

## **African Vaccine Manufacturing Initiative (AVMI) Position Paper on GAVI's African Vaccine Manufacturing Accelerator (AVMA)**

*The AVMI provides a consensus voice for African Vaccine Manufacturers, specifically within the context of the African Union call for a New Public Health Order aimed at safeguarding the health and economic security of the continent. This encompasses the Africa CDC / Partnership for African Vaccine Manufacturing (PAVM) objective of ensuring at least 60% of Africa's vaccine requirements is supplied by African manufacturers by 2040, up from the dangerously low 1% today.*

**AVMI considers the AVMA to be a critical lever of achieving the continent's objectives and appreciates and acknowledges the efforts of GAVI thus far. We hereby request the favourable review and support of the AVMA by GAVI's Programme and Policy Committee (PPC) for approval at the December 2023 GAVI Board meeting.**

This briefing note documents AVMI's position and recommendations on the AVMA given that African Manufacturers currently have no formal representation at PPC and the Board. While three African vaccine manufacturers are members of the Developing Countries Vaccine Manufacturers Network (DCVMN), the DCVMN has a large constituent base with diverse interests and therefore does not have a mandate to represent the African vaccine manufacturing industry. Given GAVI's publicly stated strategic aim to support African Vaccine Manufacturing via the AVMA, the intent of this document is to provide a consensus African industry view. In the future, it is hoped that AVMI is granted representation on the various committees of GAVI similar to what has been afforded to both the DCVMN and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), particularly as the majority of vaccines procured by GAVI are destined for the African continent.

There are three themes that the AVMI would like to propose be addressed to improve and accelerate the return on investment of the AVMA for GAVI funders and investors. These are as follows:

1. **Scope** – broaden the range of vaccines covered by the regulatory milestone payment beyond what GAVI has described as Priority Antigens to cover a broader subset of vaccines in the interest of healthy current and future markets.
2. **Scale** – increase the incentive available for the Fill & Finish component of the AVMA to more meaningfully offset the medium-term cost of manufacture on the continent, and essentially to enhance competitiveness against incumbent high volume/low-cost manufacturers in UNICEF tenders.
3. **Advocacy** – to ensure that the WHO Pre-Qualification (PQ) process supports the AVMA with prioritisation and the resourcing of submissions from African manufacturers.

### **1. Scope – Broaden the range of vaccines covered by the AVMA**

By restricting the milestone payment to only the 4 GAVI designated priority antigens of Cholera, Hexavalent (whole cell Pertussis), Measles/Rubella and Malaria, the unintended consequence could be overinvestment in these 4 antigens creating unhealthy markets with multiple manufacturers investing in both Fill finish (DP) and Drug Substance (DS) of these antigens.

Without a similar milestone incentive, the other vaccines – which are all of importance to Africa – may be perceived as less attractive to manufacturers and, importantly technology transfer partners/ investors as they would need to bear the full development costs until commercial success is attained, if at all. The reality is even if investors aligned with manufacturers on these other antigens, there would be limited chance of successful tendering against incumbents. This altered risk profile may in fact lead to weaker 'organic development' for African vaccine manufacturing.

### Recommendation:

Whilst African manufacturers would like to see *all* antigens covered by milestone payments, within the context of constrained resources, AVMI recommends that GAVI's Priority B antigens (GAVI Healthy Market Framework) be included in the AVMA construct. This would also allow African manufacturers an opportunity to participate in existing "higher volume" markets such as those for Rotavirus, Pneumococcal, Human Papilloma Virus, and Meningitis vaccines, and at the same time would contribute to globally healthier markets as well as regional access to technologies that can be leveraged for outbreak, epidemic and pandemic vaccines.

Judicious application of the funding caps per 'Priority Antigen' funding caps, taking into consideration of the number of DS manufacturers needed to sustain healthy markets for these vaccines, creates the opportunity to expand the list of funded vaccines beyond what is proposed without significantly expanding the total expenditure of the AVMA.

Furthermore, AVMI recommends that potential candidates for future priority antigens from the GAVI Vaccine Investment Strategy be added when appropriate to ensure a sustainable long term African and global vaccines market.

## **2. Scale – Proposal for increasing the Fill & Finish component of the AVMA**

Demand allocation (volumes) and demand predictability (long term agreements and offtakes) are critical elements of sustainability. Achieving economies of scale through volumes is essentially the only way African manufacturers can reduce the cost of manufacture to compete, considering current UNICEF market pricing.

