Scaling Up African Vaccine Manufacturing Capacity

Perspectives from the African vaccine-manufacturing industry on the challenges and the need for support

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About Wellcome

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About Biovac

Biovac is a biopharmaceutical company based in Cape Town, South Africa, that is the result of a partnership formed with the South African government in 2003 to establish local vaccine-manufacturing capability to provide vaccines for national health management and security. Biovac's vision is to establish a sustainable, world-class, international African vaccine-manufacturing capability by helping to protect life through the development, manufacture, and supply of much-needed vaccines and other biologicals.

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I. Acknowledgements

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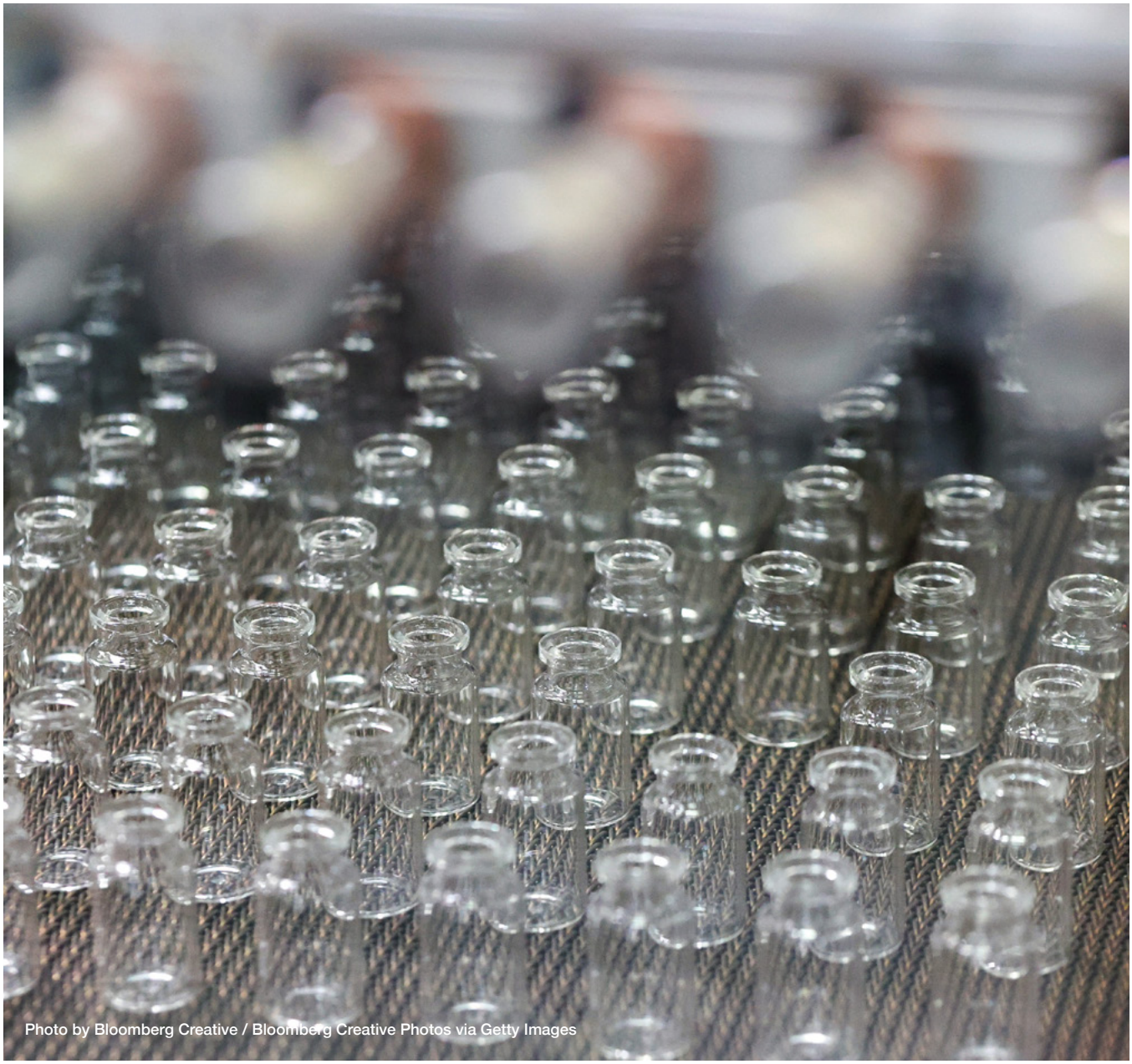

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II. Executive Summary

The Covid-19 pandemic served as a wake-up call for many global health organisations and policy-makers. It alerted them to the **compelling need for expanding vaccine-manufacturing capacity and capabilities across the African continent,** in order to strengthen pandemic preparedness, to improve vaccine-supply security, and to better tackle endemic diseases. To meet these challenges, the vast majority of stakeholders – at national, continental, and global level – appreciate the value of the ambitious target defined by the Partnerships for African Vaccine Manufacturing Framework For Action (PAVM FFA): 60% of Africa's vaccine demand to be supplied by Africa's own vaccine-manufacturing industry by 2040.

The African vaccine-manufacturing industry today is still in its very early stages. It supplies less than 1% of the continental market. But it does have some capabilities and experience, which are ready to leverage. There are thirteen operational vaccine companies and organisations across Africa. Ten have developed Fill & Finish (F&F) capacity, five have demonstrated Drug Substance (DS) capabilities, and three conduct Research & Development (R&D).

The PAVM FFA has put forward one vision of the African vaccine-manufacturing ecosystem – by 2040 in their assessment, the continent could feature 23 manufacturing facilities, including 12 end-to-end facilities and 11 F&F-only facilities, supplying 22 priority products. How this ecosystem will actually evolve remains to be seen, though the initial steps on this journey have already begun.

The past 18 months have produced **many promising announcements and initiatives**. The PAVM FFA is praised for defining a continental strategy. Gavi, the Vaccine Alliance, is reviewing its market-shaping approach to further diversify its supplier base, particularly in Africa. Many manufacturing projects have been announced (30 projects in 14 countries),[1] and promising partnerships have been signed between African manufacturers and Multinational Corporations (MNCs) or Developing Country Vaccine Manufacturers (DCVMs). Finally, more than $4 billion has been committed by private and public organisations.

Manufacturers stress that **economic viability still needs to be demonstrated, and is crucial to the success of this strategy**. The business case for vaccine manufacturing in Africa is certainly not straightforward, as African companies will struggle to be competitive. On top of large investment costs, the manufacturers will also incur higher cost of goods sold (COGS) and higher operating costs (labour, repairs, utilities) than established DCVMs. As the manufacturers scale up, continuous innovations in the vaccine-manufacturing space should improve economics, but that will happen in the long term at best.

To improve economic viability, a few success factors should be considered. First, large-scale facilities (about 50 million vials capacity per year) need to be prioritised, as smaller-scale F&F facilities are unviable without substantial subsidies. Second, manufacturers will need to export their products beyond their borders, as national or regional markets are undersized. Third, locally manufactured vaccines will have to compete with the low-price vaccines from DCVMs, so a mechanism will be needed to subsidise a portion of the extra costs.

African manufacturers identify **three major risks to the desired economic viability:**

- **Sustainability risk:** The historical dynamic, described by Gavi as the "high-price and low-volume trap", persists, and concrete measures are required to change it. Meanwhile, manufacturing initiatives remain uncoordinated, creating a risk of overcapacity (current and announced F&F capacity is more than 60% above 2040 PAVM targets).
- **Strategic risk:** Current strategy and set of possible initiatives are fairly broad, and manufacturers need further prioritisation (products, technology platforms) to guide their efforts and investments in the short- and mid-term.
- **Support risk:** As the Covid-19 pandemic recedes, the attention and efforts currently being offered by national, continental, and global stakeholders could recede as well.

There are several prerequisites to creating conditions for a sustainable ecosystem for African vaccine manufacturers:

1. Governments need to support manufacturers. One key enabler for manufacturers to access funding and secure technology transfers would be **Advance Purchase Agreements**. African countries procuring through Gavi are also expected to prioritise African supply.

2. A **review of the procurement mechanisms** is needed – one that would facilitate market access and offer predictable demand. Manufacturers' suggestions include: the introduction by Gavi of a minimum share of African supply and/or the introduction of a continental pooling arrangement.

3. Clarity is needed on the **financial mechanism to counterbalance the lack of price-competitiveness** (funding of the investments and/or operations, agreements to pay a price premium per dose, etc.) and on the source of such funding (governments and/or donors).

4. A coordination mechanism should be defined and launched – potentially through PAVM or other continental organisations – to **improve information-sharing** between stakeholders, and thereby help manufacturers to make business decisions, and help donors to identify where to direct their support.

African manufacturers should focus on strategic and realistic priorities to initiate change. They need to prioritise **supply-constrained products with less complex end-to-end manufacturing processes** (six short- to mid-term priority products have been identified), and to start building F&F capabilities for more complex products. R&D efforts should concentrate in the short term on improving existing products, and thereby build capabilities across platforms. Manufacturers could also consider producing biological products aside from human vaccines; that could utilise part of the capacity of their facilities to improve the economic viability.

Donors must provide manufacturers with sufficient and sustained support, specifically for meeting the three main challenges beyond the market-access prerequisites:

- **Access to finance:** Offer tailored and low-cost funding with longer payback periods.
- **Talent:** Support African manufacturers to gain practical experience by funding secondments with experienced manufacturers, and by bringing global experts to work on manufacturing sites.
- **Technology transfers:** Collaborate with African manufacturers and partners on technology transfer to support capacity building, before the manufacturers attract potential private partnerships.

African vaccine manufacturers want and deserve support to overcome their existing challenges. There is an imperative for global health stakeholders, in particular donors, to recognize the economic and operational reality of the African manufacturers, who have such a crucial role in attaining the public-health objectives. Immediate changes are essential – changes to the current procurement, financial, and coordination mechanisms. As other changes will take time, the mechanisms will also need regular revisiting and adaptation, taking into consideration the global demand-supply dynamics.

The mood among stakeholders is one of optimism – that the current and forthcoming efforts will succeed in scaling up Africa's vaccine-manufacturing capacity.

III. Context and objectives

Low- and middle-income countries (LMICs) face various challenges in accessing vaccines, including a heavy dependence on external supply chains. Those supply chains, particularly in Africa, are subject to gaps and vulnerabilities, as the Covid-19 pandemic has dramatically reminded us. Despite unprecedented global and continental mobilisation – notably through Covid-19 Vaccines Global Access (COVAX) and the Africa Vaccine Acquisition Task Team (AVATT) – early access to Covid-19 vaccines was seriously inadequate. In May 2021, while high-income countries (HICs) had administered 60 doses/100p, LMICs had administered just 0.8 doses/100p.[2]

Being dependent on external supply chains means that Africa will always risk being last in line for vital supplies. This alarming shortfall served as a wake-up call and prompted renewed efforts to build vaccine-manufacturing capacity and capabilities in Africa. African leaders, continental organisations, and global institutions all helped to steer the African vaccine-manufacturing agenda.

In 2021, the African Union (AU) and Africa Centres for Disease Control and Prevention (Africa CDC) established PAVM. In March 2022, PAVM detailed a continental strategy in a Framework for Action, with a bold goal: by 2040, the African vaccine-manufacturing industry would develop, produce, and supply over 60% of the continent's total vaccine doses – from a base of less than 1% today. The framework outlined eight ambitious programmes to help reach the goal.[3]

This report seeks to provide an actionable synthesis of African manufacturers' perspectives on the challenges to scaling up vaccine-manufacturing capacity and capabilities, and the areas where manufacturers most need support. This report lays out priority support in the short-term (by 2025), in the mid-term (by 2030) and in the long-term (by 2040).

The motivation for this report stems both from the public-health imperative and the economic-equity needs that can be addressed by improving the vaccine manufacturing ecosystem in Africa. This work used the PAVM FFA as a starting point for the assessment. The aim of this report is to extend and complement all the excellent efforts of the various stakeholders supporting the future of the African vaccine manufacturing ecosystem.

This summary provides a guide for public-health initiatives and investment decisions, while recognising that each manufacturer has its own needs and areas of focus.

The manufacturers' views shared in this report are not meant to steer the full set of activities and initiatives to support the African vaccine manufacturing ecosystem. The ecosystem involves other aspects, notably regulatory and R&D, and these aspects obviously have to be considered too.

Photo by Neznam via iStock

IV. Methodology

This report was commissioned by the Wellcome Trust and Biovac, and completed by Boston Consulting Group.

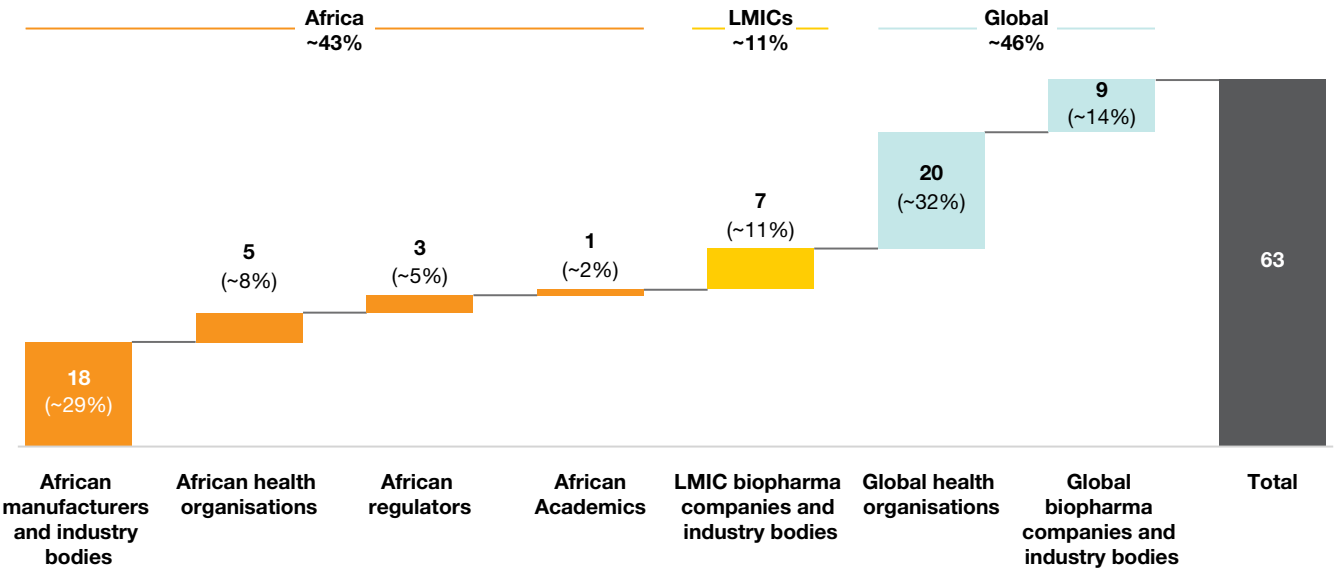
The report explicitly focuses on the manufacturers' point of view in order to synthesise and articulate their priorities. It reviews how support initiatives – globally and in Africa – have worked in the past, and hence suggests ways of scoping priority future initiatives. This manufacturer perspective has then been complemented with insights from global and continental experts.

