

SUBJECT: GAVI'S POTENTIAL ROLE IN PANDEMIC PREPAREDNESS RESPONSE

Agenda item: 06

Category: For Guidance

Section A: Executive Summary

This paper sets out a proposition for Gavi's strategic engagement in the pandemic preparedness and response (PPR) agenda, building on the significant capacity Gavi has developed over more than twenty years of experience in routine immunisation (RI), and lessons learned from COVID-19 and COVAX.

Firstly, Gavi has a vital role to play in PPR as a vaccine alliance which builds countries' capacity to respond in emergencies by strengthening RI programmes, increasing efficiency, focusing on equity and reaching missed communities. In addition, the Alliance, together with CEPI (Coalition for Epidemic Preparedness Innovations), provides a unique, networked end-to-end view, from 'lab to jab', across an extensive portfolio of diseases and vaccines. Going forward, the Alliance can use this strategic position, aided by learning from COVID-19, to better define, communicate and deliver a substantial future role in PPR.

Secondly, a key lesson is that risk-tolerant, liquid resources are critical for equitable vaccine access for lower-income countries in emergencies. Gavi's financial tools and capacity to innovate at pace can play a role in future responses.

Thirdly, Gavi has a core role in addressing inadequate manufacturing diversity in the face of COVID-19, and calls for support to African vaccine manufacturing. Gavi's experience in market-shaping for vaccines should be leveraged to inform the intentional design of a vaccine ecosystem that supports the sustainability of African manufacturing facilities, and the health of the global market more broadly.

Board guidance is requested on three actions Gavi would like to take in the next six months as part of the articulation of Gavi 5.1 to help mainstream these strengths into the global health architecture:

- Ensure the provision of epidemic and pandemic vaccines as a core component of PPR, are recognised and embedded in discussions at the WHO, G20 and G7. That the resulting architecture reflects and enables the Gavi Alliances' expanded contribution to PPR, reflecting learning from the COVID-19 response.
- Incorporate PPR considerations and innovations, including financing instruments and support to the manufacturing agenda, into Gavi 5.1.
- Work proactively with partners, including the African Union (AU), to set out a position on how Gavi can support sustainable manufacturing in Africa.

Assessing how demand could be part-filled by African manufacturers, developing options for pull financing, and including proposals in Gavi 5.1 for Board approval.

Section B: Gavi's engagement in the PPR agenda

1. The case for Gavi's engagement

- 1.1 COVID-19 caught the world off guard; however, experts had long warned of the risks of a new pathogen spreading across the globe. Since the 1940s, more than 330 emerging infectious diseases have been identified, of which 60% were zoonotic. Trends such as climate change, population growth, changes in land use, urbanisation, migration and travel are exacerbating the threat. Zika, increases in avian influenza in Europe, and monkeypox demonstrates the recent increases in the **number** of novel disease threats emerging and the **frequency** of these events occurring.¹
- 1.2 There is broad consensus that preparedness and response for emerging diseases, new variants, and drug resistance will require substantial additional investments. Estimates are at least US\$ 15 billion per year for at least the next five years². Through the G20 and G7 and a WHO-led process to develop a legal instrument for PPR, global health stakeholders are working to learn from what has worked and avoid repeating past mistakes.
- 1.3 The Board stressed at its April 2022 retreat that Gavi should consider the implications of supporting vaccine-relevant aspects of PPR, beyond the current pandemic. There is also concern that **current global PPR policy processes undervalue immunisation as a core PPR intervention.**³ Without Gavi's voice, there is the risk that the next pandemic will again require the development of new systems, and see lower-income nations at the back of the queue for vaccines. This paper considers how the Alliance can play an even more impactful role in PPR going forward: firstly, influencing the PPR agenda to ensure vaccines feature appropriately; and secondly, building on learning from COVID-19 and COVAX to secure an appropriate role for Gavi in future PPR architecture, in line with its mission.

2. Building Capacity for Preparedness

- 2.1 Vaccines have been the core response intervention for five of the six Public Health Emergencies of International Concern (PHEIC) declared since 2007

¹ Global rise in human infectious disease outbreaks. Smith et.al 2014. <https://royalsocietypublishing.org/doi/10.1098/rsif.2014.0950> & The Global Risks Report 2019. World Economic Forum

² A Global Deal for Our Pandemic Age. Report of the G20 High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response.

