached, decisions shall be taken by vote and considered approved if a majority of those present in the meeting, and entitled to vote, vote in favour of the decision.

G. Minutes

The ExCom shall keep minutes of its meetings. The ExCom may approve the minutes of its meetings on a no-objection basis. The minutes shall be deemed approved if the following conditions are met: (i) draft minutes are circulated to the ExCom for review and comment; (ii) a period of no less than five business days is given for ExCom Members to provide comments to the initial draft minutes ("Review Period"); (iii) notice of a request to approve the minutes is made after the conclusion of the Review Period; (iv) a period of no less than five business days is given for ExCom members to signal an objection in writing ("Objection Period"); (v) no objections to the motion are received by the Secretary by the conclusion of the Objection Period.

H. Executive Sessions

From time to time, at the discretion of the Co-Chairs, the ExCom may hold closed sessions with such parties as it deems appropriate, together or separately without members of the Office of the COVAX Facility present.

September 2020

COVAX AMC ENGAGEMENT GROUP
TERMS OF REFERENCE

1. Purpose

The COVAX Facility Advance Market Commitment ("AMC") Engagement Group ("the AMC Group") is established by the Board ("Board") of the Gavi Alliance ("Gavi") to convene representatives from implementing countries, donors and other parties engaged in the financing and operation of the AMC portion of the Facility, with the aim of providing strategic guidance and advice to the Office of the COVAX Facility ("the Office") on the operational aspects of the COVAX Facility.

The AMC Group is not deemed to be a committee of the Board in that its primary role is essentially an advisory function as contemplated under Article 20 of the Statues. It is empowered by the Board to undertake the responsibilities outlined in these terms of reference.

2. Membership

Membership of the AMC Group will be open to representatives of implementing countries, donors and other parties engaged in the financing and operation of the AMC portion of the Facility.

A. Composition and size

Given the large number of parties engaged in the AMC, it is expected that the AMC Group will normally meet as a representative group, drawing on Gavi Implementing Country Board members, representatives of the non-Gavi AMC countries, and other relevant Board members.

All members are treated equally in terms of membership, rights and privileges.

B. Competencies and skills

All members are expected to act in a manner consistent with the Facility's goals.

The criteria for AMC Group membership shall be consistent with Gavi's guiding principles on gender for Board and Board Committee nominations and Gavi's Conflicts of Interest Policy for Governance Bodies.

AMC Group Co-Chairs shall be selected from among its members. The Co-Chairs should normally comprise one Co-Chair from an AMC donor and one from an AMC funded participant.

The Co-Chairs of the Council shall:

- Plan, lead and facilitate the conduct of AMC Group meetings;
- Facilitate and summarise discussions objectively and with clarity seeking to gain consensus and exert authority when necessary;

- Ensure all AMC Group members appropriately contribute to deliberations and regularly participate in meetings;
- Collaborate with the Office of the COVAX Facility as appropriate;
- Collaborate with relevant bodies engaged in providing independent technical advice or governance of the ACT-Accelerator
- Report to the Board on relevant matters as appropriate.

C. Appointment and term

Membership in the AMC Group lasts for the duration of an economy or organisation's participation in the AMC.

The work of the AMC Group will be supported by a Secretary from the Office of the COVAX Facility. The Secretary shall:

- Provide the link between the AMC group, the Board and the Office of the COVAX Facility;
- Assist the AMC Group in developing good governance practices; and
- Ensure that the agenda, meeting papers and minutes and other materials to support the AMC group are provided in a timely manner.

3. Authority

The AMC Group represents the interests of AMC Participants in the governance of the COVAX Facility and serves as a platform for engagement with other COVAX governance bodies.

The AMC Group will have reasonable access to information, Gavi personnel and relevant other Gavi parties, and external expertise, particularly relating to parties engaged in/other governance bodies of the ACT-Accelerator as appropriate.

The AMC Group may delegate its power and authority to its Co-Chairs as deemed appropriate.

