

Subject	Gavi's Role in Regional and African Vaccine Manufacturing
Agenda item	08
Category	For Decision

Section A: Executive Summary

Context

The COVID-19 pandemic demonstrated that vaccine supply security varies by region and impacts vaccine equity. Limited regional manufacturing capacity, particularly in Africa, may have contributed to delays in progressing towards equitable access of COVID-19 vaccines. This renewed commitment at the highest levels of governments to establish industrial capacities on the continent for both pandemic response and routine immunisation. The African Union (AU) set out a bold agenda to develop sustainable local vaccine manufacturing, supported by the European Union (EU), G7, G20 and international partners. 20 years' experience in vaccine market shaping, pooled procurement and design of innovative financial instruments position Gavi well to support the downstream elements of this vision (e.g. via strategically curated product portfolios), whilst preserving and, wherever possible, enhancing global market health for vaccine markets. In June 2022, Gavi's Board requested that the Alliance align behind African manufacturing as supportive of pandemic preparedness and response (PPR) in the context of the Gavi 5.1 strategy. Over the past six months, Gavi has led extensive consultations, including with AU counterparts and the Board, to develop the four-Pillar strategy described in this paper.

Questions this paper addresses

As interventions are required across the value chain, where should Gavi focus? How can Gavi help new African market entrants find a pathway to sustainability, whilst preserving market health? How can Gavi's processes be adapted to make it easier for African/regional products to be selected? How can Gavi anticipate & manage expected high initial costs from new entrants, and the risk of price increases (or market exits) by incumbent suppliers? How can Gavi work with other partners to provide indications of future demand to manufacturers, whilst respecting its country-led model? How could a new financial instrument best incentivise new manufacturers & investors in Africa?

Conclusions

Gavi should use its comparative advantage to focus on a downstream approach that offers clear incentives and a path to commercial viability to partners and investors operating upstream. This approach has four Pillars: 1) advisory support for antigen & platform selection; 2) evolution of Gavi's market shaping principles; 3) seeking demand assurances; 4) a new financial instrument for Africa. The Pillars are designed to work in synergy as a coherent "bundle" of interventions, with Pillar 4 lending significantly more leverage to Pillars 1-3 than if Gavi were to deploy 1-3 only.

Section B: Facts and Data

1. A role for Gavi, The Vaccine Alliance: key considerations

- 1.1 Africa imports 99% of its vaccines. During the COVID-19 pandemic, and despite concerted international efforts, including through COVAX, Africa faced significant delays receiving vaccines in the initial months of 2021 due to vaccine hoarding and export restrictions. Whilst the COVAX AMC has now delivered over 600 million COVID-19 doses to Africa, the pandemic has shown that reliance on an import-only model for vaccines and medical countermeasures, which works well in normal times, comes with risk in emergency situations.
- 1.2 In response, African Heads of Government agreed a unified goal to develop, produce and supply over 60% of the vaccine doses required on the continent by 2040. The Africa Centre for Disease Control and Prevention (Africa CDC) working with the Partnership for African Vaccine Manufacturing (PAVM) has developed an ambitious plan to turn the nascent African manufacturing sector into an end-to-end industry by 2040 (Appendix 1). The momentum has seen over 30 manufacturing projects announced across 14 African countries. A communiqué by the African Union Bureau of Heads of State called on Gavi to commit to procuring 30% of vaccines for Gavi programmes from African manufacturers (Appendix 2). Political, financial, policy and technical support has materialised from the EU, G7, development finance institutions and international organisations including WHO, UNICEF and CEPI. Concurrently, a 3-year Memorandum of Understanding is being devised between AU and Gavi to support immunisation programmes, ensure equitable access to Gavi-eligible vaccines, and strengthen delivery of primary health care in Gavi-supported African countries.
- 1.3 To promote a sustainable distributed manufacturing ecosystem, any market/demand-based (downstream) strategy must work in synergy with upstream interventions. Without coordination, project failures are more likely, especially when emerging African manufacturers are faced with significant set-up costs, unfavourable economies of scale and relatively high Cost of Goods Sold (COGS).
- 1.4 The approach set out in this paper leverages Gavi's comparative advantage, i.e. is focused on downstream markets interventions, and with a necessarily long-term perspective, given timelines to establish new supply. This does not involve Gavi taking an enhanced role in R&D, capital investment, training & human resources, technology transfer, regulatory matters or intellectual property. Alliance Partners already have well circumscribed roles upstream in the value chain which would work in synergy with the downstream elements of this strategy. Programme and Policy Committee (PPC) members emphasised development of an enabling regulatory environment in Africa as especially important, which is expected to be supported by WHO's critical work in regulatory strengthening, Prequalification (PQ) and local production assistance.