³ For example, the recent WHO draft HEPR (Health Emergency Preparedness, Response, and Resilience) proposal mentions vaccines once in relation to forward PPR. The G20 Finance-Health Taskforce paper on Global Finance & Health Coordination for PPR Financing similarly makes one reference, whilst the G20 White Paper for the proposed Financial Intermediary Fund makes a single reference to 'countermeasures'.

(i.e. all except Zika). The work to build capacity for vaccine delivery must remain at the core of the PPR agenda, and not be taken for granted.

2.2 COVAX has demonstrated that rapidly delivering vaccines to communities is predicated on long-term investment in routine immunisation; the ability to establish end to end solutions from early R&D, scaling-up manufacturing, securing deals, and setting up the regulatory and legal frameworks, all the way along the value chain to shots-in-arms. **This requires the capacity, partnerships and networks that underpin the Gavi Alliance, established over decades.** Sustaining these core PPR capacities, and the many innovations developed during the current pandemic will require strong international support, and internal reflection on Gavi's future role.

2.3 Gavi has been a major actor in PPR from the beginning (see Annex 1), and approximately 70% of Gavi 5.0 investments can be considered relevant to outbreak prevention and response⁴. Based on this early analysis, during the Gavi 5.0 strategic period, Gavi will contribute over US\$ 7 billion to preventing and controlling outbreaks.

- In Gavi 4.0, 60,000 items of cold chain equipment were added through the Cold Chain Equipment Optimisation Platform (CCEOP) initiative, contributing toward Gavi countries' delivery of COVID-19 vaccines through their routine immunisation supply chain system.
- The vast network of technical partners created under the Partners' Engagement Framework in Gavi 4.0 was utilised by countries to plan and deliver COVID-19 vaccines while minimising disruptions to RI.
- Several countries used the Gavi funded District Health Information System for COVID-19 surveillance capacity and information systems.
- Vaccine stockpiles (e.g. Cholera, Yellow Fever, Meningitis, Ebola) provide substantial support for outbreak response.

⁴ The 70% (strictly 74%) figure is defined as the projected expenditures of the Gavi 5.0 programme (2021-2025) which arguably have an impact on PPR. It includes Gavi support for vaccines that can be used flexibly to reflect the variability of the diseases they prevent across different areas or time periods, as opposed to vaccines recommended for routine use in all areas. This approach used builds on Boyce et.al (Global Fund contributions to health security in ten countries, 2014-2020: mapping synergies between vertical disease programmes and capacities for preventing, detecting, and responding to public health emergencies. Lancet Glob Health. 2021), which would yield a figure of 100% of Gavi delivery being directly or indirectly supportive of health security (based on mapping the Joint External Evaluation indicators against budget spending categories, and vaccine support being one of the major JEE indicators), but nuances that analysis with reference to Hampton et.al. (Diagnostics to make immunisation programmes more efficient, equitable, and effective: The Lancet Microbe 2022) by removing Gavi spending on non-targeted immunisation from that equation – i.e. PCV, rotavirus, pentavalent, and HPV vaccines. This results in a figure of up to 74% of 5.0 projected expenditures i.e. those falling in to the 'supporting health security' category, as a modification to the Boyce et.al. methodology. This percentage includes the projected operating expenditure of US\$ 749 million. The exclusion of this projected operating expenditure would suggest a percentage of around 67% of Gavi 5.0 projected PPR expenditure.

Hampton, Lee M., Hope L. Johnson, and Seth F. Berkley. "Diagnostics to make immunisation programmes more efficient, equitable, and effective." The Lancet Microbe (2022)