The mandate of the AMC Group is established in these terms of reference.

4. Responsibilities

The AMC Group will:

- Receive regular updates from the Office of the COVAX Facility, and receive reports on all decisions or recommendations made by technical bodies and the Gavi Board.
- Provide strategic guidance and advice to the Office of the COVAX Facility on:
  - all non-technical elements of COVAX Facility strategy, policy and performance for all AMC funded participants ; and
  - issues relevant for management and oversight of activities, including tools necessary for monitoring progress and achievements.
- Share information with the COVAX Facility and other Shareholders.

- Facilitate the operations of the AMC Stakeholders Group and receive regular updates on its work.

5. Mode of Operation

The AMC Engagement Group is a self-organising body and as such will determine its own Operating Procedures.

6. Conflicts of Interest

All AMC Group members shall adhere to Gavi's Conflicts of Interest Policy for Governance Bodies and Ethics Policy and shall annually complete an Annual Declaration Form in accordance with these policies. The Declaration shall be updated by AMC Group members when required.

At the commencement of each meeting, each Stakeholders Group member shall declare any actual or perceived conflict of interest arising in the matters before the Stakeholders Group. The relevant provisions in the Gavi Conflicts of Interest Policy for Governance Bodies shall regulate participation.

September 2020

COVAX AMC STAKEHOLDERS GROUP
TERMS OF REFERENCE

1. Purpose

The Gavi COVID-19 vaccine ("COVAX") Advance Market Commitment ("AMC") Stakeholders Group is established by the Board of the Gavi Alliance ("Gavi") to convene the AMC Stakeholders with the aims of performing the functions as set out in the Stakeholders Agreement and receiving information about the AMC from the Gavi Secretariat. These aims are in support of the objective of the AMC, which is to reduce the impact of COVID-19 within AMC eligible economies by accelerating the introduction and scale up of vaccines that protect against COVID-19.

2. Membership

The following shall be members of the Stakeholders Group:

- Founding members of the PCV AMC and which decide to transfer their surplus funds from the PCV AMC to the AMC;
- Countries entering into AMC Grant Agreements for more than US$10 million;
- Private and/or not-for-profit donors entering into AMC Grant Agreements for more than US$ 10 million;
- Multilateral development banks providing support to the AMC

The COVAX Facility Procurement Coordinator and PAHO will also be invited to attend the Stakeholders Group as observers.

A. Composition and size

Each Member may appoint one formal representative to the Stakeholders Group. All members are treated equally in terms of membership, rights and privileges.

B. Competencies and skills

Stakeholders Group representatives should be empowered to represent their government's or organisation's policies and priorities, and reach agreements on their behalf. Members are expected to be willing and able to dedicate sufficient time to fulfil Stakeholders Group roles and responsibilities. All members are expected to act in a manner consistent with the Facility's goals.

The criteria for Stakeholders Group membership shall be consistent with Gavi's guiding principles on gender for Board and Board Committee nominations and Gavi's Conflicts of Interest Policy for Governance Bodies.

C. Appointment and term

Membership in the Stakeholders Group lasts for the duration of an organisation's participation in the AMC (i.e. membership ceases if an economy withdraws). Each organisation represented on the Stakeholders Group shall determine which person represents that organisation.

D. Secretariat

The work of the Stakeholders Group will be supported by the Gavi Secretariat. The Secretariat shall:

- Regularly inform the AMC Stakeholders Group on the following:
  - Subject to strict commercial confidentiality on market information, when it enters into Advance Purchase Commitments with manufacturers of COVID-19 vaccines or candidate vaccines and the amount and timing of such deals, in particular with reference to the AMC-eligible economies;
  - Cost estimates for the supply of Approved Vaccine to the AMC-eligible economies and details of the allocation to and introduction of Approved Vaccines in specific AMC-eligible economies;
  - Updates to the AMC Funding Requirement, including the use and balance of Grant funds;
- Provide the link between the Stakeholders Group, the Board, MSDC and the COVAX Facility;
- Ensure that the agenda, meeting papers and minutes and other materials to support the Stakeholders Group are provided in a timely manner.