- 1.5 A key Alliance focus throughout will be to preserve or enhance, to the extent possible, global market health for all vaccine categories that come into scope; the arrival of new (African) market entrants will have implications (of importance varying by market) for incumbent suppliers. Annex A sets this out in more detail.
2. **Pillar 1: Support shaping of regional product portfolios to ensure targeting of vaccines most likely to enhance global market health, with a deliberate approach to drug substance (bulk) platform diversity and unaddressed diseases**
 - 2.1 Gavi intends to help shape the manufacturing initiatives underway by playing a more active role in the choice of vaccines targeted for production. Gavi can do this by providing independent analysis on likely global and regional demand for vaccines, particularly those with opportunities for improving market health. A convening, advisory role will ensure a shared focus on priority antigens to maximise the sustainability of new entrants, and to minimise instances of multiple manufacturers targeting the same vaccine markets. With widespread availability of COVID-19 vaccines, and given the uncertain demand outlook, projects that rely on COVID-19 vaccine manufacturing alone will face much higher commercial risk.
 - 2.2 Initial analysis identifies vaccine markets with opportunities for diversification to improve market health and to build sustainable new enterprises. Other markets also have the potential for future growth, including products with improved profiles, and a longer-term pipeline of novel products against currently unaddressed diseases. During the operationalisation phase, extensive consultation and analysis on antigen priority lists will be necessary, with direct involvement of African countries themselves (as this will link also to Pillar 3 below). Annex B gives an illustrative categorisation of potential vaccine product priorities.
 - 2.3 There would be a close ongoing link with Gavi's broader role in PPR and monitoring of diseases with epidemic & pandemic potential in collaboration with WHO and CEPI (Coalition for Epidemic Preparedness Innovations), which would further inform advice on future vaccine needs. The Alliance will also provide transparency on those vaccine categories where a new supplier would not improve (or may be detrimental to) overall global market health. These typically are markets where significant further product evolution is not a priority, where there is already (or will soon be) diversified global overcapacity and where competition has already led to low and sustainable pricing.
 - 2.4 The Secretariat has begun proactively engaging with AU Commission/Africa CDC/PAVM, the World Economic Forum's Distributed Vaccine Manufacturing Initiative, and bilateral and multilateral financing institutions, to begin to play this

enhanced role in portfolio shaping and coordination. This has been welcomed as a valuable additional source of analysis and counsel.¹

3. Pillar 2: Adaptation of the Healthy Market Framework and Product Menu Criteria to facilitate listing and adoption of new regional products

3.1 Gavi is proposing a clear and fundamental change to the way that the Alliance selects new vaccines for the portfolio to make it easier for manufacturers in regions with low representation, including Africa, to be selected. Gavi's evaluations are driven by the Healthy Market Framework (HMF) which is used to assess global vaccine markets. For a new product to be adopted for Gavi support, the Secretariat and UNICEF evaluate the product according to Product Menu Criteria which are informed by that market's HMF status. Gavi is proposing modifications to language in the HMF and the Product Menu Criteria to enable higher value to be attributed to supply from diverse geographies. This would facilitate the listing of new regional products, including at differential price points to incumbents, if within reasonable bounds and justified. This would be the foundation upon which Gavi-supported countries would be able to choose new African products through Gavi.