- Neither the 50+ workstreams and innovations developed under COVAX, nor the resulting scale-up in delivery, would have been possible without decades of Gavi-supported capacity building globally.
 - Missed communities, including people in remote rural areas, dense urban slums or displaced communities, are major sources of global health inequity and blind-spots for PPR. The 78% coverage achieved for DTP3 (three doses of diphtheria, tetanus and pertussis vaccines), and 332 million reached with the meningitis-A vaccine, builds links with communities, both to prevent and respond to disease outbreaks, and establish the access required to save lives and mitigate pandemics.
- 2.4 Building systems that reach communities between pandemics must be a core part of global preparations to ensure rapid, equitable access in response to an emergency. Sustained attention to delivery bottlenecks must be matched with active support to sustain and develop the many tools and workstreams that will be vital in preventing and responding to the net pandemic threat.
- 2.5 **As a priority:** the Secretariat will ensure Gavi's role as a unique end-to-end vaccine partnership which delivers PPR through its core functions is embedded into discussions at the WHO, G20 and G7.
- 2.6 **Concurrently,** the Secretariat will draw from a learning approach to PPR. Over the next six months, Gavi will ensure that external policy engagement, and aspects of Gavi 5.1 that are relevant to PPR, are informed by the full range of reviews and independent evaluations planned for COVAX.
- 2.7 As part of looking ahead to the 5.1 and 6.0 periods, further work is also needed to understand how synergies between RI and PPR investments can be exploited to yield maximum public health benefits, for example, as outlined in Doc 03, seeking opportunities to pivot COVID-19 delivery support (CDS) toward integrated planning with routine immunisation programmes (see Doc 05).
- 2.8 There are a number of questions relating to life course immunisation, expansion of antigens for epidemic preparedness and response, and optimal investments for both RI and HSS, which will be considered as part of Gavi 5.1 (see Doc 03).
- 3. Financial Innovation for Response**
- 3.1 Gavi's experience as a public-private partnership, with strong resource mobilisation capacities and the ability to bring together key partners (WHO, UNICEF, The Bill & Melinda Gates Foundation, CEPI, the pharmaceutical industry and civil society), means it is uniquely equipped to respond at pace to new challenges.
- 3.2 Gavi's financial instruments and capacity to innovate at pace can play a **key role in future pandemic response. Contingent financing and surge capacity are critical for vaccine equity in lower-income countries.** Any future pandemic response is likely to require substantial finance at scale,

very early on, delivered through robust and innovative financial mechanisms to help ensure equitable access to vaccines. This requires an organisation equipped to rapidly adapt existing structures to the nature of the pandemic.

- 3.3 Gavi has a long track record of financial innovation, most notably forming the International Finance Facility for Immunisation (IFFIm) in 2006. IFFIm's pioneering work to create vaccine bonds through raising finance on capital markets backed by long-term donor pledges meant that a billion-dollar frontloading tool was available to provide additional resources to the COVAX Advanced Market Commitment (AMC). Gavi also stepped forward to ensure this tool was available to CEPI, whilst simultaneously supporting a substantial part of the COVID-19 vaccine value chain.
- 3.4 Gavi's experience developing and deploying 'advance' commitments to manufacturers as 'pull' mechanisms to secure vaccines on better terms for lower-income countries is an equally important part of the PPR toolkit. The Pneumococcal AMC is estimated to have yielded US\$ 50-100 million in additional savings for Gavi and Gavi countries over its ten years of operation. Gavi also uses advance commitments to secure crucial stockpiles of vaccines against dangerous diseases, which are another key contributor to the PPR agenda by helping prevent outbreaks from becoming pandemics. In 2014, in the context of the West African Ebola outbreak, the Board endorsed up to US\$ 390 million for the procurement and delivery of licensed Ebola vaccines. In 2015 the Executive Committee approved an Advance Purchase Commitment (APC) with Merck, which provided an investigational vaccine stockpile of 300,000 doses for use in outbreaks until the licensed product was stockpiled and available in quantity.
- 3.5 These strong foundations were the bedrock which allowed Gavi to respond to COVID-19 and develop the COVAX AMC to provide support to lower-income countries. Even then, further innovation was needed to respond to the unique and continually evolving pressures of the pandemic. When the pandemic began, Gavi lacked pre-agreed and contingent financing mechanisms able to tolerate risk and strike early deals with vaccine manufacturers. It also lacked sufficient frontloading facilities alongside IFFIm to support surge capacity that worked for all donors. Nine months after the declaration of a pandemic, the COVAX AMC had only received US\$ 400 million in cash. That is, nearly a year from the first case, sufficient liquid resources to procure vaccines for only circa. 50 million people.⁵
- 3.6 Throughout 2020 and 2021, Gavi developed new mechanisms at pace to fill some of those gaps - helped by repeated engagement with the Board and generous donors. Risk tolerance levels were increased, establishing bespoke ways to strike Advance Purchase Agreements (APAs) ahead of other bodies (including ahead of regulatory approval). Gavi established a