3. Authority

The Stakeholders Group will have reasonable access to information, Gavi personnel and relevant other Gavi parties, including the Office of the COVAX Facility, and external expertise, particularly relating to parties engaged in/ other governance bodies of the ACT-Accelerator as appropriate.

The mandate of the Stakeholders Group is established in this terms of reference.

4. Mode of Operation

The AMC Stakeholders Group is a self-organising body. Its Operating Procedures will be agreed at its first meeting.

5. Conflicts of Interest

All Stakeholders Group members shall adhere to Gavi's Conflicts of Interest Policy for Governance Bodies and Ethics Policy and shall annually complete an Annual Declaration Form in accordance with these policies. The Declaration shall be updated by Stakeholders Group members when required.

At the start of each meeting, each Stakeholders Group member shall declare any actual or perceived conflict of interest arising in the matters before the Stakeholders Group. The relevant provisions in the Conflicts of Interest Policy for Governance Bodies shall regulate participation.

September 2020

COVAX FACILITY CONSENSUS GROUP
TERMS OF REFERENCE

1. Purpose

The COVAX Facility Consensus Group ("the COVAX Consensus Group") is established by the Board of the Gavi Alliance ("Gavi") to support effective operation of the COVAX Facility ("the Facility") through consensus-based decision-making.

2. Membership

The COVAX Consensus Group shall comprise the Chair and Vice Chair of the Gavi Board; the Co-Chairs of the COVAX Shareholders Council; the Co-Chairs of the COVAX AMC Engagement Group; and – in an ex-officio, non-voting, capacity - the three leads of the ACT-Accelerator vaccine pillar, namely the CEO of Gavi, the CEO of CEPI (Coalition for Epidemic Preparedness Innovations) and the Chief Scientist of WHO.

The COVAX Consensus Group shall be chaired by the Gavi Board Chair.

The work of the COVAX Consensus Group will be supported by a Secretary from the Office of the COVAX Facility.

3. Authority

The COVAX Consensus Group serves as a platform to reach consensus within the Facility on matters arising where all other possible avenues to resolve the matters have been exhausted.

It will have reasonable access to information, governance bodies, personnel, and relevant other parties within the Facility, as well as external expertise, as required to achieve consensus.

Decisions reached by the COVAX Consensus Group are final.

4. Responsibilities

The COVAX Consensus Group is responsible to ensure that any disputes or challenges arising in the governance bodies of the Facility can be addressed swiftly and in the best interests of the aims of the Facility.

5. Mode of Operation

A. Meeting attendance

Only members of the COVAX Consensus Group shall be entitled to attend meetings of the COVAX Consensus Group.

Members of the Office of the COVAX Facility shall make themselves available to attend meetings of the COVAX Consensus Group as appropriate.

B. Frequency of meetings

The COVAX Consensus Group shall be convened as required at the request of any of the governance or technical bodies within the Facility, should lack of consensus prevent them delivering on their mandate.

C. Notice of meetings

The minimum notice that must be given to COVAX Consensus Group members for a meeting is two business days.

The notice will normally include relevant supporting papers for the matters to be discussed. All papers circulated to the COVAX Consensus Group members shall be retained in the strictest confidence for their specific reference and use and may not be circulated or distributed in any manner or form.

D. Quorum

All voting members are required for a quorum.

E. Conflict(s) of interest and declarations of interest

All COVAX Consensus Group members shall adhere to Gavi's Conflicts of Interest Policy for Governance Bodies and Ethics Policy and shall annually complete an Annual Declaration form in accordance with these policies. The Declaration shall be updated by COVAX Consensus Group members when required.

At the commencement of each meeting, each COVAX Consensus Group member shall declare any actual or perceived conflict of intreat arising in the matters before the Group and the relevant provisions in the Conflicts of Interest Policy for Governance Bodies shall regulate participation.

