

Innovation Council Member Q&A: The African Manufacturing Vaccine Initiative (AVMI) In March 2023, Innovation Council sat down with Patrick Tippoo, a founding member of the African Vaccine Manufacturing Initiative (AVMI).

Tell us about AVMI and its mission.

Our mission is to advocate for manufacturing capacity and development for vaccines on the continent. We are a not-for-profit organisation legally registered in South Africa. Our membership base comes from all parts of Africa. We have two categories of members: individual members, and companies and institutions. Individual members don't pay a membership fee, as they are expected to voluntarily contribute in terms of their personal expertise and experience towards the mission of AVMI. The manufacturing members are expected to pay a membership fee.

We have a Secretariat in Cape Town which I lead as the Executive Director. It is a voluntary, non-remunerated position which Biovac very generously allows me to allocate some of my time to. The Secretariat and Executive Director are accountable to a Board.

What are the challenges faced by vaccine manufacturers in Africa, and how does AVMI help to address them?

We draw attention to key issues and challenges. We also engage to support new initiatives on the continent and elsewhere. Over time we have been invited to more and more conversations around the globe, to share the experiences and insights of our members.

Today we are the voice of the industry in Africa. We work to elevate some of the specific issues confronting African vaccine manufacturers. A recent publication was published by the Boston Consulting Group, with funding from the Wellcome Trust, as part of a collaboration between Biovac and the Wellcome Trust. It looked at scaling up vaccine manufacturing on the continent, from a manufacturer's perspective. There have been many opinions published about what needs to happen in Africa concerning

2

vaccine manufacturing, but the vaccine manufacturers have not always been front and center in that conversation. This analysis is an important contribution given that, ultimately, it is this group that must make it happen. Everyone else can help to put the right enabling environment in place, but it's the producers that will ultimately demonstrate that it can be done.

What is AVMI's priority at this time?

Our priority has always been to draw attention to the need to build vaccine capacity on the African continent. The key priority is to ensure that vaccine procurement for Africa is restructured to support sustainable vaccine manufacturing in Africa. Without guaranteed access to the African market investments, time, effort, and finance in builiding capacity would be wasted. The market is a critical factor in ensuring continuity of operations and sustainability.

I would say there are three additional aspects to our work.

The first is general advocacy around vaccine production and development. The Covid pandemic changed the game completely. We are very encouraged by the efforts of the African Centres for Disease Control and Prevention (CDC) in forming the Partnership for African Vaccine Manufacturing (PAVM). We have been involved with the PAVM through our involvement in the work streams that generated the Framework for Action. The Framework presents key findings about the current vaccine manufacturing environment in Africa and has identified 8 bold programs required to enable vaccine manufacturing on the continent. AVMI has been appointed as the lead for bold program 4 in the Framework for Action. Our work will focus on technology transfer and IP through the establishment of a technology transfer and IP enablement unit..

A second aspect of our work is focused on workforce development, and the third aspect is about carrying the industry voice in Africa, as proposed and supported by an increasing number of African vaccine manufacturers. In this regard, AVMI can continue to provide a powerful voice for the industry in Africa, in addition to being an

interlocutor for African manufacturers seeking to enter into multilateral policy discussions.

Is the notion that there isn't widespread vaccine manufacturing and R&D capacity in Africa a misconception?

When you look at that landscape pre-Covid, you could only find manufacturers in a few countries such as South Africa, Senegal, Tunisia, Egypt, and Nigeria. With Covid and the attention drawn to the need to bolster vaccine manufacturing across the continent, we've seen a lot of new players. We have two new entities in Ghana who came forward, plus new entities in Morocco, several more in Egypt, manufacturers in Ethiopia, Kenya, Rwanda, and two more in South Africa.

How does AVMI contribute to better vaccine availability?

Our contribution to better vaccine availability is tied to our efforts to expand the number of vaccine manufacturing operations in Africa, for routine vaccines as well as pandemic vaccines. We do have great African examples of vaccine manufacturing successes among our members. Examples include Biovac and Aspen in South Africa. Afrigen is another example; this company is working with the WHO to develop and disseminate mRNA vaccine technology through the mRNA Technology Hub. There's also the Pasteur Institute in Dakar which has been producing yellow fever vaccine for many years. This is the only WHO pre-qualified vaccine that comes out of the continent.

What do you think must be addressed as a priority to advance biomanufacturing and R&D in Africa?

We need to have a market that is organised to support local production. With that in place, the rest will follow. For example, Biovac was established in 2003 and we struggled through the first few years, trying to build and draw attention to ourselves. Around 2012, Sanofi won a vaccine supply tender for Prevnar 13 for South Africa.