The compilers of the report followed a rigorous process of information- and perspective-gathering, from a diverse pool of stakeholders and a wide-ranging knowledge base:

An extensive review of published and grey literature, involving **50+ publications**, to establish the lessons learned from historical projects; the list of relevant literature can be found in Appendix C.

Interviews with 60+ stakeholders from a variety of backgrounds and expertise, including continental and global manufacturers, biopharma companies, industry bodies, health organisations, regulators, and academics.

Figure 1: Diversity of interviewed profiles



Source: BCG interviews

Four focus groups, convened in order to refine emerging themes, with participation from a diverse set of stakeholders (manufacturers, regulators, health organisations, academics), in order to pressure-test and refine emerging findings.

A quantitative and qualitative survey conducted among African vaccine manufacturers (nine respondents) to assess barriers and priority support areas.

Desk research and multiple analyses to validate emerging themes, bringing in relevant data to assess the merits of emerging hypotheses.

The development of a theoretical financial model to assess the financial viability of various manufacturing models in the African context.

The findings from this comprehensive research form the substance of this report.

V. Key findings

1. A long journey ahead to develop the African vaccine manufacturing industry

The Covid-19 pandemic provided a sharp reminder of the need for building vaccine-manufacturing capacity and capabilities across the African continent. Previous crises have shown the dangers of Africa's over-reliance on external supply chains, and the Covid crisis has now created an unprecedented momentum to do something about it, and to realise the long-held vision of moving towards greater independence in vaccine-manufacturing.

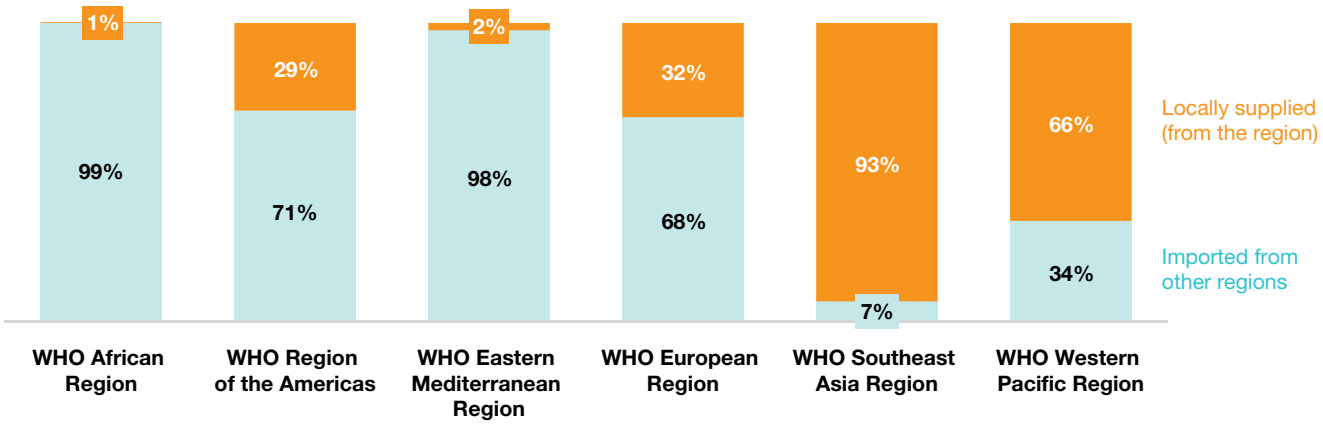
African and global stakeholders alike recognise how crucial it is to scale up African vaccine-manufacturing capacity. An extensive vaccine-manufacturing industry within Africa would improve vaccine-supply security, help to better tackle endemic diseases, and contribute to global pandemic preparedness, while also boosting the continent's socio-economic development.

Accordingly, the target set by the PAVM FFA – 60% of Africa's vaccine demand to be met by Africa's own vaccine-manufacturing industry by 2040 – is rightly regarded as an ambitious but necessary one. And many encouraging announcements have been made in the past 18 months, in regards to funding, manufacturing partnerships, and review of the current procurement mechanism.

Africa today produces less than 1% of the vaccines it uses.[4] It is the region most dependent on imports for its vaccine supply (though in fact very few regions – even developed regions – have self-sufficiency of vaccine supply). Global manufacturing is concentrated in Southeast Asia, and the entire world is highly dependent on these supply chains. This dependence shows that global efforts have so far prioritised affordability over self-sufficiency, with a clear mission to improve global immunisation rates rather than establish supply independence.

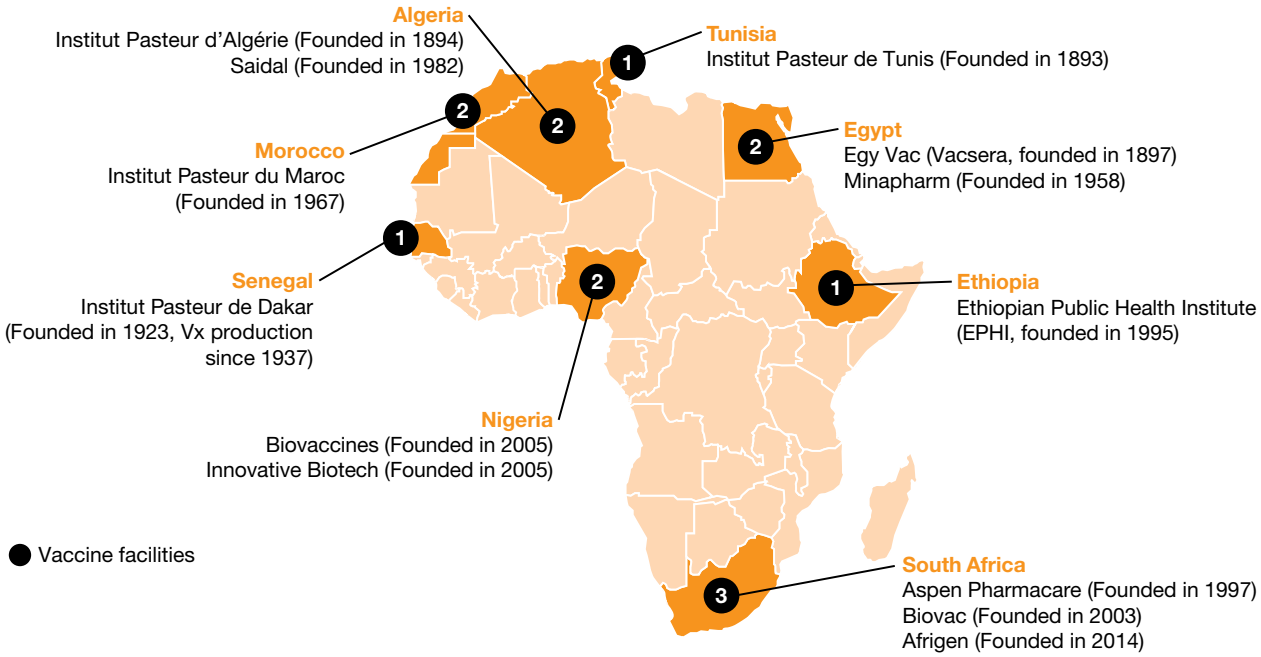
Figure 2: Share of vaccine volumes supplied locally per region

Share of vaccine volumes by manufacturer origin
Based on 2019 public vaccine purchase



Note: Based on 2019 public vaccine purchase
Source: MI4A database; BCG analysis

Figure 3: Africa's vaccine manufacturing landscape – operational stakeholders



Source: WHO; UNICEF; PATH Center For Vaccine Innovation & Access capacity mapping 2022; BCG analysis

While the African vaccine-manufacturing industry is nascent, it is not starting from zero. The continent has some modest capabilities and experience, and these are ripe for developing. In fact, numerous efforts have been underway, for several decades now, to extend vaccine-manufacturing capabilities. As of today, there are 13 vaccine companies and organisations across the continent, with competences that can be expanded, and many more projects have been announced (see Section V.4).

Ten of the manufacturers have operational F&F capacities, five have already demonstrated DS capabilities, and three companies have R&D capabilities. Jointly, the African manufacturers fill-and-finish 11 vaccines, manufacture the DS for four antigens, and leverage various technology platforms such as live-attenuated virus, inactivated virus, and messenger ribonucleic acid (mRNA). One vaccine, the yellow fever vaccine of Institut Pasteur de Dakar, is World Health Organisation (WHO) prequalified.

Figure 4: Capacity mapping – Existing capabilities per manufacturer in Africa

Manufacturer	Country	Vaccines	R&D	DS	F&F	Import for distribution
Afrigen	South Africa	Covid-19	●	●	●	
		Hepatitis B	●			
		Rift Valley Fever	●			
		TB	●			
Aspen	South Africa	Covid-19			●	
Biovac	South Africa	BCG				●
		Covid-19			●	
		GBS	●			
		Hepatitis B				●
		Hexavalent			●	
		OCV	●			
		OPV				●
		Pneumococcus			●	
		Measles				●
EPHI	Ethiopia	Rabies		●	●	
Innovative Biotech	Nigeria	Covid-19	●			
		Ebola	●			
		HIV	●			
		HPV	●			
		Yellow Fever	●			
Institut Pasteur d'Algérie	Algeria	Rabies		●	●	
Institut Pasteur de Dakar	Senegal	Yellow fever		●	●	
Institut Pasteur Morocco	Morocco	BCG				●
		Influenza				●
		Rabies				●
		Tetanus				●
		Typhoid				●
		Yellow Fever				●
Institut Pasteur Tunis	Tunisia	BCG		●	●	
Saidal	Algeria	Covid-19			●	
Vacsera	Egypt	BCG				●
		Cholera			●	
		Covid-19			●	
		DT			●	
		DTP			●	
		Hib				●
		Hepatitis A/B/A+B				●
		HPV				●
		Influenza				●
		IPV				●
		Meningitis				●
		MMR				●
		OPV				●
		Pentavalent				●
		Pneumococcal				●
		Rabies				●
		Rotavirus				●
		Tetanus			●	
		Typhoid			●	
		Varicella				●
		Yellow Fever				●

Note: Information based on Q4 2022 operations; Two existing manufacturers with operational facilities are not manufacturing vaccine as of the time that this report is being prepared (Biovaccines, Minapharm)

Source: Publicly available information; interviews; survey; BCG analysis

Note, however, that many stakeholders, and in particular African manufacturers, warn that building a sustainable vaccine-manufacturing industry will be lengthy process. As shown by the industry's development timeline in India and other LMICs, the process needs sustained engagement over several decades, with no easy shortcuts.

First, lead time for supplying manufacturing equipment can be up to 24 months for some machinery (e.g. filling line). And it then takes further time to reach Good Manufacturing Practice (GMP) standard. In most cases, it is unrealistic to expect a greenfield operational manufacturing facility to be up and running in less than three years.

Second, technology transfers themselves can take years. For one thing, it is difficult to secure partners; for another technology transfers can be highly complex, as African manufacturers, MNCs and DCVMs know all too well. When partnering with an African manufacturer, providers need not only to transfer the technology itself, but also to transfer capabilities and train the local talent. There are numerous examples of technology transfer taking up to ten years. Experienced manufacturers on the continent are well aware of this challenge, and make it a top priority to enable smooth technology transfer with reliable partners.

"Extremely long lead time needed to get where manufacturers need to be in terms of people and skills. Technology you can solve in the short term by purchasing the equipment, but having skilled scientists in those labs to operate machinery is another factor completely"

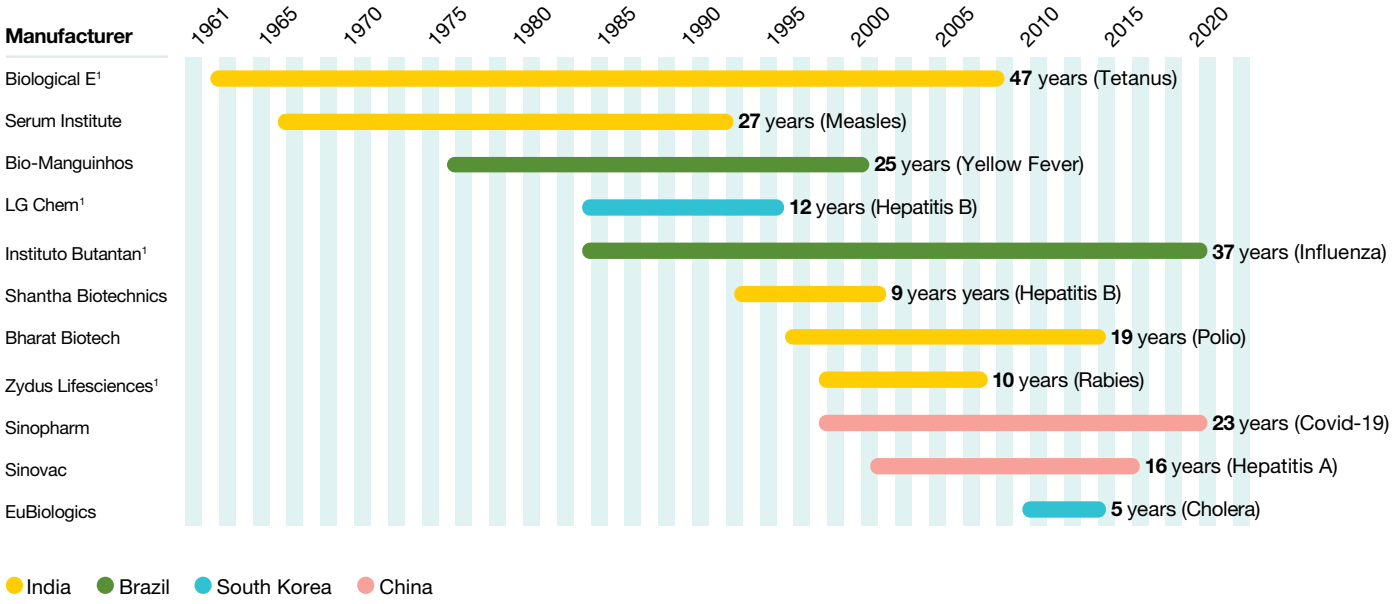
– Global biopharmaceutical company

Third – once the manufacturing site is operational, capabilities have been built, tech transfer has been completed, and the manufacturer is able to produce a vaccine – it may still take many more years before the manufacturer is allowed to export it to other markets. Indeed, to ensure safety, quality and efficacy of the products, Gavi has a policy of procuring only those vaccines that are WHO-prequalified. Typically, it takes DCVMs more than ten years (on average 20 years)[5] to secure prequalification from the time that they first started building vaccine-manufacturing capabilities.