⁵ Working on the basis of a weighted average cost of capital (WACC)-of approximately US\$ 3.55 per dose including ancillary costs at end 2020 (and that vaccines would have been freely available in the market), with the US\$ 400 million received, around 112.6 million vaccine doses could have been procured for around 56.3 million people. These procurements were based on a two-dose regimen.

suite of new frontloading and guarantee facilities to rapidly finance surge capacity (including with the European Investment Bank and US Development Finance Corporation). The cost-sharing mechanism enabled AMC countries to acquire additional COVAX doses backed by cheap loans and grants from multilateral development banks (MDBs). These tools now represent a vital global resource for PPR - and would be challenging to replicate outside of the Gavi institutional framework.

- 3.7 But there is still more to do. Gavi's recently launched Pandemic Vaccine Pool, which represents a mechanism that could be further adapted to provide immediate financial resources at scale for a future pandemic. And while Gavi has found ways to frontload funding and access the larger balance sheets of the MDBs through mechanisms like cost-sharing, there is still a lack of global agreement on how to provide significant contingent financing - to be deployed rapidly, and with an appropriate risk tolerance - for the benefit of lower-income countries in the event of a new pandemic.
- 3.8 The recent analysis of the proposed World Bank Financial Intermediary Fund for Pandemic Preparedness and Response (FIF) by the Independent Panel for Pandemic Preparedness and Response (IPPR) critiques the initial proposal noting that *"a clear and reliable mechanism is needed to surge financing for a response within weeks, not months, of an outbreak at a scale of potentially billions of dollars"*. Many of these considerations are currently missing from mainstream global dialogue on PPR; increasing the risk that the core components for an *equitable* pandemic response will again be omitted. Gavi will continue to work hard with all partners to address that gap.
- 3.9 Going forward, the Secretariat will work to ensure that the significant financial and risk management innovations driven by Gavi through the COVAX AMC are retained and strengthened as part of an updated global PPR architecture – including the Pandemic Vaccine Pool. Gavi will work to ensure a waiver is secured to obtain Implementing Partner (IP) status for the new Financial Intermediary Fund (FIF) for PPR⁶, and, Gavi will take a joined-up approach with CEPI, the Global Fund and others to ensure that new proposals have the scope to support a flexible, agile and networked response appropriate to the next, as yet unknown, threat.

4. Market Shaping for Resilience

- 4.1 At its April 2022 Retreat, the Board also made clear that Gavi has an important strategic role to play in this agenda within the ecosystem of global and local partners. Gavi has a long history of contributing to the diversification of manufacturing supply chains and improving business resilience for vaccine manufacturers. Gavi has achieved this primarily by providing reliable demand projections and predictable long term procurement financing. Ensuring sustainable, healthy market dynamics for vaccines is one of the four strategic goals for Gavi 5.0. Before COVID-19,

⁶ A Proposed Financial Intermediary Fund (FIF) for PPR hosted by the World Bank, submitted to the G20 Task Force May 2022. As at 1 June 2022, the US, EU, UK, Italy, South Africa and Saudi Arabia have made public statements in support of Gavi having Implementing partner status.

Gavi's Market Shaping Strategy, focusing on healthy markets with multiple suppliers, had already helped build manufacturing capacity across diverse geographies and in developing countries. Gavi's five initial suppliers in 2001 were based in Europe or North America. In contrast, today, Gavi procures (through UNICEF) from eighteen manufacturers, only four of which are European or North America.