F. Voting

The Chair should aim for consensus on all decisions. If consensus cannot be reached, decisions shall be taken by vote and considered approved if a majority of those present in the meeting, and entitled to vote, vote in favour of the decision. In the event of a tie, the Chair shall have a casting vote.

September 2020

COVAX FACILITY INDEPENDENT PRODUCT GROUP TERMS OF REFERENCE

1. Purpose

The Independent Product Group ("IPG") is established to make recommendations to the Office of the COVAX Facility on the inclusion of vaccines in the COVAX Facility, regularly review the COVAX Facility portfolio for balance and review updates on timing and availability of doses and consider any implications for the COVAX Facility portfolio.

The IPG is not deemed to be a committee of the Board in that its primary role is essentially an advisory function as contemplated under Article 20 of the Statues. As outlined in these Terms of Reference the IPG does not have decision-making powers. The aim of the IPG review process is to make a recommendation to the Office of the COVAX Facility on vaccine candidate prioritisation and portfolio balance. Once the Office of the COVAX Facility has negotiated the ensuing deal terms, taking into consideration independent technical advice from the Procurement Reference Group (PRG), the deal is then considered by the Market Sensitive Decisions Committee.

Words and expressions used in this Terms of Reference shall, unless the context requires otherwise, have the meaning attributed to them in the Board and Committee Operating Procedures.

2. Membership

The membership, resources, responsibilities and authorities of the IPG to perform its role effectively is stipulated in these Terms of Reference which may be amended as and when required or deemed necessary.

A. Composition and size

The composition of the IPG shall allow it to function efficiently and effectively in fulfilling its functions and responsibilities. The composition of the IPG is intended to comprise individuals suitably competent in the affairs and issues falling within the Terms of Reference so as to be able to provide the Office of the COVAX Facility with sound advice on matters set out in this Terms of Reference.

The IPG shall comprise not less than five persons and no more than fifteen comprising members and observers. A majority of the IPG members shall comprise independent scientific and

technical experts with a minority of observers. Independent experts should be institutionally independent of the Gavi Secretariat, Board and Board Committees. IPG members will serve in their personal capacities and will not represent their employers, government, Gavi partner organisations or organisations engaged in the ACT Accelerator.

Observers may include Board and Alternate Board Members and other ex-officio members. Observers must adhere to confidentiality and declare any conflicts of interest.

The selection of IPG members shall be guided by the following criteria: credibility and independence; commitment and availability to participate in meetings; geographical and gender diversity; absence of conflict of interest.

Independence should be determined by considering the following questions, the answers to which will assist in ascertaining independence:

- Is the candidate institutionally independent of the Secretariat, Board, Board Committees and any committees or advisory bodies affiliated with the ACT Accelerator Vaccine Pillar (such as CEPI, DCVMN, IFPMA or WHO)?
- Is/has the candidate been an employee of the Gavi Secretariat within the last three years?
- Does/has the candidate had, within the last three years, a material business relationship with Gavi Alliance, whether directly as a partner, shareholder, contractor, grantee, director or senior employee of a body that has such a relationship with Gavi Alliance?
- Does/has the candidate had, within the last three years, a material business relationship with any of the organisations involved in the ACT Accelerator Vaccines Pillar (i.e. CEPI, DCVMN, IFPMA and WHO), whether directly as a partner, shareholder, contractor, grantee or senior employee of a body that has such a relationship with any of the ACT Accelerator Vaccines Pillar bodies.
- Has the candidate received remuneration from Gavi, CEPI or WHO within the last three years?
- Does the candidate have any close family ties with any of Gavi's advisers, Board or Board Committee members, or senior employees?
- Does the candidate have any conflict of interest, as defined in Gavi's Conflicts of Interest Policy for Governance Bodies, and if so, can they be managed appropriately?

