AVMI Reflections on AVMA – 6 months post launch
January 2025

Introduction

In June 2024, GAVI launched the $1.2B African Vaccine Manufacturing Accelerator (AVMA) at an event in Paris attended by dignitaries, donors and stakeholders from across the continent and the world. Six months post this milestone event, the African Vaccine Manufacturing Initiative (AVMI), the consensus voice for the African Vx industry, has the following reflections and suggestions in relation to the AVMA

1. Duration of the AVMA mechanism
2. Revision of the CAPS
3. Addition of antigens to Priority category
4. Potential use for additional $200m AVMA funding pledged by donors

1. Duration of the AVMA mechanism

The broader purpose of GAVI's AVMA is to assist Africa in achieving its aim of enhanced vaccine equity and improved health security, which the African Union has articulated as having 60% of the circa 1.4B doses needed to protect its children and citizens manufactured on the content by 2040.

GAVI's stated objectives/outcomes of the AVMA are defined as:

- A sustainable African vaccine manufacturing base that is contributory to healthy global vaccine markets (At least 4 vaccine manufacturers who secure at least one UNICEF tender with AVMA support , >0.8 billion cumulative doses supported by AVMA until 2035)
- Improved African pandemic and outbreak vaccine supply resilience (3 or more Drug Substance platform technologies supported by AVMA until 2035, >0.7 billion Drug Product capacity (in doses) of AVMA supported supply base when repurposed in a potential outbreak scenario)

In October 2024 Africa CDC, Clinton Health Access Initiative (CHAI) and PATH 2024 provided an update on the status of vaccine manufacturing on the continent. The data in this report underscores that whilst Africa has successfully built Drug Product (DP) capacity and is striving to build Drug Substance (DS) capabilities and capacity, more support is needed in terms of ensuring African made has access to African need. Furthermore, the time required to realise drug product technology transfers and establishing drug substance is significant, particularly in the case of manufacturers establishing these processes for the first time. This leads AVMI to recommending that the AVMA be extended from 10 to 15 years :

i. Only 3 African vx manufacturers will have marketable vaccines for the continent through UNICEF and other means by 2030,
ii. Of the 8 vaccines by African vx manufacturers that will be available for the continent by 2030, the market opportunity due to the lengthy and fixed tender process will be modest

and will not come close to the required volumes mandated by the African Union or even the volume objectives of the AVMA

iii. Whilst arguably Africa has sufficient DP capacity, DS capacity is currently limited. Building DS capacity and capabilities has a longer timeframe and consequently there is a risk that significant AVMA funds are not disbursed within the 10 year period

iv. The return on investment for African vaccine makers would be aided by a longer AVMA commitment – this would support business cases and funding requirements

Extending the AVMA by a period of 5 years would ensure that manufacturers have an opportunity to better mitigate the development and access risks of committing to vaccine manufacturing investment, especially in DS activities. It would also give an opportunity to more manufacturers to access the funds available. Lastly this would ensure that there is sufficient time to achieve the critical objective of expanding DS capacities and capabilities on the continent.

2. Revision of the incentive CAPS

Disbursement caps as per AVMA:

- $250 mn per manufacturer of which $50 mn for F&F
- $250 mn for total milestone payments
- $250 mn for total F&F support
- $300 mn total per vaccine

There has been significant debate regarding the disbursement caps specifically around the low F&F cap of $50m. The reality is that in order to ensure Drug Substance capability is supported on the continent we need sustainable manufacturers. Given that the initial pathway is largely through fill and finish, this requires sufficient support for these activities.

Our ask is that in order to ensure the sustainability of manufacturers such that they are able to then focus on Drug Substance capacities and capabilities, the Fill Finish Cap be removed (whilst still maintaining the overall cap per manufacturer).

There is a risk with these caps that there is limited disbursement of AVMA in the first 5 years, and consequently that existing AVMs are unable to compete with low cost high volume incumbents by the time they enter the market. Removing the FF cap thus allows higher disbursement earlier in the AVMA term, whilst at the same time supports the sustainability journey of manufacturers such that they are able to commence with DS projects.

3. Addition of antigens to Priority category

The current proposal to review antigens for addition to Priority category at the 3 year review periods is welcome. However it does not take into account the lead time in terms of the timeline for

investment decisions. It is thus requested that Priority antigen list be reviewed and updated in line with GAVI's Vaccine Investment Strategy.

4. Potential use for additional $200m AVMA funding pledged by donors

It is AVMI's understanding that an additional $200M in AVMA funding was raised. We share insights on some of the gaps so that this funding can be deployed to support solving current challenges for manufacturers.

