

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

Summary:

The paper outlines the results of the analysis conducted to date on a potential financial instrument, “Phase I”.

On this basis, approval is sought for Secretariat to develop full proposals (“Phase II”) for an AMC to accelerate the expansion of end-to-end African vaccine Manufacturing – with the detailed design returning to the Board for consideration and approval in 2023.

Analysis to date indicates the role for a time-limited, Africa-focused Advance Market Commitment with the following objectives:

- **Supporting healthy global markets** – minimise market distortions and help to sustain low global prices and resilient supply for priority vaccines
- **Driving efficient market outcomes** – provide a signal to guide and align new manufacturers and investors behind resilient, sustainable business propositions
- **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

- guided by the following initial design considerations:

(i) minimising market distortions through a post-tender incentive payment (ii) time-limited (iii) independent of Gavi’s core funding and (iv) Gavi designed, with an option for an external partner to host all or part of the instrument.

Background

This Annex summarises work conducted to date in Phase I of the scoping of a proposed instrument to incentivise African vaccine manufacturers & investors in Africa. It addresses the strategic objectives of the instrument, its potential scope, and proposes a process for its further development. The Gavi Board is recommended to approve embarking on Phase II; the development of a detailed proposal for the design and operationalisation of the AMC.

To reach this stage, the Secretariat conducted detailed reviews of existing work on African vaccine market dynamics undertaken by the Clinton Health Access Initiative, McKinsey and Company, Africa CDC Partnership for African Vaccine Manufacturing (PAVM) together with reviews carried out into the Pneumococcal AMC. In addition, detailed consultations were held with the AU, Multilateral and Bilateral Development

Financial Institutions, and Civil Society Organisations. Conversations were also held with representative organisations on behalf of Vaccine Manufacturers (via the IFPMA and DCVMN).

New analysis was also commissioned to better understand market dynamics. Taken together, this process informed the scoping of potential downstream market interventions required to support the objectives. The clear conclusion was the need for a targeted and time-limited financial incentive mechanism to be both complementary and additive to Pillars 1-3.

Aims and objectives of a new instrument

The stakeholder consultations carried out over the past five months revealed broad support for a new instrument, with the objective of **accelerating the expansion of end-to-end African vaccine manufacturing capacity**¹. It would do so by providing support for new African Manufacturers to overcome higher costs of entry – in recognition of the specific circumstances of Africa and the supply-chain vulnerabilities exposed during the pandemic. The mechanism would adhere to the following underpinning objectives to guide detailed design work in 2023.

- **Supporting healthy global markets** – minimise market distortions and help to sustain low global prices and resilient supply for priority vaccines.
- **Driving efficient market outcomes** – provide a signal to guide and align new manufacturers and investors behind resilient and sustainable business propositions.
- **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.

The objective of supporting **healthy global markets** recognises that any new market intervention is likely to lead to reactions from incumbents. These would need to be carefully assessed (more detail on possible impacts is set out in Annex A). The aim of targeting incentives where additional manufacturers are required to strengthen global markets or where new product profiles would lead to better immunisation outcomes should be a key feature of how the instrument is developed.

With 30+ projects across Africa in various stages of development, a new mechanism should help **drive efficient market outcomes**. This indicates the need to structure a financial instrument to encourage manufacturers to bid competitively into tenders at prevailing global prices, and at volumes that would lead to sustainable production.

¹ 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.

The instrument should be right-sized to **reduce barriers to investment** and accelerate new production, whilst providing value for money and a clear runway to successfully close the instrument – ensuring any incentives are well-targeted to avoid long-term reliance on financial support. Ideally, an instrument that reduces risk should not only bridge part of the delta between African and non-African Costs of Good Sold (COGS), but also serve to leverage *other sources of finance* – such as helping to facilitate cheaper access to working capital.

Choosing an appropriate instrument

The Secretariat reviewed different types of mechanisms that would be most appropriate to support the objectives above. This included looking at a full range of instruments that could be used to send clear downstream market signals to aspirant African Vaccine Manufacturers – ranging from direct financing and payments upfront to manufacturers, to providing volume guarantees to manufacturers.

