INNOVATION COUNCIL

# Spotlight on South Africa:
## 10 Questions for Biovac's Patrick Tippoo

Innovation Council sat down with Patrick Tippoo, the Head of Science and Innovation at The Biovac Institute in South Africa to learn more about its activities and innovations. Established in 2003 in Cape Town, Biovac was created to distribute, manufacture, and develop vaccines and biologics for Southern Africa. Patrick, who has been with Biovac since its establishment, has more than 30 years in the industry.

## 1 How did Biovac get its start?

Biovac was established in 2003 by the South African government in partnership with a South African based private sector consortium with the strategic objective of rebuilding vaccine development and manufacturing in South Africa to supply vaccines to South Africa and into export markets in Africa and beyond.

## 2 What was the moment when you knew Biovac was on track for a successful future?

I don't think it's possible to identify a single moment. Looking back, there's been a series of events and achievements (amidst ever present challenges) over time which provided growing confidence that we were on the right track. We developed a technology package for a Haemophilus Influenza b (Hib) conjugate vaccine which we ended up transferring to 3 partners, one in the US and two in the Asia. One of these companies went on to achieve WHO Pre-Qualification for a product containing Hib manufactured using Biovac's technology. Leveraging the conjugation technology platform capability further, we initiated work on the development on a novel multivalent Group B Streptococcus conjugate vaccine. We've concluded the proof-of-concept testing in animals and once funding is secured will proceed with clinical testing in a Phase 1 clinical trial.

Then there were the technology transfers with Sanofi and Pfizer for their blockbuster products, Hexaxim and Prevnar vaccines respectively. Securing licensing from the South African Health Products Regulatory Agency allowed us to initiate commercial manufacture (fill/finish in vials) of Hexaxim in 2020. If all goes according to plan, we will be licensed by SAHPRA to start commercial production of Prevnar in pre-filled syringes later in 2021.

In parallel significant investments of time, effort and money have gone into infrastructure expansion and skills development. We started off with 24 staff and now have over 330 staff across the different skill sets required for vaccine development, manufacture and distribution.

## 3 Name a few key factors behind the organization's success to date.

Following a reverse integration approach to building capacity when access to capital was difficult and government creating an enabling environment to incentivize the technology transfer partnerships with the two multinational companies. Another factor worth highlighting is the focus on building vaccine R&D capacity since day 1 and deciding to develop the Hib conjugate vaccine technology which brought attention to Biovac from global stakeholders. Furthermore, Biovac's progress and achievements have been intrinsically linked to the multiple partnerships which we've secured with technology transfer partners, funders, universities, product development partners, both locally in SA and abroad.

## 4 What is the role of innovation at Biovac – past, present, future?

Innovation plays a big part at Biovac. The back story to developing the Hib conjugate vaccine technology is an example of this. In the early days of Biovac we were working on the formulation of a liquid stable pentavelnt vaccine (DTP-HepB-Hib) and managed to secure D, T, P and HepB through collaborative partnerships but could not find a source of Hib. We decided to take the risk at the time to develop the technology ourselves. As described above it ended up a success and allowed us to establish conjugate vaccine platform technology capability which we further exploited to work on the development of a novel GBS conjugate vaccine. We are currently working on expanding our technology know-how into adenoviral vectored vaccines and are developing plans to build mRNA technology capability at Biovac.

## 5 Does collaboration matter for Biovac's work?

Absolutely! Without the multiple and varied partnerships over time we would not have progressed and achieved what we have today. There is no doubt that this has been a critical success factor for Biovac, the ability to attract and establish collaborative partnerships on many different levels.

## 6 What about government policies: What kind of support has facilitated your R&D and production activities?

One of the key policies has been the preferred supplier status given to Biovac during the first 15 years of Biovac's existence. This has allowed us to generate income from the start. Albeit it very modest, Biovac could reinvest some of the revenue generated through vaccine procurement and distribution into building capability. It also allowed us to leverage debt funding which we used to invest in new infrastructure and skills development. Initially Biovac secured seed funding for vaccine product development projects from government created agencies like the Innovation Fund and the Technology Innovation Agency in SA.