In the absence of any Advanced Market Commitment (AMC), African manufacturers cannot support \$0.3 per vial for a 10-dose vial presentation (i.e \$0.03 per dose for 10 dose vials, the presentation required for large campaigns for most vaccines and programmes.) This 3c per dose will not be sufficient to meaningfully reduce the cost of manufacture in the medium term (especially when the higher cost of DS (likely to include some profit component for the technology transferor) and the likely volumes (not at scale at least initially) are considered.)

### Recommendation:

On the basis of bilateral discussions amongst manufacturers, the general expectation was a 30% premium in the medium term to be competitive against well-established high volume / low-cost manufacturers already operating at scale.

Ideally AVMI would like to review the GAVI modelling, however given the limited time available to do so and in the interests of supporting the urgent adoption and implementation of the AVMA by December 2023, the following is proposed:

- \$0.30 / dose for Fill & Finish
- Cap of \$1.50 per vial

The recommendation above translates to less than 20% premium (vs initial expectation of 30% premium). | Assumes an average price per dose of circa ~\$1.50 for GAVI funded vaccines |

The \$0.30 per dose results in an incentive /cost subsidy that more realistically reflects the higher costs incurred by nascent manufacturers and also considers different platforms and costs of manufacture.

It is critical that the incentive be sufficient to provide meaningful support on the journey to cost competitiveness → in this way manufacturers will be able to compete with incumbents who have cost structures at scale to win volumes and reduce costs through economies of scale. This will enable African manufacturers to be competitive at the end of the AVMA period. In the absence of volume allocations and demand certainty via offtakes, this will only be possible with meaningful incentives.

Importantly, this recommendation provides greater certainty that any funds approved for AVMA are actually paid out during the 10-year period of the scheme as opposed to waiting longer for DS manufacturers who will inevitably only come on stream later risking not all funding allocated and approved being utilised. It also would likely result in a meaningful share of the funds flowing to manufacturers in the earlier years.

AVMI recommends that this component of the AVMA be subject to annual review providing all parties to review their real time costs.

***This recommendation by no means implies any less focus on DS incentivisation which is currently included in AVMA – industry supports this given the need to strategically direct investment towards DS for continental vaccine health & security. Meaningful fill finish incentives reflect the initial need as we work towards longer term objectives of DS capacity and capability on the continent.***

### **3. Advocacy – Ensuring that the WHO PQ process is supportive to the AVMA**

GAVI has a leading and central advocacy role with critical multilateral and domestic partners. The latter is key for improving predictability of country-led demand for regional products, and the former vital to ensuring operational alignment with the strategic aim of supporting African Vaccine Manufacturing.

As the basis for the AVMA milestone payments and key requirement for UNICEF tender participation, the WHO PQ is central to the AVMA being operational and meeting its objective of supporting African regional manufacturing. From recent bilateral discussions and multilateral presentations including September's UNICEF Vaccine Industry Consultation, AVMI is concerned that no accommodation for regionalising vaccine manufacture – a key learning from the myriad of pandemic reviews – has been reflected in the PQ process.

#### Recommendation:

Whilst AVMI will be engaging with WHO on its Prequalification Process for African manufacturers, AVMI is seeking GAVI's advocacy, resourcing, and support in asking for:

- Priority review of dossiers from African Manufacturers
- Dedicated WHO PQ resources and personnel to support African dossiers
- Adoption of the expediency measures used in the pandemic process – e.g. rolling submissions
- To put in place measures to align regulatory and procurement cycles – this is a key ask and has the potential to significantly impact the effectiveness of AVMA

### **Conclusion**

AVMI is supportive of GAVI's AVMA. In the interests of expediency, the 3 proposals above are all designed with the intent to make the AVMA meaningful for African manufacturers and a success in terms of increased return on investment for GAVI's funders and investors.

A successful AVMA is crucial to the enhancement of health security for Africa through support for continental vaccine manufacturing. In parallel, AVMI will continue working with the African Union through Africa CDC and member states on pooled procurement mechanisms, related policies and demand generation initiatives as it is clear that this is an equally important lever in securing the continent's objectives for vaccine manufacturing.

**About AVMI:** The African Vaccine Manufacturing Initiative is a not for profit organisation established in 2012 with the mission of advancing sustainable human vaccine manufacturing capacity in Africa. AVMI is positioned as the voice of African vaccine manufacturing industry representing more than 20 manufacturers on the continent and works closely with the Africa CDC and other key stakeholders in support of the Partnership for African Vaccine Manufacturing (PAVM).