Photo by Smederevac via iStock / Getty Images Plus

Figure 5: Time to first WHO vaccine prequalification for select DCVMs (not exhaustive)

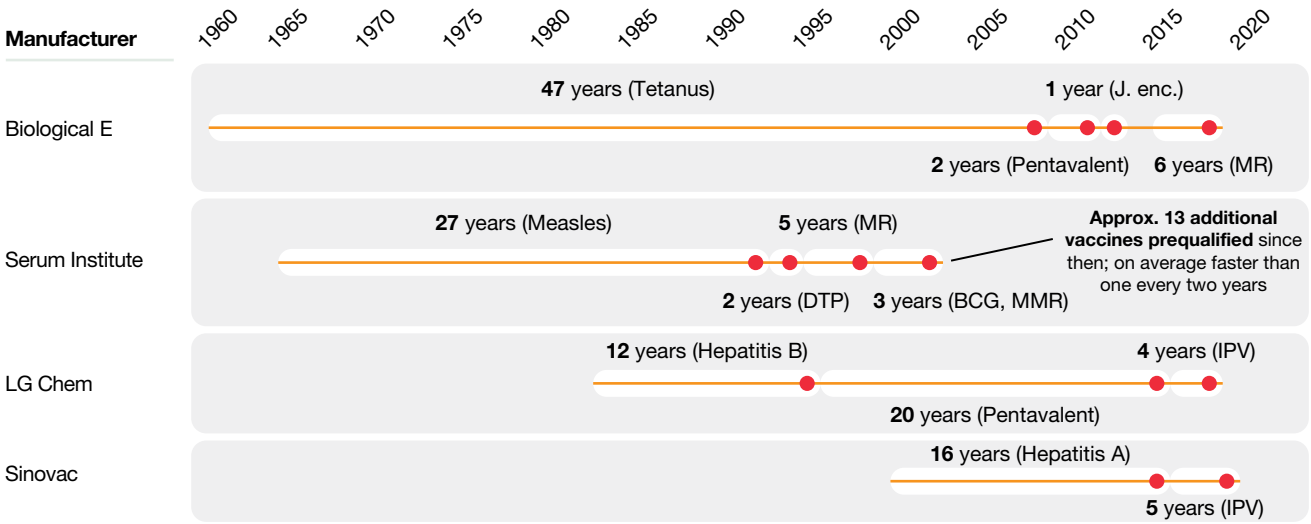
Number of years to first WHO prequalification, from start of vaccine manufacturing[1]



1. Start of vaccine manufacturing is considered to be the year in which the company was founded, with the following exceptions: Zydus Lifesciences (year it entered into JV to research human vaccines), LG Chem (year it established a biopharmaceutical division), Instituto Butantan (year a biotechnology centre was created), Biological E (year it expanded into vaccine production)

Figure 6: Time from first prequalification to additional product WHO approvals (not exhaustive)

Number of years from first WHO prequalification to further prequalified products



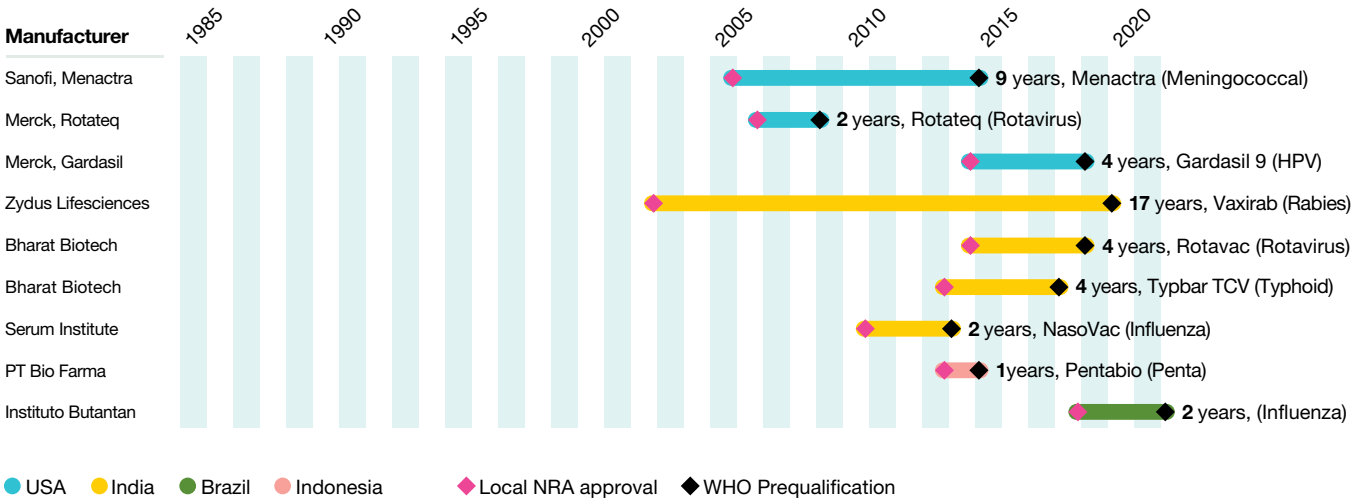
Source: Evaluate Pharma; company websites; desktop research

Once this first milestone is reached, however, growth proceeds apace. Although not all DCVMs have gone on to secure prequalification for additional products, those that have done so generally managed to do so much faster, having already been through the process and having established the necessary competences and expertise. Subsequent prequalification for vaccines takes usually just two to five years on average.

There is strong variability in the timeline from local registration to WHO prequalification. It can take up to 20 years, though several vaccines received WHO prequalification in two years or less.

Figure 7: Time from local marketing authorisation to WHO prequalification (not exhaustive)

Number of years from local NRA approval to WHO-prequalification



Source: : WHO, NRA website; company websites; desktop research

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Case study:
India's journey to becoming a vaccine powerhouse took decades

India is today a global vaccine-manufacturing powerhouse: it produces more than 50% of the world's vaccines, and is the home of some of the world's major vaccine manufacturers, such as Serum Institute of India (SII) and Bharat Biotech.

The journey to develop its world-class vaccine ecosystem has been a long one, developing over decades. It has been helped by supportive structures from government and regulatory agencies. Consider, for example, the launch of the government-run Universal Immunisation Programme, or the introduction of revised clinical-trial guidelines by the Indian Council of Medical Research.

Figure 8: Timeline of selected milestones in the Indian vaccine industry

- **1897** First plague vaccine developed in lab in Mumbai prior to establishment of Haffkine Institute in 1899
- **1905** First vaccine research institute established
- **1910s-1970s** Several vaccine institutes set up in different provinces
- **1967** Serum Institute of India starts investing in vaccines, producing tetanus antitoxin
- **1971** By this year, 19 vaccine manufacturing units in public sector and 12 in private sector
- **1985** Government-run Universal Immunisation Programme launched with OPV, BCG, DTP and Measles vaccines (no new vaccine is added until 2003)
- **1980s-1990s** Increasing number of private vaccine manufacturers enter the market (Bharat Biotech, Panacea Biotec, Shantha Biotechnic, and others)
- **1993** First WHO-prequalified vaccine from India – Measles, from Serum Institute of India
- **2006** New guidelines for clinical trials by Indian Council of Medical Research
- **2009** Three manufacturers able to rapidly develop pandemic H1N1 vaccine
- **2019** Procures 56% of global public purchases of vaccines
- **2022** By this year, over 40 WHO-prequalified vaccines[1] from multiple manufacturers (Serum Institute of India, Bharat Biotech, Biological E, Sanofi Healthcare India, etc.)

1. Paediatric and adult variations of the same vaccine counted as one vaccine; different packaging formats of the same vaccine counted as one vaccine (e.g. single-dose vial and ten-dose vial versions counted as one vaccine)

Source: "A Brief History of Vaccines & Vaccination in India", Indian Journal of Medical Research, April 2014; WHO Global Vaccine Market Report; MI4A Database; WHO Prequalified Vaccines database; desktop research

India has a large market, with a population of more than a billion. Its immunisation programme is one of the largest public-health programmes in the world, targeting an annual birth cohort of about 25 million, and offering vaccination for 12 diseases. The size of the local market has enabled the industry to invest in large-scale manufacturing capacity. Cumulatively, Indian manufacturers have installed capacity to manufacture more than eight billion vaccine doses per year.[6]

Indian manufacturers were also able to access a large pool of qualified and relatively low-cost talent that keeps manufacturing costs competitive. In addition, the government supports investments by providing access to low-cost debt options.

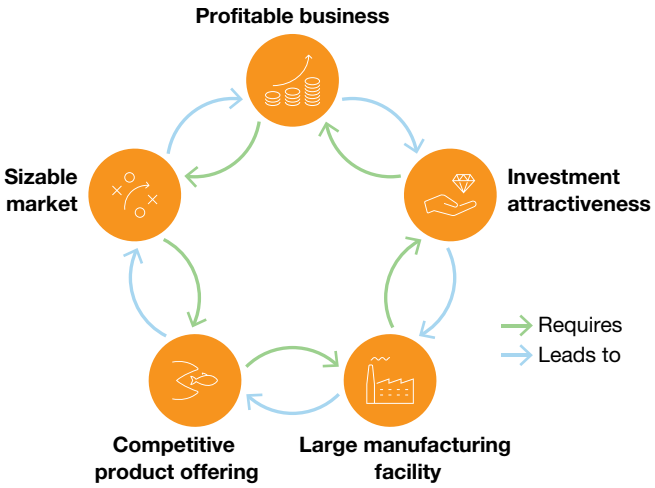
2. Economic viability still to be demonstrated

If vaccine manufacturing in Africa is to scale up, the economic model has to be a fully viable one. As the manufacturers made clear in interviews, if they could generate profits, they could then attract investment in larger facilities that can produce at scale, and that in turn would lead to lower costs and greater competitiveness, and hence a sizeable market demand. However, most of the manufacturers also made clear that they are not profitable yet. So they remain at risk of what Gavi has called "the potential high-price and low-volume trap", whereby they cannot secure the necessary funding and volumes to manufacture at scale, leading them to have even higher prices and lower volumes.[7]

From a financial perspective, the business case for vaccine manufacturing in Africa is far from straightforward, and economic viability still needs to be demonstrated. African manufacturers find themselves in a very different position from that of their counterparts in India, for example. When Indian manufacturers started scaling up capacity decades ago, the field was relatively open, whereas African manufacturers today have to contend with many manufacturers that are already price-competitive. In the short- to mid-term, African manufacturers cannot realistically expect to be cost-competitive.

Photo by Emilija Manevska / Moment via Getty Images

Figure 9: Requirements for and consequences of devising a viable business model



The manufacturing facilities will require large capital investment, and will incur higher COGS and operating costs (notably labour, repairs and utilities).

Many innovations will decrease manufacturing costs in the future, notably by decreasing the initial investment required (e.g. small-scale disposable technologies), simplifying the manufacturing process and reducing operational costs (e.g. technology platforms like mRNA), and facilitating mass manufacturing (e.g. high-density bioreactors). As the African manufacturers gain scale and as innovations in vaccine manufacturing continue, the economics are expected to improve, but at best in the longer term.