- 4.2 Africa however, is still underrepresented in the global vaccine supplier landscape. According to the WHO, there are fewer than ten manufacturers with vaccine production on the African continent – and only one WHO pre-qualified supplier. Calls from the African Union to manufacture 60% of Africa's routine immunisation needs on the continent by 2040 have gained momentum in light of COVID-19 vaccine inequity. The recent G7 Development Ministers' Meeting Communiqué similarly called for *“sustainable, regionally diverse vaccine and essential medical product manufacturing capacity in developing countries, supported by the creation of sustainable markets”*, noting, *“In this regard, we would welcome Gavi to work with other relevant stakeholders such as the Global Fund on elaborating a market-shaping strategy”*.
- 4.3 Widespread calls for geographic diversification and increased equity in the global distribution of production capacity have led to multiple public-private initiatives. These largely focus on building COVID-19 vaccine manufacturing capacity, with unprecedented amounts of donor and private sector funding. The speed and political imperative to establish new suppliers could represent opportunities for pandemic preparedness. Their success, and impact on vaccine markets are important considerations for Gavi 5.1, including as a bridge to the Gavi 6.0 strategy development cycle. If managed carefully and with adequate planning and support, new entrants could bring potential benefits to global vaccine security as well as to healthy markets more generally.
- 4.4 There are also potential risks, the key one being distortion to established healthy global markets. Great care will need to be taken to ensure price increases are both minimised and accommodated. New entrants will almost certainly demand or require a 'diversification and resilience price premium'. At the same time, potential reduced demand-volume from certain established suppliers could also result in lost economies of scale.
- 4.5 Structured and strategic approaches to the selection of antigens and technology platforms, as well as financing mechanisms, are essential to retain the dual-win of sustainability (for the manufacturers) and affordability (in both Gavi and non-Gavi markets). Gavi is willing and well-positioned to play a constructive role in the continued short- and long-term design and diversification of the vaccine supplier base.
- 4.6 Whilst others are actively engaged in capital investment, technology transfer and capacity building, as the world's biggest funder of vaccines for developing countries, Gavi's comparative strength is on the procurement side. Gavi supports, in principle, purchasing COVID-19 vaccines from African suppliers, and is exploring opportunities to do so. We must also

acknowledge that oversupply (relative to demand) makes COVID-19 a challenging market for new entrants to compete within. Gavi will follow the established process of bringing any proposals for purchase to the Market-Sensitive Decisions Committee.

- 4.7 Beyond COVID-19 and with regards to African production of routine vaccines, the Secretariat would wish to see a coherent and evidence-based strategy for the agenda; one in which the roles and responsibilities of different agencies are clearly delineated. This can ensure the significant planned capital investments are aligned with vaccine market dynamics. There is concern that with the current rush to finance new capacity, this may not be happening.
- 4.8 Going forward, the Secretariat proposes to work proactively with partners, including the African Union and Partnership for African Vaccine Manufacturing, to set out a clear position on how Gavi can support sustainable regional manufacturing, including and beyond COVID-19 vaccines. The Secretariat will do this by adopting a two-stage process in the coming months.
- 4.9 **Firstly**, by working with partners to set out a shared vision for how Africa can develop regional capacity and where, and as the largest purchaser of vaccines for developing countries, Gavi can play a crucial role. **Secondly**, by scoping out potential new financial instrument(s) to provide increased support on the demand side. A proactive, but clearly defined role for Gavi will both help pull in, and reduce risk for, upstream investments, whilst also avoiding any perception of conflict of interest. The Secretariat will come back on its proposed approach at the December 2022 Board meeting as part of the articulation of Gavi 5.1, highlighting any implications for Gavi's operating model.

Section C: Actions requested of the Board

The Gavi Alliance Board is requested to **provide guidance** on the following three specific actions the Secretariat proposes to take over the next six months which are aimed at helping Gavi influence international processes and develop concrete new initiatives in support of the PPR agenda. Updates will be provided to the December 2022 Board meeting. The Secretariat will:

1. Ensure the benefits of the provision of epidemic and pandemic vaccines as a tool to strengthen PPR are embedded in the discussions at the WHO, G20 and G7 and that the resulting architecture reflects and enables Gavi's unique contribution to PPR, and reflects learning from the COVID-19 response.
2. Ensure the considerations outlined in this paper, including in relation to PPR-related financing instruments and support to the manufacturing agenda, will, where appropriate, be incorporated into the consideration of Gavi 5.1, pending Board approval in December, including any financial considerations (as per Doc 03).
3. Work proactively with partners, including the African Union and Partnership for African Vaccine Manufacturing (PAVM), to set out a clear position on how Gavi

can support sustainable regional manufacturing: providing an assessment of demand in the global vaccine market that could be filled by African manufacturers, and then developing options for pull-financing through new instruments, while considering the implications for the Gavi operating model. The Secretariat will provide the Board with an update on Gavi's support to this agenda in December 2022 as part of Gavi 5.1, reflecting inputs into the G7 (as requested by G7 Health and Development Ministers in May 2022) and ongoing engagement with AU and other partners.

Annexes

Annex A: End-to-end approach