Each option was also assessed against factors that had been raised with Gavi by stakeholders. Firstly, whether the mechanism would have a broad market shaping impact, able to target expansion of several products and facilities; secondly, whether it would be able to send a strong, transformative signal across the market and thirdly – emphasised by many – whether it could be designed to be pro-competitive, avoiding Gavi ‘picking winners’ and limiting barriers for future entrants. The results are summarised in the table below.

Figure 1 – Options appraisal for a new financial instrument

INSTRUMENTS	Description	Market-shaping: Influence direction/ pace of expansion and can target multiple products	Transformative: Delivers strong, market signal that secure entry	Pro-competition: Avoids picking winners and limits barriers for future entrants
Direct financing (subsidy/ buy-down/ reward)	Direct payment to manufacturer to reward entry/ near-term COGS support	✓	✗	✗
Catalytic procurement	Commitment + funding to purchase initial production	✓	✗	✗
Volume guarantee	Commitment to purchase minimum volume if there is a demand shortfall	✓	?	?
Advance Purchase Commitment	Pre-payment for a new product/ innovation; used to credit future purchases	✓	✓	✗
Advance Market Commitment	Per-dose incentive to encourage / de-risk investment in competitive antigen production consistent with market health objectives	✓	✓	✓

Based on this analysis, further consultation with stakeholders, and prior experience within the Secretariat on previous similar instruments (including the PCV AMC, Ebola APC, COVAX), an Advance Market Commitment with a post-tender top-up payment emerged as the instrument likely to be most suitable. The specific structuring of any

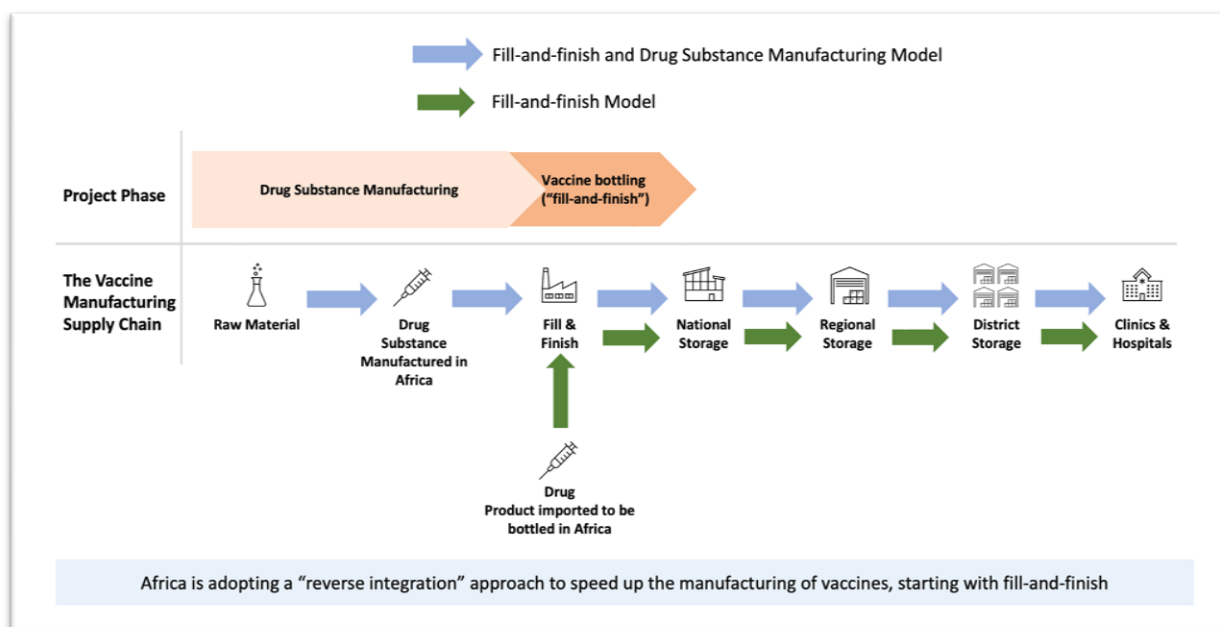
AMC must learn lessons from prior mechanisms, leading to a number of specific considerations to carry into any Phase II.