The Government of South Africa then approached Sanofi with a proposition to extend the tender period from 2 to 5 years if they would be willing to transfer part of their manufacturing process to Biovac. Based on that proposition, Sanofi agreed to a technology transfer program with Biovac. It was a win-win situation. This is what I mean when I say the market needs to be there. If you offer a foreign technology transfer partner preferred access to the market, it incentivises partnerships.

A country like South Africa can decide to do this because it pays for its own vaccines, but not all countries can do this. Around 40 of the 54 countries in Africa depend entirely or partially on GAVI for the supply of their vaccines. GAVI subsidises or covers the price of the vaccines, which are then provided via UNICEF. 60 percent of GAVI's vaccine volume goes to the African market. However, the current GAVI model does not incentivise the sustainability of vaccine manufacturing on the continent from African suppliers. Gavi is working on a new model to incentivise local vaccine manufacturing in Africa which will encourage foreign suppliers to partner with African producers.

How can we address the higher cost of vaccines that will come from shifting to manufacturing locally in Africa?

It will be more expensive initially to shift to local production as companies will need to ramp up their volumes over time to achieve the necessary economies of scale. We will also need to grow our manufacturing experience base to build production efficiencies to get to a cost of goods that is as possible. This will take time. A mechanism therefore needs to be created which includes a defined window within which a premium is paid for locally produced vaccines. This will rely on support from GAVI, the AU, and/or others to provide funding to finance a premium for local procurement and to support the creation of the new approach for vaccine supply.

Do you have constraints in some of your funding partnerships on how you manage your IP?

There seems to be a consistent approach to this. We share the IP, but one has full rights to utilise the IP. However, the funder has the right to share the IP with third parties should we decide not to progress it.

What comparative advantages exist for making vaccines and other biologics in Africa?

If we manage to create the necessary momentum - and I am very optimistic that it can be done - then the cost base in Africa could be a little bit lower because of what the salaries are compared to Europe and elsewhere. However, this needs to be examined in real case studies because these are highly skilled people and we need to pay competitively. If we don't, they can easily move to richer countries to get a job.

The good news is that is no other region that has the type of coordinated approach that Africa has embarked on in the area of vaccine manufacturing. There is a lot of attention from governments, funding partners, and global tech transfer partners to see what is happening and what lessons can be learned, and to have a strategy for building manufacturing expertise on the continent. This is a real advantage.

What types of government initiatives can help to increase capacity?

High-level political support is very important. Countries like Rwanda, South Africa, and Senegal are prioritising the creation of manufacturing capacity. The ideal combination is government support plus partnerships. Policy certainty in support of local vaccine manufacture cannot be over-emphasised. To provide one example, the Institut Pasteur de Dakar has an expansion program for yellow fever that predated Covid, including expansion into new product development. The country is fully committed to enhancing its manufacturing capacity, and it has a good enabling policy environment. They have plans and projects for further bio-infrastructure development, and the Bill & Melinda Gates Foundation is investing in this. The Institut Pasteur is well-placed to get funded because it is a non-profit organisation of public utility.

How can we ensure the workforce is trained for biologics manufacturing? Does the WHO training center in Korea provide a model?

There is certainly value in having access to that type of training facility (the WHO-Korea collaboration). However, it is not cheap to establish this type of center, to develop these programs, and then to get the people in place to teach these programs. There's a need for a combination of programs. Also, you need to set up facilities closer to home.

For example, at Biovac we have accessed these types of centralised training facilities, and we have also focused on on-the-job training. We had internships where people come to work with Biovac and train at our facility. Often, after this training, we will employ them.

I believe we should push to establish apprenticeship programs. Big projects provide a very good apprenticeship opportunity. During multi-year projects, you could get additional people to work on those projects from start to finish, they could learn by doing and being exposed to all steps from product to process development, to scale up, to clinical trials, all the way through. At the end of 3-4 four years, or however long, you have skilled and experienced people.

What are your thoughts about the future of vaccine and biologics manufacturing in Africa?

I believe that the future will definitely be better than the past. I have a very optimistic view, and I believe that things are getting better over time. There has been good traction in terms of announcements and expansions. There have also been other initiatives with concrete plans to advance capacity.

I think it's important for us to create a space where there's collaboration, competition, and the sharing of innovation. Where there's also a fair amount of competition that takes place because that brings efficiency into the equation.

We've never been better placed to make a success of it. We need to build sufficient momentum to make sure this continues even when the interest is redirected to other priorities in the coming months and years.

Critically important will be continued real support from African governments and other procurement agencies for local manufacture through guaranteed access to markets (advanced market commitments).

Click <u>here</u> for more information about AVMI. To learn more about Innovation Council, please visit our <u>website</u> or contact Jennifer Brant at jbrant@innovationcouncil.org.

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