3.2 These HMF and Menu Criteria changes are necessary, but not sufficient, to provide the level of assurance that upstream investors would ideally like, and will underpin Pillars 1, 3 & 4 by easing the potential barriers for new vaccines from geographically diverse suppliers to be listed in the first place, at potentially different price points from existing products. Another critical function of Pillar 2 will be to provide a gateway for new African products to access the market in all Gavi-supported countries (not just African) if they attract the demand. New WHO PQ'd products with innovative and attractive profiles should be made available widely, to all Gavi-supported countries and beyond, as a key element of sustainability.

3.3 To avoid higher COGS manifesting as market-distorting price premiums financed through increasing Gavi core programme budgets, the standalone financing facility (Pillar 4) is recommended as the main vehicle for absorbing the higher COGS of new market entrants. The preference of Alliance Market Shaping partners is for new entrants to arrive to market competitive from the outset, regardless of initial volumes.²

4. Pillar 3: Providing investors in new manufacturing capacity with more predictability around eventual demand

4.1 Gavi accounts for approximately half (by value) of all vaccines consumed in Africa, and Africa is expected to account for 70% all vaccines financed by Gavi

¹ See for example devex Opinion: How to make Africa's vaccine manufacturing sustainable By Acting Director Africa CDC Dr. Ahmed Ogwel Ouma & Gavi CEO Dr. Seth Berkley, 7 November 2022

² Further studies may be warranted on Costs of Goods Sold of new suppliers using various technology platforms under different volume assumptions, alongside estimates of savings on freight and import taxes

globally in 2022.³ Given these statistics, aspiring manufacturers and other interested parties have voiced the expectation that Gavi should provide market certainty to African manufacturers, i.e. reducing (or even eliminating) commercial risk, through “demand guarantees” or “offtake agreements”.

- 4.2 Since one of the principles at the heart of the overall Gavi model is country product choice through healthy competition, Alliance Partners are aligned that Gavi, in isolation, cannot guarantee the uptake of any future vaccine of uncertain price or profile. Three options were therefore evaluated: (i) Continental Demand Solidarity, (ii) Gavi-Mediated Demand Pact, (iii) Gavi Country Choice Over-Ride.
- 4.3 These options were assessed and presented to the PPC which concurred with the Secretariat’s analysis that options (ii) and (iii) are sub-optimal; they necessarily restrict the impact of the intervention to Gavi countries & antigens, and undermine the primacy of country choice as a core tenet of the Gavi model. To keep the emphasis on country product choice and self-determination, the recommended option is (i): to advocate for African countries themselves to provide new suppliers with demand assurances. There has been positive initial feedback from AU Commission/Africa CDC stakeholders on potential mediation of a multi-country pact or declaration that suitable African-sourced vaccines will be adopted for their programmes, in both Gavi and, critically, non-Gavi supported programmes. This regional action will go a meaningful way to de-risking the demand outlook and brings the very strong credibility of African solidarity into play. Although demand visibility across Gavi-supported African countries and antigens would certainly help, demand confidence emanating from the entire continent will go even further; it would be with this confidence that manufacturers and investors make their own commercial risk assessments.

5. Pillar 4: A new financial instrument to incentivise manufacturers and investors in Africa

- 5.1 Pandemic supply resilience and market fragmentation can come at a cost. While the preference would be for new entrants to arrive to market competitive from the outset, regardless of initial volumes, modelling and Secretariat consultation with multiple partners indicates this is unlikely. Without additional support, new African market entrants will initially struggle to be competitive. High initial set-up costs (and potentially higher direct/indirect production costs) would need to be reflected in higher prices. This is driven by initial capital costs, low initial volumes, and higher labour costs, and would likely exceed levels that could be accommodated by Gavi core funds and national budgets.