Below we have listed some existing challenges being experienced by current Vx manufacturers:

- Access to demand/volumes -
    - to secure funding, manufacturers need demand commitments and demand guarantees (Demand certainty has been experienced as a key challenge in unlocking debt financing).
    - currently there is no visibility of offtakes/volume commitments against even vaccines which are expected to be WHO Prequalified by African manufacturers between 2025 and 2030 – this poses a challenge in terms of sustainability of technology transfers and securing necessary funding to execute even those projects planned for commercialisation by 2030 (thus impacting the viability of the AVMA)

- Regulatory realities which are resulting in long lead times to access market – capacities and capabilities of local NRAs, resourcing at WHO to enable prioritisation of African Vx submissions and to reduce timelines to market
    - There is a need for funding & resourcing to support capacity and capability building of local NRAs on their journey to ML3 and those ML3 NRAs to reach WHO Listed Authority status and ultimately to solve potential bottlenecks given the volume of submissions
    - The timelines for local NRA approval and subsequent WHO prequalification are currently likely to result that the first manufacturers are only able to access the UNICEF market towards the end of the 2025 – 2030 period, at which point it would also be challenging to compete with low cost high volume incumbent manufacturers. It is critical for the sustainability of these manufacturers that we accelerate regulatory timelines to accelerate access to market.

- Funding challenges for African Vx manufacturers pre-commercialisation of pipeline
    - High working capital costs in period between commencing a tech transfer and commercialisation – significant costs of procuring Drug substance from technology transfer partners ahead of commercialisation for purposes of PPQ batches. Given the timeline for local NRA approval and subsequent WHO prequalification the cost

of these batches is unlikely to be recovered through sale. Hence per project, vaccine tech transfer costs of $5-7m is estimated.

- Capex costs (parts/change parts), regulatory costs per technology transfer need to occur before commercialisation
- There is also a gap in terms of grant funding or any innovative financial mechanism to support the high risk high cost associated with research and development on the continent. Whilst the continent has the disease burden, its researchers and scientists are faced with limited funding. We risk a post AVMA scenario where the continent is still reliant on the global north for development and assets remain owned and controlled outside of the continent. Supporting development projects also helps to create healthy markets by doing end to end projects for new antigens on the continent.

Our ask is thus that this **$200m be used to create an innovative funding mechanism** and or other solutions to achieve progress in terms of below

1. Support initiatives that create demand certainty
2. Support key local NRAs to resource capacity & capability development and support WHO with resources to provide dedicated support to accelerating review timelines of African Vx submissions
3. provide low cost working capital funding,
4. support African research/development projects,

Further, such additional funds could also be considered to assist with pandemic emergency response capacity reservation.

AVMI looks forward to continuing it's collaboration with GAVI to ensure a well functioning AVMA which achieves it's stated objectives and supports long term health equity and security through sustainable vaccine manufacturing on the continent.

<u>Further considerations and calls for support:</u>

AVMI considers the AVMA as a key lever for driving sustainable vaccine manufacturing on the African continent. It is however critical that African Union member states commit to preferential procurement of WHO prequalified African manufactured vaccines – this is the key success factor in ensuring sustainable manufacturing facilities and lower costs in the longer term. To this end,

- We call on African Union member states to robustly support African vaccine manufacturers and to work with industry to understand how this can work for each country in balancing sovereign strategic objectives with the support for African vaccine manufacturers
- We call on GAVI, it's donors and all key stakeholders to support this ask and the work of Africa CDC and to engage in these discussions with African member states to understand what support they need to commit to procuring African manufactured vaccines.

- We call on GAVI and UNICEF to provide mechanisms which facilitate preferential selection of WHO Prequalified vaccines by GAVI supported countries
- We call on UNICEF to commit to procuring targeted volumes of vaccines, at least 30% of required volumes, from African vaccine manufacturers where the vaccines are available and are WHO prequalified

We further call on development partners and global organisations to select African manufacturing partners for development projects. These investments and partnerships are required from development, drug substance to fill finish and commercialisation to ensure that we create healthy markets for diseases with vaccines such as TB, where Africa bears the burden of disease, has the scientists, researchers and the capacities and capabilities for end to end manufacture. These decisions are critical to ensuring that the continent can be self-sufficient, and that ultimately we break the cycle of dependency through continental health security. It is more importantly critical to ensure global health equity.

We will continue our deep working relationships with the African Union and Africa CDC as well as engaging with global donors and stakeholders such as UNICEF, GAVI, and the Regionalised Vaccine Manufacturing Collaborative (RVMC) towards achieving sustainable vaccine manufacturing on the African continent. We again request that GAVI allows representation of African vaccine manufacturers through AVMI representation on the various committees and the Board, similar to that afforded to IFPMA and DCVMN.