Further considerations for an AMC mechanism

Phase 1 considered additional priorities in the initial scoping of a potential AMC:

- **Minimising market disruption through a post-tender award:** It is important that the incentive provided by the AMC is carefully designed to minimise market disruptions. Analysis of different incentive structures indicated that per-dose incentive payment may be the best option for the AMC. This could be awarded to African Vaccine Manufacturers that successfully win volume through Gavi Alliance tenders up to a pre-agreed volume of doses/or financial value. The incentive payment could therefore be awarded post-tender, without predefining tender award strategy or outcomes, and indeed, with no substantial change or interference with Alliance tendering practices and payments.
- **Time-limited:** The AMC would not offer incentive payments in perpetuity. Aimed at incentivising the expansion of a nascent industry, the AMC would seek to promote competitiveness via an incentive payment to address the initial costs of manufacturing in Africa **until** human resource differentials and production volumes offer a more level playing field. An appropriate time period would be determined in Phase II, stretching across one or (likely) more Gavi 5-year strategic periods (bearing in mind the need to consider tender award periods).
- **Independent of Gavi's core funding:** The AMC would be set up independently from the Gavi Alliance standard tendering processes. New funding would be raised for the AMC.
- **Accommodate both Drug Substance and Fill & Finish manufacturing:** Vaccine manufacturing involves two core steps (Figure 2). Step 1, Manufacturing the antigen through "Drug Substance manufacturing" (DS). Step 2, (after "formulating" the DS), bottling the vaccine in a vial, through a process commonly referred to as "Fill-and-Finish" (F&F). The majority of new vaccine manufacturing initiatives in Africa are seeking to establish qualified F&F facilities, to build up a track-record in aseptic process prior to commencing full-scale DS manufacturing. As such, F&F is necessary before investing in full DS capacity. Any strategy seeking to establish end-to-end capacity should consider actively supporting this pathway, and include support to F&F, rather than requiring/incentivising just DS manufacturing.

Figure 2: The Vaccine Manufacturing Value Chain



- **Gavi-designed, with an option for an external partner to host:** It is anticipated that during Phase II, Gavi will look to bring a range of stakeholders into the design discussion. Proposals would include the option for the mechanism, or components of the mechanism, to be hosted by an external partner if required.

Timelines to setting up the AMC: two-phased implementation process

Building on a similar process (albeit over a much shorter timeline) that was used to design and implement the PCV AMC, the Secretariat has been working on the basis that the AMC design would build on Phase 1, to continue under Phase II in 2023:

- **Phase I:** The first phase has responded to Board’s direction to further scope and explore the financial instrument, consult the PPC on findings, and seek specific Board approval to move forward with detailed proposals for the design and operationalisation of Pillar 4.
- **Pending this approval, Phase II:** would last approximately 12 months, starting January 2023, and involve a multi-stakeholder process to further define the structure and size of the AMC mechanism. The Gavi Secretariat would lead an inclusive design process, as with Phase 1, with the support of external consultants to facilitate underpinning analysis, design work and consultation, with the objective of presenting the key terms of the instrument at the June Board in 2023.

- In order to maximise opportunities to complement and leverage Pillars 1-3, the AU, Africa CDC and Alliance partner UNICEF would be particularly closely involved in the detail of the design process. In parallel, the Secretariat would convene regular consultations with Multilateral and Bilateral Development Financial Institutions, Civil Society Organisations, interested Board Members and potential donors and reach out to vaccine market experts, in a similar approach that was taken to the design of the PCV AMC. Vaccine Manufacturers would be engaged appropriately, mindful of potential competition issues, and most likely via the IFPMA/AVMI and DCVMN.

Next Steps

Pending Board approval, additional work to structure the AMC in 2023 would include:

- Scoping and structuring the specific incentives for F&F and DS by analysing market data using sophisticated modelling, in a process that directly involves a range of stakeholders to build ownership and understanding. Appropriate care will be taken when engaging with industry partners.
- Work on options for the operational structuring of the AMC, including fiduciary and detailed working arrangements, again in consultation, including with donors and multilateral development finance institutions.
- Develop a proposed governance framework for the AMC, building on substantial learning from similar initiatives.