"It's important to build capabilities that consider long-term feasibility – whatever is created must be able to fund itself over time and be profitable"

- Global Development Finance Institution (DFI)

To identify the key success factors for a viable business plan for African manufacturers, we devised a financial model to assess the theoretical profitability of African vaccine manufacturing. The model calculates the net present value (NPV) of an African manufacturing facility. NPV is a method used to calculate the current value of future cash flows, and it feeds into an investor's decision-making process. A positive NPV means the rate of return of the investment is above the discount rate, and the investor should consider moving forward with the investment; a negative NPV means the investor should not make the investment. The model considers the NPV for various manufacturing options:

1. **Size of the facility:** smaller-scale (about ten million vials per year) or larger-scale (about 50 million vials per year)
2. **Value-chain step:** F&F-only or end-to-end manufacturing
3. **Vaccines manufactured:** different vaccines, each with its own market price and manufacturing complexity (based on their technology platforms)

Building a viable F&F manufacturing facility:

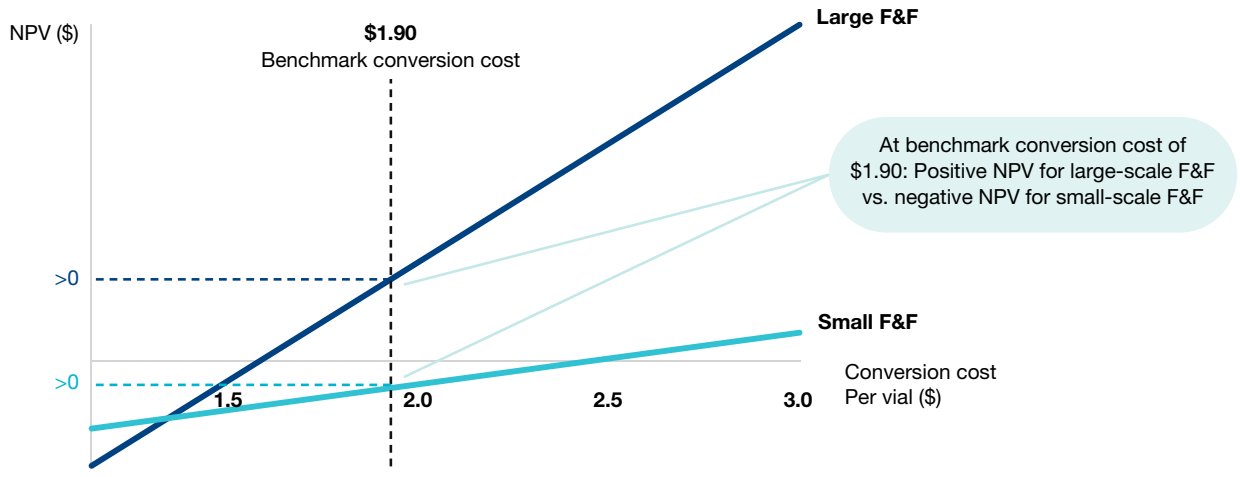
One finding is that small-scale F&F facilities are unlikely to prove a viable investment without substantial premiums and/or subsidies. Our analysis first modelled a negative NPV, indicating a non-profitable investment, at the benchmarked conversion cost per vial. In interviews, stakeholders said that they could see almost no business case for small-scale facilities. Further analysis showed that investing in small-scale facilities would make financial sense only if a premium of at least 25% per vial was paid for.

By contrast, large-scale F&F facilities can be viable investments. Our analysis modelled a positive NPV without a premium for large-scale F&F. Large-scale facilities would need to be prioritised, probably with fewer sites on the continent – 10 to 15 large-scale facilities on the continent in the longer-term - than initially specified by PAVM FFA.

For a manufacturer to break even with such a large-scale facility, however, it would have to achieve high utilisation of its manufacturing capacity (about 60%; i.e. 30 million vials per year).

If each large-scale F&F facility were to focus on manufacturing one vaccine only, that vaccine would need to capture a large share of the total African market for the facility to economically break even – about 60% of the oral cholera vaccine (OCV) market, 95% of the human papillomavirus (HPV) market, 110% of the rotavirus market, 140% of the pneumococcal market.

Figure 10: NPV of small-scale F&F vs. large-scale F&F facility based on conversion cost per vial



Source: Literature review; expert interviews; global benchmarks; BCG financial modelling

In interviews, the manufacturers themselves showed that they are aware of this reality. They realise that country-level and regional-level demand are undersized for the capacity of such large-scale facilities. A viable business model, they suggested, would be one in which manufacturers can sell their products beyond their national or regional borders and supply the broad African market. Some interviewees even said that African manufacturers could consider exports beyond the African market. Given the capacity of these large-scale facilities, there is no economic rationale in having numerous manufacturers producing the same vaccine. One or two manufacturers per product could cover the continental demand. On the other hand, F&F manufacturers should strive to maximise their capacity utilisation, and that would usually mean manufacturing more than one product (either vaccines or other biological products). Not too many, however: if their portfolio of products becomes unwieldy, that would increase changeover losses, which would then reduce utilisation – manufacturers generally consider that manufacturing three to five products is ideal.

Building a viable end-to-end manufacturing facility:

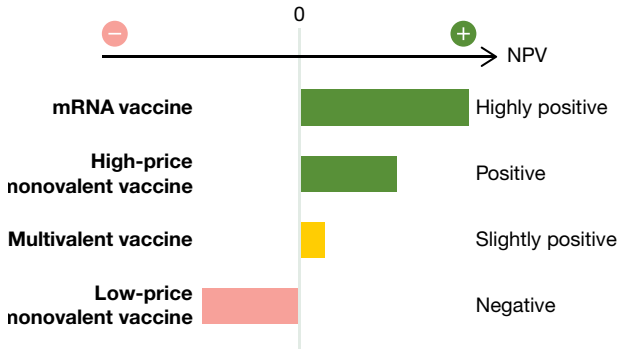
The vision is for Africa to approach self-sufficiency in vaccine production, so our analysis also had to consider the economic viability of end-to-end manufacturing. That meant factoring in additional complexities, from pathogen type to valency (monovalent or multivalent) to technology platforms. Our model concentrated on four groupings of vaccines, to represent the range of possibilities in vaccine development:

1. Low-price monovalent vaccines (e.g. Hepatitis B)
2. High-price monovalent vaccines (e.g. Rotavirus)
3. Multivalent vaccines (e.g. HPV)
4. mRNA vaccines (e.g. Covid-19)

Unsurprisingly, it turns out that the profitability of investment in end-to-end facilities varies greatly, depending on the technology platform and the vaccine complexity.

For less complex, higher-priced vaccines like rotavirus and mRNA Covid-19 vaccines, we modelled a high-positive NPV at the forecasted market price. Our finding was that for these vaccines, DS manufacturing improves the overall profitability of the facility, and can even improve the viability of small-scale F&F facilities.

Figure 11: Illustrative NPV for large-scale end-to-end manufacturing projects for four groups of vaccines



Note: NPV calculation based on forecasted 2030 price and assuming sufficient demand

Source: Literature review; expert interviews; global benchmarks; BCG analysis

On the other hand, for low-price monovalent vaccines and multivalent vaccines, end-to-end manufacturing looks less viable, at least in the short- to mid- term.

For low-price monovalent vaccines like Hepatitis B, we modelled a very large loss, since such vaccines are currently commoditised (very low market price, sufficient supply). For such vaccines, a viable business model is almost impossible, even with a high price premium.

For multivalent vaccines like HPV, we modelled a barely positive NPV. It turns out, however, that while profitability might be low in the short- to mid-term, manufacturing projects for such multivalent vaccines can still be viable – particularly if an appropriate financial mechanism is introduced.

Given the complexities described above and the narrow path to economic viability, stakeholders need to move astutely, ensuring that investments are directed only to sensible manufacturing projects, and that the right conditions are in place for manufacturers to become profitable.

3. Prerequisites for a sustainable ecosystem

One major risk identified by African manufacturers is the risk to sustainability. The optimism about Africa's vaccine-manufacturing prospects is, in the view of most manufacturers, based on little more than announcements. If the continent really is to disrupt the past dynamic and accelerate the scale-up, specific concrete measures will have to be taken.

Manufacturers have identified two particular "must-haves": better market access to establish demand certainty and predictability, and a financial mechanism to cover the price premium of African vaccine manufacturing in the mid-term.

The first of these prerequisites, **market access**, is necessary to unlock African vaccine manufacturing by creating trust. Without adequate demand for locally manufactured vaccines, investment in facilities could end up being a waste of money. Historically, technology transfers – whether in Africa or elsewhere – have been facilitated and incentivised by special market access in the host country. Many of the manufacturers in our survey mentioned Advance Purchase Agreements as a crucial enabler – to unlock growth, secure financing, and attract commercial partners for technology transfers – and hoped for stronger engagement from national governments to prioritise local supply.

"In the private sector, we are losing a bit of patience – tangible, actionable change has still to be made"

– African manufacturer

Case study:
Aspen's lack of purchase orders for the Covid-19 vaccine[8]

Context

In March 2022, Johnson & Johnson (J&J) and the South African pharmaceutical company Aspen Pharmacare concluded an agreement to fill, finish, package and distribute J&J's Covid-19 vaccine in Africa. This licensing agreement would allow Aspen to sell the product under its own brand name, up to December 2026. The arrangement proved to be short-lived, however, with Aspen halting production of the vaccine less than half a year later. In August 2022, Aspen reported that demand for the vaccine was non-existent, and the company had received zero orders for it beyond that month. Production lines – having anticipated a major ramp-up that would increase output by 1 billion doses a year to meet demand – were at risk to lay dormant if Aspen had not rapidly found a new partner in SII

Impact

The hope was that African governments and multilateral procurement mechanisms would provide support via long-term purchasing agreements. But when such support failed to materialise, and market demand proved inadequate, the promising Aspen initiative came to a premature end.

Lessons

This sorry episode, and the lack of government commitment underlying it, could well make manufacturing partners wary of dealings with Africa in the future. Of course, there is inherent risk in the vaccine industry. However, as an article in The Lancet put it, "African countries' reluctance to buy locally produced vaccines raises concerns regarding the fate of […] manufacturing initiatives in Africa" (Adepoju, 2022).[9] Following the setback, Aspen pivoted plans rapidly and found a new partner in SII, thereby minimising any wastage of capacity and trained talent.

While local Advance Purchase Agreements would certainly signal a country's commitment, they won't suffice. As mentioned, if an African manufacturing project is to be economically viable, the manufacturer has to be able to target the continental market. Currently, more than 50% of vaccines in value in Africa are procured by Gavi,[10] so a reform of Gavi's procurement mechanism could make a big difference.

"Sustainable economic viability is the primary reason many MNCs are not investing in Africa. The market is too small without at least some form of regional pooled procurement"

– African vaccine manufacturer

To date, Gavi's vaccine procurement for Africa derives less than 1% of vaccines from African manufacturers, both in volume and in value. In comparison, non-African DCVMs account for 75% of the volume and 36% of the value, and MNCs account for 24% of the volume and 64% of the value.[11] Gavi has already announced its willingness to "update the Alliance's market shaping to place a higher value on the benefits of diversification to supply security, with a focus on Africa," and is currently reviewing how to "change the way products are assessed for inclusion in the Gavi product menu" and is working to "find ways to provide more predictability around future African demand".[12]

Manufacturers, while aware of the complexity of global demand-supply dynamics[13], would welcome the introduction of a minimum share of African supply. If a vaccine is manufactured locally, then the African supply should be prioritised to some extent, even if it is not the most affordable option. The minimum share still needs to be defined, but it will have to be substantial if the PAVM FFA targets are to be reached.

"If we are committed to scale up African vaccine manufacturing in Africa, the manufacturers need a guarantee that they will be bought and preferred."

– African manufacturer

The manufacturers also raised concerns over how actionable these proposed changes would be in the short term. In particular, one of Gavi's current regulatory requirements is that a vaccine should be WHO-prequalified in order to be eligible for Gavi procurement. But as mentioned, it can take years for a manufacturer to get its first prequalified products (see section V.1). So in the short term, there seems little chance of a substantial increase of African vaccines in the Gavi supply. Manufacturers want to initiate a discussion on these requirements and processes, to ensure reasonable time-to-market. At the same time, they do acknowledge how important it is not to compromise on quality, safety, and efficacy.

The second prerequisite identified by manufacturers – a specific **financial mechanism** – would cover the price premium of African vaccine manufacturing (see section V.2). The price premium is unavoidable because African manufacturers cannot in the short- or even mid-term match the prices set by non-African DCVMs.

Manufacturers note the current lack of clarity on such a financial mechanism. The mechanism remains undefined, though stakeholders have identified a range of options – whether funding the manufacturing investments, or subsidising manufacturers' operations, or simply agreeing to pay a higher price per dose. In its latest paper, Gavi said they are exploring the options for "*a targeted and time-limited financial instrument*" such as an Advance Market Commitment mechanism[14].

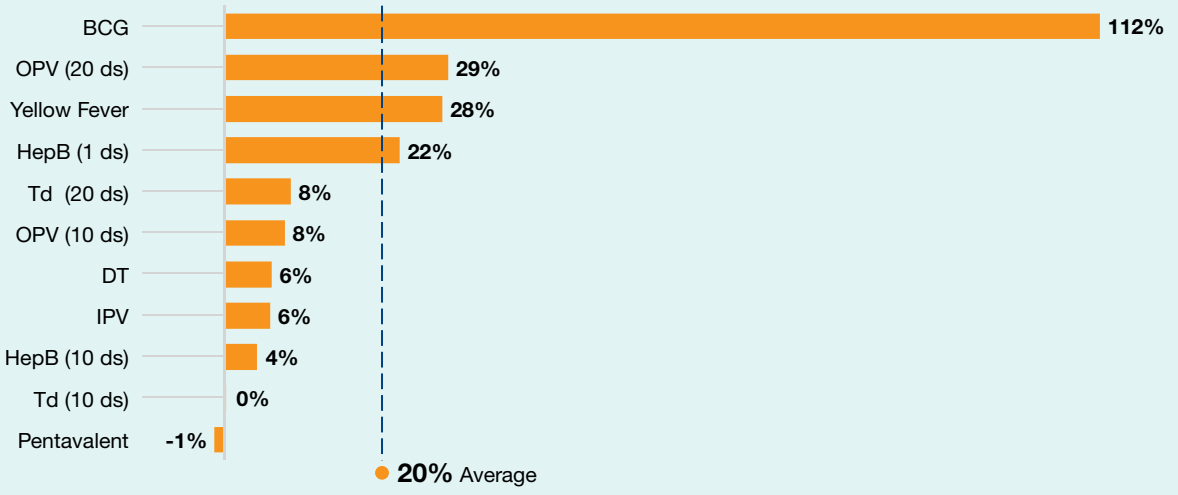
The *extent* of the financial mechanism also needs to be established, and that will involve defining the role of national, continental, and global stakeholders – in particular, their role in contributing to the mechanism and in bearing its cost.

Case study:
Historical price premium paid by Gavi to MNCs

To explore further the idea of a price premium, at least in the short-term, we needed to understand the willingness of global health organisations to pay such a premium for vaccines. Accordingly, we conducted a price analysis of 11 vaccines, comparing the 2021 prices paid to MNCs with the average prices paid by Gavi. It turns out that Gavi, to ensure security of supply, has indeed been paying the MNCs varying levels of premium. On average, the MNC vaccine prices were 20% higher than those of DCVMs.