B. Competencies and skills

Each member of the IPG should have expertise, experience and knowledge of vaccine development and delivery. Collectively, IPG members should also have a balance of skills, recent and relevant expertise, experience and knowledge of the following:

- Coronavirus vaccines and/or COVID-19 vaccines
- Immunology, animal models and assays for vaccine evaluation
- Clinical evaluation of vaccines including vaccine evaluation in large randomised clinical trials
- Regulatory expertise in vaccine evaluation
- Vaccine manufacturing and GMP issues
- Epidemiology/public health expertise
- Expertise in immunization programmes and service delivery
- Vaccine safety evaluation and monitoring

All IPG members shall be able to act independently, ask relevant questions, act professionally and maintain the highest ethical standards and loyalty to the interests of Gavi and the organisations engaged in the ACT Accelerator Vaccines Pillar.

The overall balance of skills on the committee shall be periodically evaluated.

The criteria for the IPG membership shall be consistent with Gavi's guiding principles on gender for Board and Board Committee nominations and Gavi's Conflicts of Interest Policy for Governance Bodies.

Each member of the IPG will be required to participate in a programme of induction, training and familiarisation with the work of the IPG to enable Committee members to keep abreast of current developments in the work of the IPG and the work of the Vaccines Pillar of the ACT Accelerator more broadly.

The Chair of the IPG shall:

- Be one of the Independent Members of the IPG
- Plan, lead and facilitate the conduct of Committee meetings
- Facilitate and summarise discussions objectively and with clarity seeking to gain consensus and exert authority when necessary
- Ensure all Committee members appropriately contribute to deliberations and regularly participate in meetings
- Collaborate with the Office of the COVAX Facility as appropriate
- Collaborate with relevant bodies engaged in providing independent technical advice or governance of the ACT-Accelerator such as the CEPI RDMIC, PRG etc.
- Collaborate closely with the Gavi Chief Executive Officer (CEO) and the Office of the COVAX Facility on all matters relating to the inclusion of suitable candidates in the COVAX Facility's portfolio of vaccine candidates and the status of the portfolio
- Report to the Board through the Office of the COVAX Facility on relevant and material matters as appropriate; and
- Participate in and advise on the selection of new IPG members in conjunction with the IPG Selection and Oversight Panel, including providing guidance on matters relating to the independence of candidates.

In the event that the Chair is unable to attend a scheduled meeting, the Chair will, after consultation with other IPG members, nominate a suitable substitute (i.e. independent member) from the membership of the IPG.

In the event that an IPG member is unable to attend a schedule meeting, s/he cannot designate a replacement. If an IPG member has two consecutive absences from IPG meetings, the Chair will discuss with that IPG member the viability of his or her continued involvement on the Committee.

C. Appointment and term

All IPG members shall be appointed by the IPG Selection and Oversight Panel, comprised of the Gavi CEO, CEPI CEO and the WHO Chief Scientist. IPG members shall be appointed once every year, with a maximum of three consecutive terms. The IPG Selection and Oversight Panel shall select the Committee Chair ("Chair") every year, with a maximum of three consecutive terms. IPG Committee member and Chair terms shall be concomitant. All nominees to the IPG should be evaluated by the IPG Selection and Oversight Panel to ensure each individual meets the

membership requirements set out in 2.A & 2.B above including an independence test and ensure the individual's competencies fit with the required competencies of the IPG.

The work of the IPG will be supported by the Office of the COVAX Facility. The Office of the COVAX Facility shall:

- Provide the link between the IPG, the PRG, the MSDC and the COVAX Facility;
- Assist the IPG in developing good governance practices; and
- Ensure that the agenda, meeting papers and minutes and other materials to support the IPG are provided in a timely manner.

It is expected that meetings will take place remotely. IPG members shall receive reasonable costs for their participation in each IPG session in accordance with Gavi's policies.

3. Authority

The IPG shall maintain open communications between IPG members and the COVAX Facility as appropriate.

The Committee shall have the power to delegate on an exceptional basis its authority and duties to the IPG Chair or individual committee members as it deems appropriate. This may include engagement with the CEPI RDMIC, COVAX PRG, MSDC, SAGE WG.