³ 70% by volume, 66% by value in 2022- including Gavi supported and co-financed doses. For details see Gavi’s new publication Expanding Sustainable Vaccine Manufacturing in Africa: Priorities for Support - Appendix 3

- 5.2 A well-targeted and time-limited downstream “pull” financial instrument, directed at African manufacturers, could play an important role in amplifying the first three Pillars of this strategy and overcoming this market failure. The political will from African leaders, the strong case provided by the pandemic, and the unprecedented level of support from donors and international organisations, offer a window of opportunity to deliver this approach. Extensive consultations with providers of finance and manufacturers have suggested a Gavi-designed instrument could help create the right incentive structures to prevent market distortion. It could unlock some of the substantial “push” finance agreed in principle, but which requires greater confidence in new initiatives finding a sustainable route to market.
- 5.3 Having considered a range of models, the Secretariat proposes that an Advance Market Commitment providing an incentive to African vaccine manufacturers successful at competitively bidding for, and supplying into, Gavi programmes, both current and future, provides the best way of achieving these objectives. The PPC provided guidance on some of the initial design considerations, and an early outline of how the proposed mechanism could be structured is set out in Annex C.
- 5.4 The concept of an Advance Market Commitment aimed at accelerating the expansion of end-to-end African vaccine manufacturing has the following underpinning objectives to guide detailed design work in 2023:
- **Supporting healthy global markets** – minimise market distortions and help sustain low global prices and resilient supply for priority vaccines
 - **Driving efficient market outcomes** – provide signals to guide and align manufacturers & investors behind resilient, sustainable business propositions⁴
 - **Reducing barriers to investment** – carefully structuring the level of incentive to help offset initial costs of market entry whilst aligning support with other providers of capital for greater overall impact
- 5.5 The Secretariat proposes that the AMC is further designed over 6-12 months starting January 2023, through a multi-stakeholder process to finalise the structure and size of the mechanism, followed by implementation. Approval from Gavi’s Board of the detailed programmatic and design parameters, along with estimated resource requirements and funding sources, will be sought in 2023.

6. Resourcing implications

- 6.1 The Gavi Secretariat will need incremental resources through 5.1 to operationalise, including essential work on unaddressed diseases that Market

⁴ The AMC is anticipated to provide support to both fill-finish and drug substance (bulk) manufacturing, with eligibility extending to any entity producing qualifying vaccines on the African continent

Shaping does not currently cover, as well as vaccine markets expertise, analytics and engagement necessary for design and execution of Pillar 4. As set out in the Secretariat budget presented to the Audit and Finance Committee, operating costs of regional manufacturing diversification are included within the current budget. Funding for the proposed AMC would be raised outside of Gavi “core” funding.

Section C: Actions requested of the Board

The Gavi Alliance Programme and Policy Committee **recommends** to the Gavi Alliance Board that it:

Approve the first three pillars of the new approach, namely 1) support for antigen and product portfolio planning; 2) adaptation of the Healthy Market Framework and Product Menu Criteria to facilitate listing and adoption of new regional products; and 3) providing investors in new manufacturing capacity with more predictability around eventual demand.

Noting information provided in Annex C following guidance from the Gavi Alliance Programme and Policy Committee, it is **recommended** that the Gavi Alliance Board:

Request that the Secretariat work up detailed proposals for the design and operationalisation of Pillar 4: an Advance Market Commitment to accelerate the expansion of end-to-end African vaccine manufacturing, with three underlying objectives: (i) support healthy global markets, (ii) drive efficient market outcomes, (iii) reduce barriers to investment, noting that detailed parameters will return to the Gavi Alliance Board for consideration and approval in 2023.

Annexes

Annex A: Incumbent supplier and market dynamics analysis

Annex B: Rationale for initial illustrative vaccine product prioritisation

Annex C: A new financial instrument to incentivise manufacturers & investors in Africa

Additional information available on-Board Effect

Appendix 1: AU Communiqué (May 2022)

Appendix 2: Partnership for African Vaccine Manufacturing: Framework for Action

Appendix 3: Gavi Publication - Expanding Sustainable Vaccine Manufacturing in Africa: Priorities for Support (November 2022)