The analysis is summarised in Figure 12, which shows the large range of premiums. On the lower end was Pentavalent, for which Gavi paid 1% less than average because supply from DCVMs was sufficient and there was no need for a premium. At the opposite end were vaccines such as Bacillus Calmette-Guerin (BCG) and Yellow Fever, with prices 112% and 28% higher than average respectively. The BCG premium was driven largely by a need to ensure BCG supply diversity and consistency, following a 30% reduction in global supply caused by the delisting of a DCVM supplier. As for the Yellow Fever premium, it too was prompted by global capacity constraints, which enabled reliable MNCs to set above-average prices.

Figure 12: Average percentage price premium paid by Gavi to MNCs vs. DCVMs in 2021



Note: BCG = Bacillus Calmette-Guerin, DS = Dose, DT = Diphtheria-Tetanus, HepB = Hepatitis B, IPV =Inactivated Poliovirus Vaccine, OPV = Oral Poliovirus Vaccine, Td = Tetanus and Diphtheria
Source: Gavi; UNICEF; Company websites; Press releases

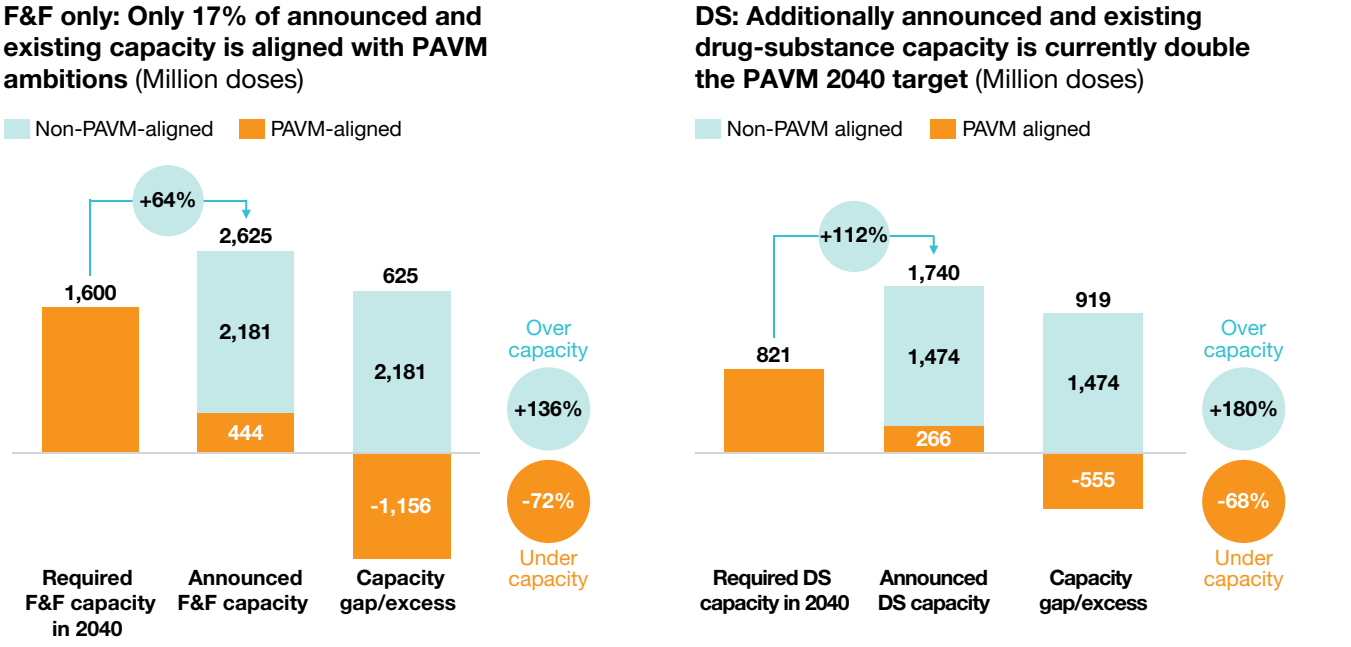
4. Need for greater collaboration

Since the Covid-19 pandemic, the African vaccine-manufacturing effort has strongly gained momentum. At the latest count, 30 vaccine-manufacturing projects in 14 countries have been announced, supplementing the facilities that already exist.[15]

While this flurry of announcements testifies to a strong commitment to scale up vaccine manufacturing, it also gives rise to strategic concerns – notably, the need for coordination. Without proper coordination, there is a risk of overcapacity for specific products. Just consider the over-representation of Covid-19 projects during the last 18 months, with more than 12 manufacturing projects announced for vaccines.

Figure 13 shows the amount of capacity that is being planned, according to publicly available announcements. Though far from exhaustive, the data already suggests how misaligned many of the plans are with the strategic priorities defined by PAVM. Of course, not all of the planned projects will materialise (some have been halted or repurposed already),[16] but the warning signs are clear. Overcapacity and/or oversupply could well emerge, and that could lead to some serious setbacks – cannibalisation among manufacturers, economic failures, and wasted investments.

Figure 13: Overview of the publicly announced vaccine manufacturing capacity in Africa



Note: "PAVM-aligned" refers to the quantity of specific vaccines that matches PAVM estimates of the quantity required in 2040. "Non-PAVM-aligned" refers to vaccines that are not specific to PAVM or that exceed PAVM estimates. Non-exhaustive analysis, based on public announcements.
Source: WHO; PAVM; company websites; UNICEF; BCG analysis

Considering current capacity and announcements made, the continent's F&F capacity would be more than 60% greater than the capacity targeted by PAVM for 2040. Moreover, it is misaligned with PAVM FFA's product priorities: it would probably lead to overcapacity for some vaccines (about 2.2 billion excess F&F doses per year) and insufficient capacity for others (about 1.2 billion F&F doses per year). For DS manufacturing, the mismatch is even worse, with the continent's current and announced capacity more than double PAVM FFA's ambition for 2040.

"Africa will be competing with giants – you need strong coordination to make it successful and ensure the capacity will be used."

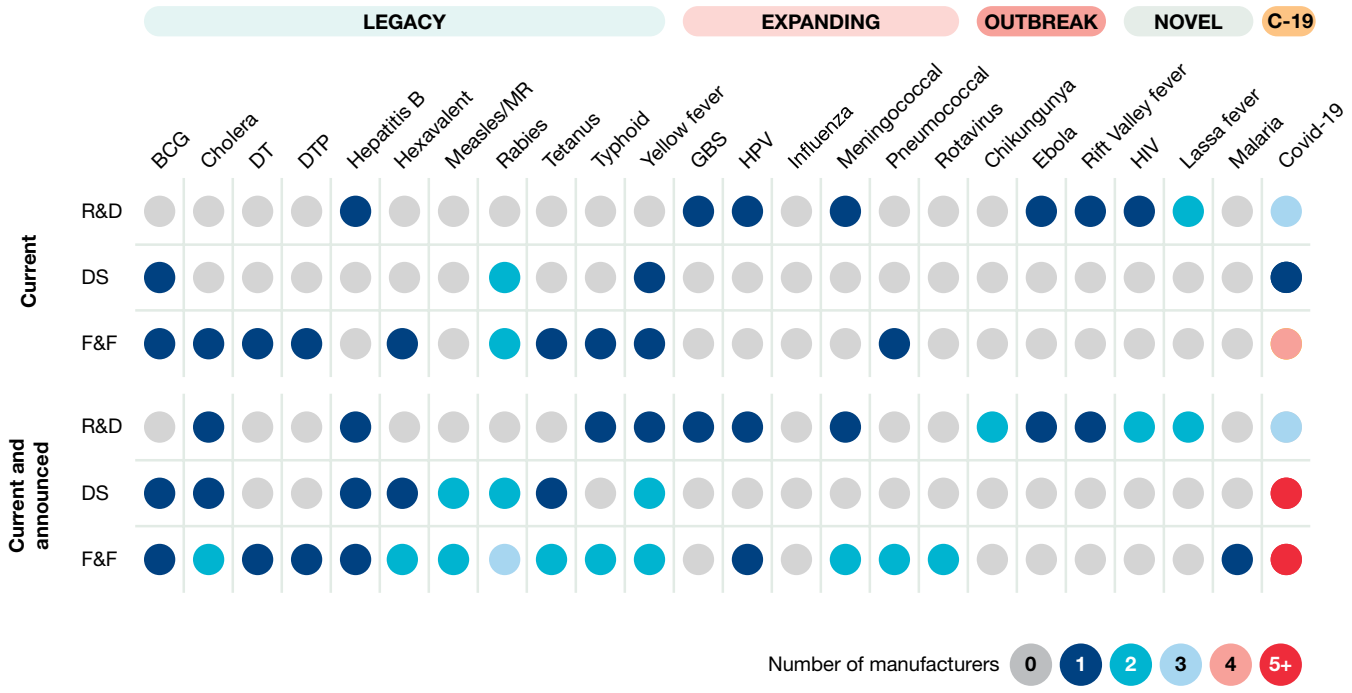
- Global health organisation

Figure 14 shows the number of manufacturers with existing capacity and/or announced plans.

The stream of announcements has shown the industry's ambition to diversify vaccine portfolios and to build upstream capabilities, but has also highlighted the likelihood of wasteful duplication. The main culprit in this potential overcapacity is the set of Covid-19 manufacturing projects. Many of the announcements were made at a time when the pandemic was raging and vaccines were difficult to come by. As the context has evolved, many of the plans are likely to be discontinued. But the potential overcapacity applies to other diseases too: rabies, for example, features high on the agenda of numerous manufacturers.

Figure 14: Heatmap of current and announced capacity in Africa for specific vaccines and value-chain steps

Number of African manufacturers with existing/announced capacity per stage of value chain



Note: BCG = Bacillus Calmette-Guerin, DT = Diphtheria-Tetanus. DTP = Diphtheria-Tetanus-Pertussis, GBS = Group B Streptococcus, HPV = Human Papillomavirus, HIV = Human Immunodeficiency Virus
Source: Desktop research; internal expertise; BCG analysis

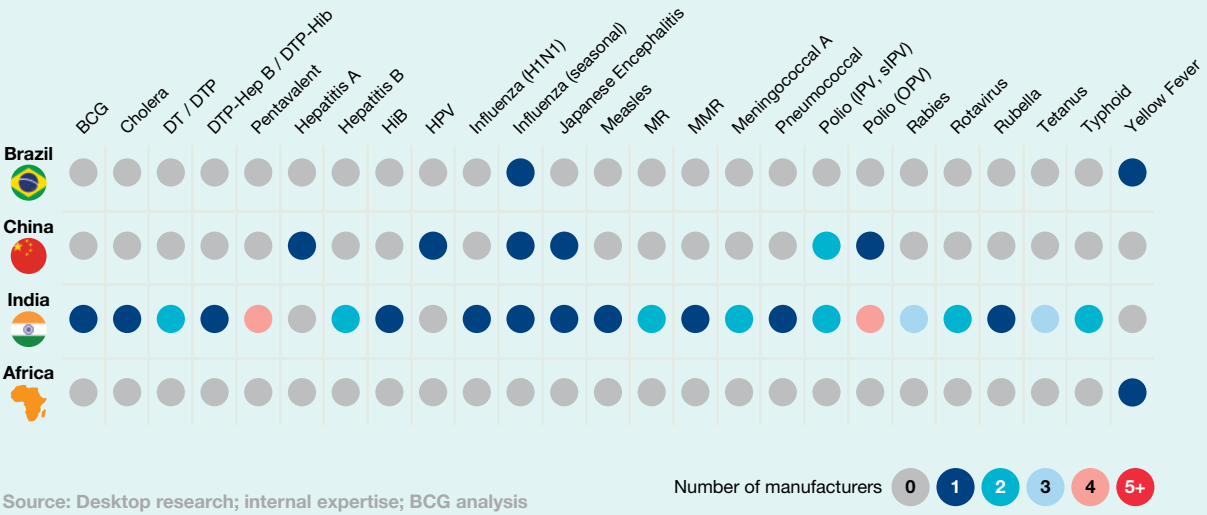
Case study:

Overlaps between manufacturers in India are associated with significant price decreases

Context

In other LMICs, manufacturing overlaps are fairly rare. India, despite a thriving vaccine-manufacturing industry, generally has only one or two manufacturers with WHO prequalification for each vaccine, though for a few antigens there are three or four different manufacturers that have prequalified products.

Figure 15: Number of manufacturers in select LMICs producing WHO-prequalified vaccines



Source: Desktop research; internal expertise; BCG analysis

Impact

Four Indian manufacturers are producing prequalified pentavalent vaccines. The resulting fierce competition has led to a marked drop in price, from about $3 per dose in 2006 to $1 or even less today. Such competition is often considered desirable, as it make vaccines more affordable across the world. But in the context of a developing vaccine-manufacturing ecosystem, with manufacturers intent on scaling up, such downward pressure on prices could dramatically reduce the prospects of economic viability. Specifically, it would reduce the ability of DCVMs to generate sufficient margin to reinvest in expanding manufacturing and product-development activities; and ultimately, it would reduce the impact achieved.

Lessons

While African manufacturers will need to compete with other DCVMs, it might be necessary to minimise overlaps on the continent in the near term, to enable companies to reach the scale necessary for a viable business.

The overcapacity risk points to one of the key challenges facing all stakeholders – the need for coordination or even collaboration. The African manufacturers in our survey were largely in agreement on this matter, while also pointing out that no mechanisms for such cooperation had been defined yet.

One specific development that they are particularly hoping for is greater information-sharing. It would benefit all stakeholders by giving them visibility on:

- market intelligence regarding supply and demand
- mid- and long-term strategic priorities
- mapping of current and planned capacity across the continent.

Of course, a degree of competition will, and should, persist – vaccine manufacturing is a business after all – but sharing and accessing such information will help manufacturers to make more informed business decisions. The increased transparency will also enable donors and investors to decide where best to direct their support.

Many manufacturers suggest that the mechanisms would best be developed by a continental organisation like PAVM, which could facilitate coordination by setting up forums, centralising and disseminating information, providing market intelligence, and identifying strategic priorities.