The IPG shall have reasonable access to information, Gavi personnel, Personnel of the Office of the COVAX Facility and relevant other Gavi parties, and external expertise, particularly relating to parties engaged in/ other governance bodies of the ACT-Accelerator as appropriate.

The mandate of the IPG is established in these Terms of Reference.

4. Responsibilities

It is the responsibility of the IPG to:

A. Regularly review data and information relating to vaccine candidates (for example, such as that received from manufacturers, WHO, CEPI and the RDMIC Secretariat)

B. Provide guidance and independent technical advice to the Office of the COVAX Facility to inform the selection of candidates to be prioritised for deal making by the COVAX Facility, and eventually considered by the Market Sensitive Decisions Committee

C. Regularly review the SARS-CoV-2 vaccine pipeline and the COVAX Facility portfolio on a rolling basis, taking into consideration updates related to clinical development, manufacturing and supply and provide advice on both the pipeline and COVAX Facility portfolio to the Office of the COVAX Facility and Board

D. Engage with other bodies including, but not limited to, the CEPI RDMIC, PRG, SAGE Working Group etc.

5. Mode of Operation

A. Meeting attendance

If required, Observers may be invited to attend to ensure cross-linkage with other bodies but may not speak or participate in the proceedings except at the invitation of the IPG Chair.

Observers are expected to uphold standards of confidentiality and declare all conflicts of interest.

Members of the Office of the COVAX Facility shall make themselves available to attend all IPG meetings as appropriate. Other observers may attend meetings under exceptional circumstances and contingent upon IPG Chair approval.

IPG members shall prepare for and actively participate in Committee meetings.

B. Frequency of meetings

Committee meetings will be scheduled based on the business needs driven by the COVAX Facility workplan. It is foreseen that the Committee shall normally meet no more than twice monthly. This could exceptionally be more frequently, if deemed necessary by the IPG Chair. It is intended that all meetings shall take place remotely.

C. Notice of meetings

The Committee shall establish a calendar of activities every month so that meetings are known well in advance.

Notice of each meeting confirming the date, time, venue and agenda shall be forwarded to each member of the Committee and other invitees not less than one week prior to the date of such meeting and sent by email. The notice will normally include relevant supporting papers for the agenda items to be discussed. Unless otherwise explicitly indicated, all papers shall be retained in confidence for their specific reference and may not be circulated or distributed in any manner or form.

Occasionally ad-hoc meetings may be required at short notice; in the event of such a meeting being planned the purpose and justification of any such meeting will be clearly communicated to members. In this case, the Chair may call a meeting on less than seven business days' notice if, in their reasonable opinion, there exist exceptional circumstances requiring a Board meeting to be held on short notice and provided however that the minimum notice that must be provided to Board members is two business days. For such ad-hoc meetings, the quorum must be met.

D. Agenda

The IPG Chair shall establish meeting agendas with the Secretary of the Committee and in consultation with IPG members and relevant members of the Secretariat. The IPG agenda and calendar of activities shall include matters for current consideration and emerging issues within its area of responsibility.

E. Quorum

The quorum for the IPG shall be a simple majority of IPG members.

F. Conflicts of Interest

All IPG members shall adhere to Gavi's Conflicts of Interest Policy for Governance Bodies and Ethics Policy and shall annually complete an Annual Declaration Form in accordance with these policies. The Declaration shall be updated by IPG members when required.

At the commencement of each meeting, each IPG member shall declare any actual or perceived conflict of interest arising in the matters before the Committee. The relevant provisions in the Statutes, By-laws and the Conflicts of Interest Policy for Governance Bodies shall regulate participation.

G. Voting/ Decision-making

Recommendations will be made by consensus. In the event that consensus cannot be reached, a vote will be considered approved if a majority of those present in the meeting and entitled to vote, vote in favour of the decision.

SUBJECT:	**REVIEW OF DECISIONS**
Agenda item:	04
	No paper

SUBJECT:	CLOSING REMARKS
Agenda item:	05
	No paper