## 7 What more do organizations like Biovac need from governments in order to thrive?

Demand certainty and access to markets are vital, not only national markets but African governments should work together to create regional or pooled markets and guarantee purchase of locally produced vaccines. This will ensure that sustainable manufacturing capacity can be established. In addition, governments need to be aware that initially locally produce vaccines will not necessarily be cheaper than imported vaccines until economies of scale can be achieved. This is

a relatively small cost to pay for ensuring timeous access to vaccines in emergency situations and breaking the dependency on external supply sources. This is critical. Governments should also create streamlined regulatory processes allowing for agile responses to accrediting vaccine manufacturing facilities and licensing product to ensure that vaccines can be available in the fastest time possible. This is important both to ensure that commercial operations can be initiated sooner to achieve financial sustainability as well as getting product to where it is needed as quickly as possible to avoid unnecessary deaths and hospitalizations.

Another essential contribution required from governments would be for them to mobilize resources and/or create enabling environments for resources to be unlocked and mobilized as vaccine production is capital intensive and requires access to innovative funding streams over 10-20 years.

## 8 Would a possible patent waiver for the Covid-19 vaccines have relevance for vaccine manufacturing on the continent?

The latest effort by SA and India, and recently endorsed by the US government of waiving IP related to covid-19 products is welcomed. We hope that this will enable accelerated access to products such as vaccines in emergency/pandemic situations. It is equally important for developers and manufacturers to share manufacturing know-how through technology transfers and other mechanisms to maximise opportunities to increase manufacturing capacity of successful vaccines in pandemic situations. In addition, huge investments in manufacturing capacity are required, for large scale production facilities and skills development.

## 9 What is Biovac's role in ensuring availability of Covid vaccines? What are the opportunities and challenges related to producing them?

Biovac is very active in assisting the SA DoH with vaccine storage and distribution and working with external developers to facilitate having their Covid-19 vaccine candidates tested in clinical trials in SA. Plans are in place for capacities in our current facilities to be optimized so that should a technology partnership be secured we could manufacture (fill/finish) around 25 million doses p.a. As you will appreciate, these are modest volumes, so we are working on securing investments in new large scale facilities which can produce in excess of 100m doses p.a. However, this cannot materialize overnight. It requires investments of 150-250 USD and will take 3-4 years to build and be ready to produce vaccines. This is obviously not going to have an immediate impact on access to Covid-19 vaccines for African countries, but it is essential that we move on this as soon as possible to ensure that we are better prepared in future.

Securing technology transfer partnerships to accelerate ability to produce vaccines at commercial scale would be key.

## 10 You also chair the AVMI. What can governments do to accelerate the establishment and scaling up of vaccines manufacturing in Africa?

**I think many of these points have been covered above, but in summary:**

I. Establish a long-term vision which integrates national (health) security and regional health security.

II. Commit time, effort and money to the realization of the vision and work together to achieve it within countries and across countries.

III. Create an enabling ecosystem:

a. Provide guarantees to purchase locally made vaccines. By local this can include pooled procurement by African governments from African vaccine manufacturers.
b. Create and provide access to vaccine markets.
c. Redesign vaccine procurement processes to incentivize local vaccine production capacities.
d. Incentivize technology transfer partnerships and financial investments in vaccine manufacturing capacity.
e. Streamline administrative and oversight processes e.g import/export permits, champion more responsive engagements from regulatory authorities to accelerate delivery timelines.
f. Facilitate the mobilization of national resources.

IV. In addition to building governments should also implement plans to sustaining vaccine development and manufacturing capacities.

## 11 What are the most important lessons learned so far? What message do you have for early-stage vaccine and biologics manufacturers elsewhere?

It is more difficult than you imagine, it takes longer than anticipated and costs more than you think.

I. Manufacturers therefore need to begin with the end in sight and be prepared for a marathon rather than 100m dash.

II. An integrated approach is essential, working on multiple fronts simultaneously.

III. Following a backward integration approach along the vaccine manufacturing value chain should be considered. It allows skills and quality systems development to occur in a manageable way especially with respect to capital requirements.

IV. Ensure that you build a track record for potential partners and stakeholders which generates confidence and trust. This is important if one intends to secure technology transfer partnerships.

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