Manufacturers are in favour of the more decentralised coordination models (the left of the spectrum on Figure 16) such as coordinated strategic vision and information sharing. The manufacturers we interviewed are not calling for a centralised supervisory body or mechanism that would restrict them to a particular technology platform and dictate what they should or should not manufacture.

"Manufacturers on the continent should not be told what to manufacture – but we need information-sharing to make good business decisions and build viable business models"

- African manufacturer

By contrast, some global and continental health organisations do favour an actual centralised coordination system (the right of the spectrum on Figure 16), regarding it as the optimal way of reducing overlaps, waste, and deviation from strategic priorities. For example, some funders are open to coordinating their funding.

Different groups of stakeholders might require different coordination mechanisms, but it remains important to ensure communication channels between the various groups and avoid duplication of effort.

Figure 16: Potential coordination models proposed in interviews

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	Strategic vision	Information and market intelligence	Coordination of funding	Joint venture structure	Regional hubs
Scope	No direct coordination; instead, defining of strategic priorities to guide and inspire manufacturers	Forums for manufacturers to discuss plans, and share regular market intelligence on opportunities	Funders collaborating to minimise overlaps and direct resources to priority strategic initiatives	Manufacturers across Africa forming joint ventures to benefit from one another's strengths and scale	Regional hubs established to collaborate within RECs and establish regional capacity
Pros	+ Least political alignment needed + Manufacturers remaining autonomous	+ Allows manufacturers to work synergistically + Helping to avoid overlap and guide priorities	+ Funds aligned w/ strategy + Reduced risk of overlaps + Positive incentives for priority areas	+ Collaboration maximised via joint ownerships + Supporting of regulatory harmonisation	+ Scale boosted through regional focus + Ability to leverage RECs' trade agreements
Cons	- High risk of overlaps - Limited scale for most manufacturers	- Persistent chance of too-small scale and fragmentation	- Frequent differing of strategies among funders - Reduced pace, owing to additional process step	- Very high complexity - Low level of competition - Need for very high level of political alignment	- Potential overlaps between regions - Need for high level of political alignment

Source: Expert interviews; desk research; BCG analysis

Figure 17: Motives for the African vaccine manufacturing strategy

Source: Expert interviews

5. Implications of the continental vision for African vaccine manufacturing

Among national, continental, and global stakeholders, there is consensus about Africa's vision for vaccine manufacturing, for both public-health reasons and economic-equity reasons. There is a wholehearted embrace of the intent of PAVM FFA and stakeholders are supportive of having an ambitious target as a rallying cry.

In interviews, the stakeholders homed in on three different reasons to scale up the continent's vaccine-manufacturing capacity and capabilities: pandemic preparedness, tackling local and regional diseases, and supply security.

Those objectives should however be further detailed to define what is actually achievable in the given timeframe.

1. Pandemic preparedness

Strengthening pandemic preparedness does not necessarily involve Africa establishing the necessary capabilities to develop and manufacture a novel vaccine for the next pandemic on its own. As the Covid-19 pandemic showed, capabilities alone are not enough to ensure self-sufficiency.

Pandemic preparedness involves more than capabilities: it involves speedy delivery too, and that requires considerable funding. To develop a Covid-19 vaccine for instance, the United States spent an estimated $20 billion in a single year. Even if Africa had world-class R&D competences, it would still struggle to muster the resources to develop a candidate vaccine as fast as HICs and MNCs do.

Instead of competing directly with the MNCs and aspiring to R&D self-sufficiency, African countries could redirect their efforts somewhat – integrating into the global vaccine-development efforts via R&D collaboration networks; and enhancing Africa's clinical-trial capacity and sequencing capabilities to ensure that vaccines developed elsewhere will be optimally effective for Africa's population.

African countries could learn from India's experience in this regard. India's Covid-19 products did not reach the global scale that other Covid-19 vaccines achieved, despite its strong vaccine sector and existing competences across most technology platforms. However, India still contributed considerably to the global response, by partnering with MNCs to manufacture their vaccines at scale. India's prowess at large-scale, low-cost end-to-end manufacturing has proved invaluable, and positioned the country as one of largest suppliers of Covid-19 vaccines around the world, particularly to LMICs. Even without self-sufficiency on the R&D front, India ensured its own supply security by becoming a prolific manufacturer.

Perhaps Africa will eventually be able to achieve its own supply security by similar means. The African continent needs to establish large-scale end-to-end manufacturing capacity and capabilities, which could then be repurposed in the event of pandemics, regardless of where the vaccine was developed.

2. Tackling local or regional diseases

Stakeholders endorse the integrated approach taken by PAVM, with investment not only in F&F but also in DS production and in R&D across technology platforms. The R&D capabilities acquired should then lead to locally developed vaccines, and also provide talent and competences to the manufacturing industry.

The R&D capabilities should focus on developing vaccines for pathogens endemic to Africa, particularly those that affect Africa disproportionately and are at risk of being under-addressed by MNCs.

The best way for stakeholders to target such diseases is via global partnerships. Several relevant African diseases, such as Chikungunya and Rift Valley fever, are already on the priority list of The Coalition for Epidemic Preparedness Innovations (CEPI). African manufacturers are enthusiastic about the International Vaccine Institute (IVI)/Hilleman model (see section VI.7), in which partnerships establish R&D labs to create a pipeline of products for manufacturing. Recent announcements are going into that direction: In November 2022, BMGF and the Wellcome Trust announced a seven million USD grant financing to support the first phase of a technology transfer from IVI to Biovac for oral cholera vaccine.

"Usually, vaccines against tropical diseases are not the most profitable ones, and may not be MNCs' priorities."

– Global biopharmaceutical company

Case study:
Malaria-vaccine development

The global quest for effective malaria vaccines shows how complex it can be to develop novel vaccines for priority diseases. The first and only successful malaria vaccine took nearly 30 years to get to market, and has drawn on more than $7 billion investment in the last ten years alone. Success was the result of a partnership – between The Bill & Melinda Gates Foundation (BMGF), GSK, and PATH. By combining their resources and capabilities, the three partners succeeded in leveraging and expanding existing knowledge, and eventually translating it into a commercial product. African organisations would do well to follow this example and develop strong partnerships with global organisations.

One particular success factor in the development of the malaria vaccine was the coordination of funding through organisations such as PATH's Malaria Vaccine Initiative or the Global Fund. Much of the financing came from donations, which minimised cost for innovators.

Case study:
CEPI's R&D programme for a Lassa fever vaccine[17]

Context

Lassa fever is a viral haemorrhagic disease, spread by mice and person-to-person contact. It is endemic to West Africa, registers about half a million cases a year, and carries the threat of serious outbreaks. The disease has been extending its influence beyond West Africa, probably owing in part to climate change. If the virus spreads aggressively to Central and East Africa, it would affect a population of more than 600 million people in the future. There are supportive treatments, but no vaccine is available yet. CEPI has launched a large-scale research programme aimed at developing a vaccine.

Impact

The vaccine programme has been backed by $26 million of investment and has recruited 23,000 participants across West Africa to participate in clinical trials. So far, five candidate vaccines have emerged, four of which have entered Phase I studies to assess safety.

Lessons

As climate change continues, diseases previously localised to smaller African regions might quickly extend their reach to other parts of the continent or even across the world. So international funding is increasing for addressing endemic African diseases, and even niche regional diseases are now attracting greater R&D interest from the vaccine industry. The lesson for African stakeholders is clear: the most promising path to successfully develop vaccines against endemic diseases is that of international or continental partnerships. A widespread pooling of resources can reduce risks, minimise wastage, and foster collaboration between centres of expertise.

3. Supply security

A major motive behind the momentum to scale up vaccine manufacturing in Africa is to strengthen supply independence, i.e. reduce the current reliance on external supply chains. For that purpose, African stakeholders must strive for large-scale end-to-end manufacturing infrastructure and competence within Africa itself. The resulting supply security would prove particularly valuable in times of pandemic or severe local outbreaks.

However, prioritisation is crucial. For many vaccines, the market is already saturated, and prices are extremely low. Any effort to build capabilities within Africa for those products would attract very little global support – and the business case for self-sufficiency is a very weak one. Accordingly, the continental effort should be concentrated on supply-constrained vaccines for the time being.

The optimal method to improve supply security across the continent requires an analytical, segmented approach – predicting supply-constrained vaccines, and manufacturing them locally, but continuing to import vaccines that have suitably low supply risks. Gavi's agenda is consistent with this approach, offering a list of specific vaccines that currently have sub-optimal market dynamics and that would benefit from additional suppliers.[18]

"The African vaccine-manufacturing industry should address markets with gaps."

– Global health organisation

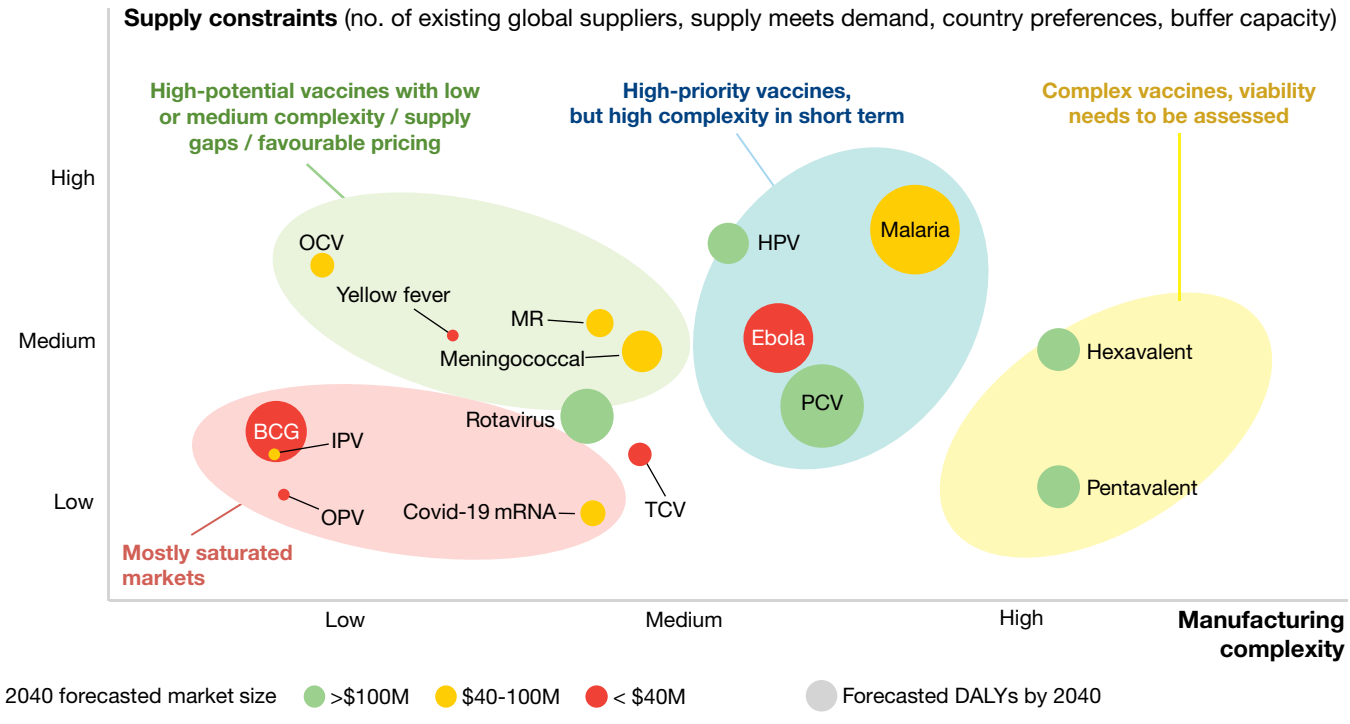
6. Strategic priorities for the African vaccine manufacturing industry

In furtherance of the vision just discussed, African manufacturers stressed the need to establish a clear set of strategic priorities. The list of 22 products named in the PAVM FFA is too broad, and manufacturers require further prioritisation (products, technology platforms) to guide their short- and mid-term activities.

Stakeholders compiling a shortlist of priority vaccines for African manufacturers would have to consider current and future global supply and demand, to identify likely supply shortfalls. They would also have to investigate manufacturing complexity, identifying platforms and vaccines that allow for relatively easier entry. In the words of a recent research paper, "African countries should not start a very big complex project plan, which costs a lot of money and requires sophisticated expertise and experience … preference should be given to already well-researched antigens or new antigens, which can be produced with simple, straightforward processes." (Makenga et al., 2019, p.11).[19]

Figure 18 shows how such an assessment could help in decision-making. The chart plots existing vaccines according to their manufacturing complexity (e.g. number of antigens, technology platform, age of technology, need for adjuvants) and their supply shortcomings (defined by the Gavi Healthy Markets Framework; e.g. number of existing global suppliers, supply vs. demand, country preferences, buffer capacity).

Figure 18: Short- and medium-term vaccine manufacturing priorities, based on complexity and market-supply shortcomings

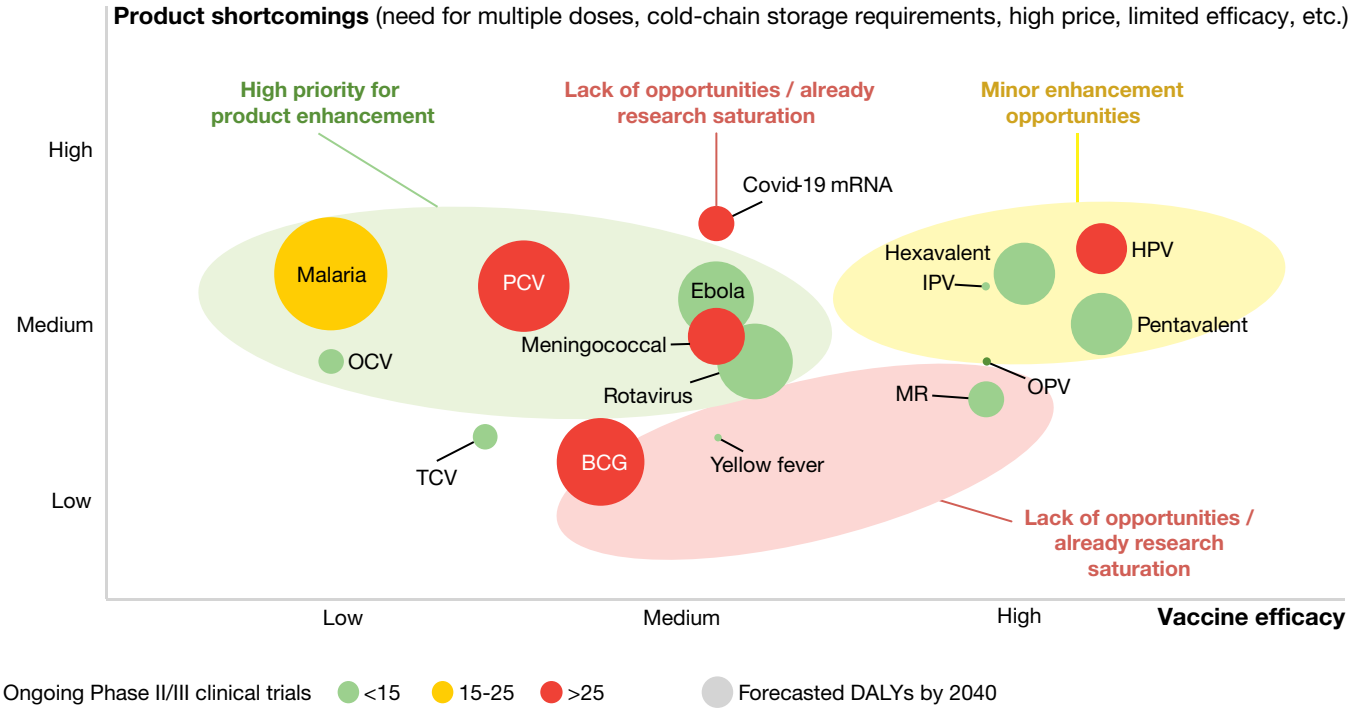


Source: Gavi; PAVM; WHO; BCG analysis

Note that this analysis is illustrative rather than exhaustive. The intention is to indicate some of the inputs that manufacturers and health organisations could use when identifying priority products. Take the example of BCG and pentavalent: they might appear attractive owing to their large market size, but the markets are characterised by fierce competition, with no supply shortage and dose prices averaging in cents rather than dollars. African manufacturers would be unable to compete effectively with the established low-cost producers in other parts of the world. Far more promising would be products like OCV, which still suffer supply shortages (despite having a smaller market) and which have relatively low manufacturing complexity.

With regard to R&D, many R&D organisations considered that the best way of building capabilities across platforms would be to focus first of all on product improvements. Again, prioritisation would be needed, by identifying vaccines characterised by various shortcomings; e.g. limited efficacy, need for multiple doses, constraining cold-chain storage requirements (see Figure 19).

Figure 19: Short- and medium-term R&D priority of existing vaccines on the basis of product shortcomings and vaccine efficacy



Source: Gavi; PAVM; WHO; BCG analysis

Malaria, for example, is a good candidate. The introduction of the RTS,S vaccine has been ground breaking. However, this first malaria vaccine requires four doses, is still relatively expensive, with modest efficacy. On the other side, the pipeline of malaria vaccines remains limited (5 candidates in Phase III clinical trial), and the forecasted disease burden is high.

Finally, for not-yet-existing vaccines, R&D priority should be given to endemic diseases that occur predominantly in Africa and that (therefore) attract less global attention. Stakeholders could assess endemic pathogens on the basis of several factors – e.g. the expected Disability-Adjusted Life Years (DALYs) if vaccines remain undeveloped, the share of global DALYs located in Africa, and the concentration of R&D efforts globally (number of ongoing advanced clinical trials) – and then prioritise them accordingly. Figure 20 illustrates such a prioritisation. A preliminary analysis suggests that high-priority targets for vaccine R&D include meningococcal serotype X or the Sudanese Ebola strain.

One related problem is that of antimicrobial resistance (AMR), increasingly a major health threat. Drug-resistant infections cause more than one million deaths per year around the world , and unless urgent action is taken, this number could rise to ten million by 2050. Here too vaccines can play an important role. In the longer term, stakeholders should promote R&D for vaccines against bacteria with high disease burden in Africa; such R&D appears technically promising and potentially impactful.

Figure 20: Short- and medium-term R&D priorities of not-yet-existing vaccines for endemic diseases

Priority	Vaccine	2040 DALYs forecast	Share of global DALYs in Africa	Number of ongoing Phase II/III clinical trials:
High-priority vaccines for diseases endemic to Africa: R&D to focus on diseases with least global attention	Meningococcal X	n/a	99%	0 / 1
	Ebola (Sudan strain)	> 1M	100%	0 / 0
	HIV	> 1M	75%	3 / 0
	Tuberculosis	> 1M	40%	6 / 1
	Lassa fever	< 0.1M	99%	0 / 0
	Rift Valley fever	< 0.1M	99%	1 / 0
Lower priority: lower relevance for Africa, and more concentrated global efforts	Chikungunya	0.2 - 1M	1%	1 / 5
	Zika	< 0.1M	3%	2 / 0

Attractive from development perspective

Somewhat attractive from development perspective

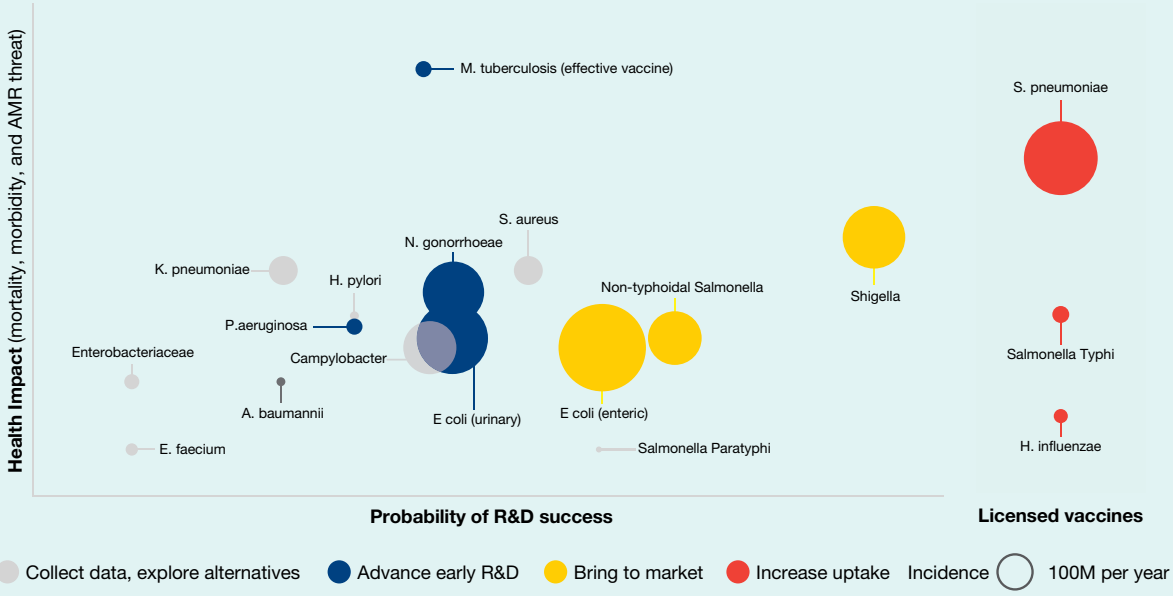
Not attractive from development perspective

Source: IHME health data on DALYs; PAVM, ClinicalTrials.gov; BCG analysis

Case study:
Evaluation of R&D opportunities for vaccines to tackle AMR[22]

A 2019 paper, co-authored by the Wellcome Trust and BCG, analysed the potential of vaccines to combat AMR. The assessment used the WHO priority-pathogen list as a starting point and identified pathogen clusters that can help in prioritising interventions, as shown in Figure 21. Many of these bacteria have a high disease burden in Africa, notably non-typhoidal Salmonella, Shigella, and Neisseria gonorrhoeae.

Figure 21: 2019 AMR pathogen segmentation



Notes: Probability of R&D success (x-axis) was scored by totalling the weighted scorecard scores for each pathogen on: pathogen biology, pre-clinical and clinical R&D, and pipeline robustness, using the weighting listed below. The range of the combined score is 0-100.
Health impact (y-axis) was scored by totalling the weighted scorecard scores for each pathogen on: mortality, morbidity, and urgency of AMR threat, using the weighting listed below. The range of the combined score is 0-100.
Source: Wellcome Trust & BCG report, "Vaccines to tackle drug resistant infections, An evaluation of R&D opportunities"

Stakeholders across the board stressed the importance of achieving early successes, to prove to the global community how promising the endeavour is, and to alert global manufacturers to the business opportunities that Africa can offer.

Figure 22, based on the assessment above, provides an illustrative summary of some products that offer high potential in the near term.

Figure 22: Summary of potential manufacturing and R&D priorities (not exhaustive)

MANUFACTURING PRIORITIES

Short-/medium-term priority to build up E2E capabilities:

Low/medium complexity, attractive market, and/or highly relevant for Africa

- Cholera
- Rotavirus
- HPV
- MR
- Meningococcal ACW
- Yellow fever

Medium-/long-term priority, worth starting F&F capabilities:

High complexity, but favourable markets and relevance for Africa

- Malaria
- Hexavalent
- Ebola
- Pneumococcal

R&D PRIORITIES

Short-/medium-term priority to improve existing products

Efficacy, number of doses needed, storage requirements, and affordability

- Cholera
- Rotavirus
- Ebola
- Malaria
- Meningococcal ACWY
- Pneumococcal

Medium-/long-term priority to develop new vaccines

New vaccines for high-priority diseases endemic to Africa (based on DALYs and percentage of DALYs located on Africa)

- HIV
- TB
- Meningococcal X
- Lassa fever
- Ebola (Sudan strain)
- Rift Valley fever
- Shingella
- N. gonorrhoeae
- Non-typhoidal Salmonella

Source: BCG analysis

Photo by DC Studio via Freepik

7. Manufacturing opportunities in other biologics

Beyond priority vaccines, manufacturers across the continent also want to consider opportunities in other biologics. The Covid-19 pandemic has energised efforts to boost human-vaccine manufacturing in Africa and break the continent's reliance on external supply chains. As it happens, African countries rely on external supply chains for other healthcare products too: essential medicines, key consumables (e.g. gloves, vials, syringes) and equipment. Close to 95% of Africa's pharmaceutical needs are currently imported.[23]

In recent decades, Africa's disease profile has been shifting toward non-communicable diseases, such as cardiovascular diseases, cancers, and diabetes. Such diseases accounted for about 42% of the total deaths in Africa in 2019, compared with about 27% in 2001.[24] This shift is reinforcing the need to invest in other biological products. In interviews, African manufacturers expressed the view that local manufacturing could gear up for such production as well.

Many African countries already have developed manufacturing capabilities for other biologics such as veterinary vaccines, monoclonal antibodies, and sera. At least 16 veterinary-vaccine manufacturing facilities exist across the continent, and more than ten facilities for other biological products.

"The vision should not be limited to vaccines. Vaccines are part of the response tools, but there are more products that are vitally needed in Africa, such as therapeutic sera and biotherapeutics."

- African manufacturer

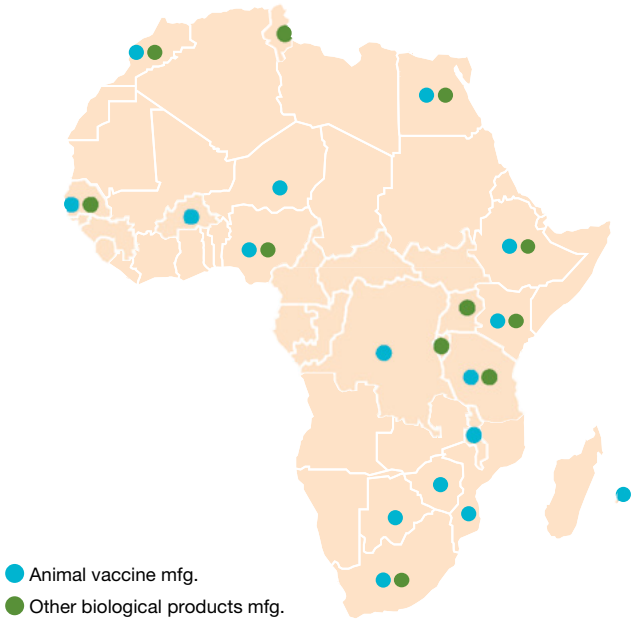
Importantly, these facilities could offer opportunities for strengthening human-vaccine manufacturing capacity. There are strong synergies between the production of human vaccines and the production of other biologics:

- R&D synergies: Similar research capabilities are required, with comparable development pathways and technology platforms.
- Manufacturing synergies: In the various complex processes involved, similar equipment is required (e.g. aseptic technique, reactors, purifiers, and fillers).
- Regulatory synergies: As with human vaccines, other biological products have to adapt their production regimes to comply with regulatory frameworks in the cause of quality, safety, and effectiveness (e.g. inspections, clinical trial oversights, authorisation, and testing).

Manufacturers across the continent can leverage these synergies to establish more resilient business models. They could utilise part of the capacity of their facilities to manufacture other biologics to improve their economic performance.

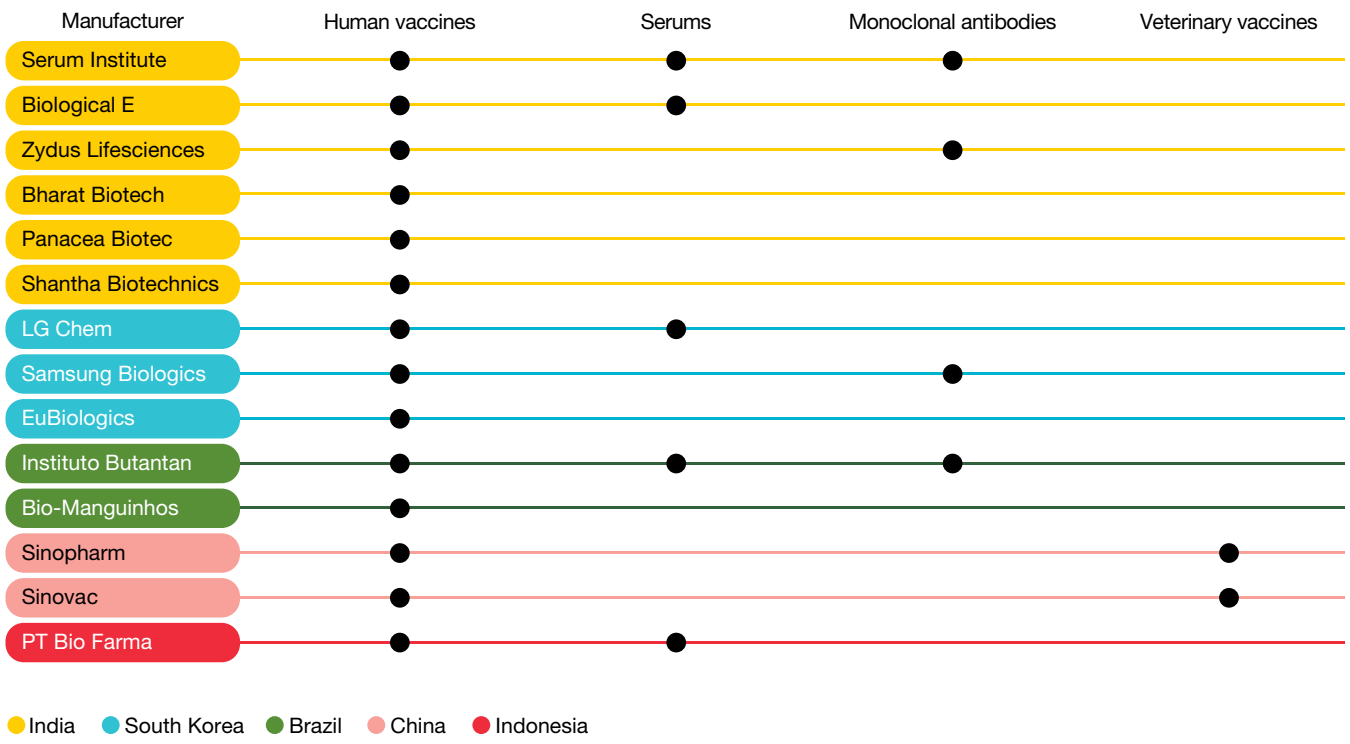
Other parts of the world have shown how it can be done. Many vaccine manufacturers in developing countries produce a wide range of other biological products as well, which in some cases generate more than half of their revenues. Our analysis studied a subset of 14 screened manufacturers from India, Korea, Brazil and China, and found that nearly two thirds of them manufacture other biological products.

Figure 23: African manufacturing facilities for other biologics



Source: "Tackling human and animal health threats through innovative vaccinology in Africa", AAS Open Research v1 2018: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7118973/; desktop research

Figure 24: Product portfolios of select DCVMs



Source: Company websites; annual reports; desktop research

Photo by Neznam via iStock / Getty Images Plus

8. Manufacturers' priority support areas

Our survey has revealed consistent support for the work done by PAVM – in particular, the identified challenges and defined enablers in the FFA (namely, access to finance, agenda-setting and coordination, infrastructure development, market design & demand intelligence, R&D & talent development, regulatory strengthening, and technology transfer & IP). On the whole, stakeholders take the view that the continent requires a systemic approach, building the entire ecosystem in a coordinated way, to ensure long-term success.

From our set of manufacturer interviews, and the qualitative survey (see Section VI for more details), it is clear that manufacturers are, in the short term, focused on building their capacity and capabilities on the ground.

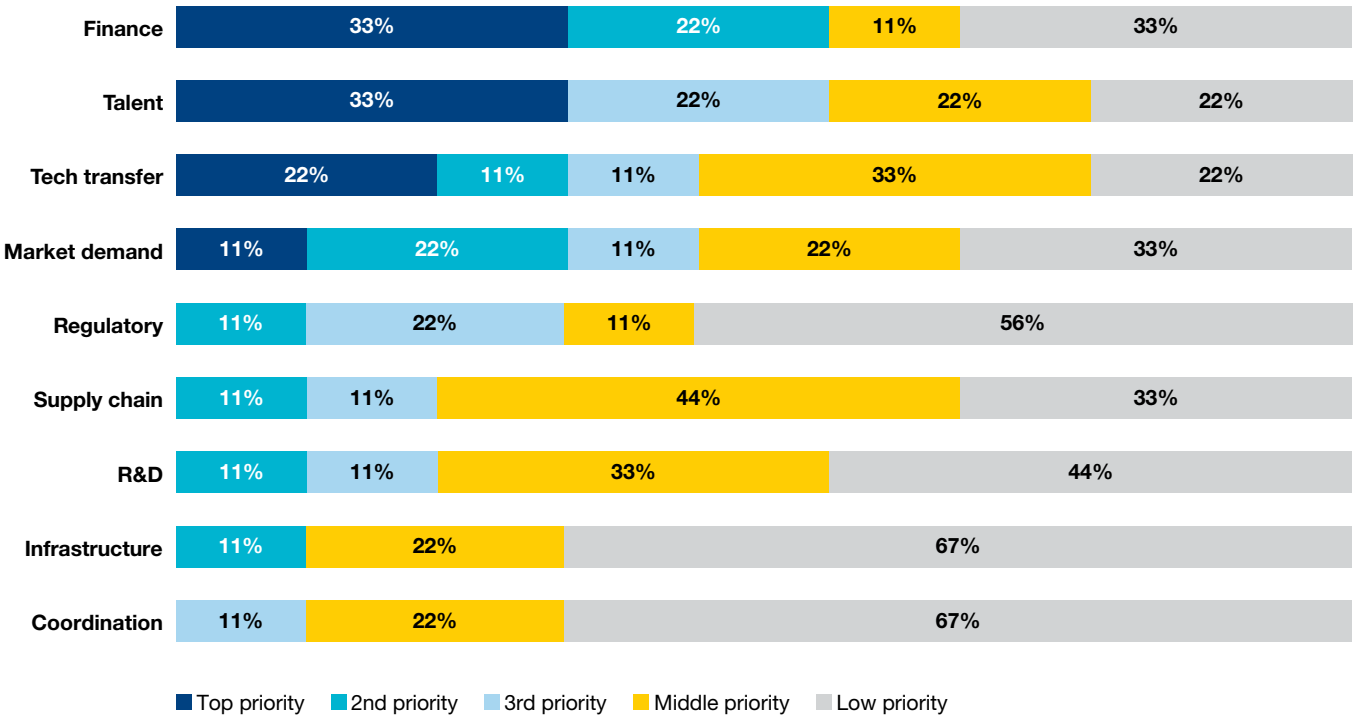
The survey asked manufacturers to rank the various challenges listed by PAVM. The results can be found in Figure 25 and were confirmed by interviews – in the short term, manufacturers consider the priority support areas to be as follows: developing local talent, improving access to finance, facilitating technology transfers, and ensuring market demand.

The manufacturers' main concerns are the everyday issues that they face as they strive to achieve scale – the more "internal" challenges, in other words. As indicated in the preamble to this report, the manufacturers' views shared in this report are not meant to steer the full set of activities and initiatives to support the African vaccine manufacturing ecosystem. The other areas are important too, of course. A mature regulatory environment and a thriving R&D ecosystem, for instance, are obviously an essential enabler for the entire ecosystem to function.

Regarding the top-ranked challenge, that of access to **Finance**, manufacturers voiced the need to design financial mechanisms specific to their context – notably, a longer repayment period, and ideally, lower interest rates. They also need support to secure the financing in the first place. In particular, funders often require manufacturers to show evidence of mechanisms which would re-risk the funders' investment, such as some sort of Advance Purchase Commitment.

Regarding **Talent**, manufacturers stressed the need to provide employees with practical learning experience – whether through secondments with MNCs and DCVMs, or by bringing in global experts to work in local sites for a time. On the longer term, there is a need to strengthen tertiary curricula in the local institutions in a way that would prepare workers for the job market.

Figure 25: Manufacturers' ranked assessment of priority challenges



Source: BCG Survey (number of respondents = 9)

Regarding **Technology transfers**, manufacturers need support in developing a value proposition for perspective partners. Such support would come through economic incentives and demand guarantees from governments, perhaps, or through funding to subsidise the costs incurred by global partners. Moreover, donors can encourage and fund technology transfers with global research organisations (such as IVI and Hilleman) to support capacity building. Such initiatives have proved remarkably valuable for manufacturers in their efforts to enhance capabilities and attract other partners.

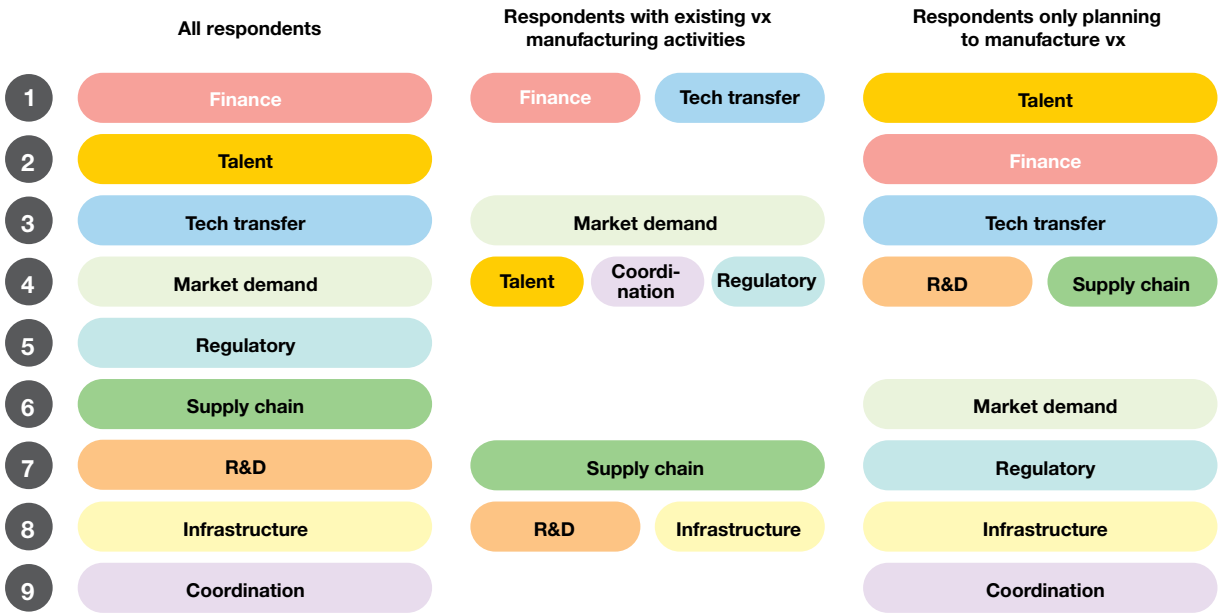
As explained above (see Section V.3), addressing those top three challenges could become pointless if the fourth challenge cannot be adequately addressed: Market demand. Manufacturing ambitions will fail without market access and demand predictability to back them up.

One interesting finding from the survey is that established manufacturers cite slightly different priorities from less mature manufacturers, i.e. those that still lack operationalised production lines. For established manufacturers, the main priorities were Technology transfer ***(they know from experience how complex such processes tend to be)***, access to Finance ***(again, they have often experienced directly the struggle for funding)***, and Market demand for their products ***(they know how competitive markets can be, and how government support can help them to construct attractive value propositions)***. The need for Coordination and for a mature Regulatory ecosystem also rank as high priority for them.

For the less mature manufacturers – still working to establish manufacturing capabilities from scratch – the top priorities cited were Talent and access to Finance.

One further note: overall, the manufacturers diverged quite considerably in their ranking of the challenges. That finding is a reminder that generalisations are not always helpful. When governments or organisations offer support, they should tailor it to the context and the specific needs of the manufacturer requesting it.

Figure 26: Assessment of key challenges based on manufacturer maturity



Source: BCG Survey (number of respondents = 9)

VI. Detailed perspectives from manufacturers on key challenges and priority support areas

Our online survey set out to show in detail how African manufacturers regard the challenges and priority support areas and is based on responses from nine African manufacturers. The sample is diverse, covering manufacturers from every African region (North Africa, West Africa, East Africa and Southern Africa) and of varying maturity (some well-established and having a long manufacturing history, others that have only recently begun manufacturing activities, and some that are still building capabilities). This sample represents close to 50% of all the manufacturers that have tangible manufacturing plans on the continent. The results were supplemented by 18 interviews, this time involving a total of 14 African manufacturers as well as the African Vaccine Manufacturing Initiative (AVMI).

The survey posed detailed questions about each of the various challenges, with the aim of characterising the barriers precisely and identifying the best ways of overcoming them. To cast light on priority support areas for manufacturers, we reviewed the programmes that have supported vaccine-manufacturing capacity in the past in Africa and globally – how they worked, which of them worked particularly well, and how they can inform future programme design on the continent. That review derived largely from a broad portfolio of interviews with continental and global stakeholders. The aim was to use their insights to identify the opportunities most likely to achieve impact for vaccine manufacture in Africa.

The consolidated picture of manufacturers' priorities is presented in section V.8. We summarise the African manufacturers' perspectives on each of the nine priorities areas identified; namely, access to Finance, Talent, Technology transfers, Market demand and intelligence, Regulatory ecosystem, Supply chain, R&D, Infrastructure, and Coordination, Infrastructure. The sequence in which these items are discussed below is based on the overall priority rankings assigned to them by the manufacturers in the survey. (See Figure 25). Figure 27 presents a summary of the manufacturers' perspectives for each area and the implications in each case.

Photo by Comezora / Moment via Getty Images

Figure 27: Summary of priority support areas for manufacturers

Area	Manufacturers' perspectives	Implications for African governments	Implications for Global Health stakeholders
Access to finance	Lack of local purchase commitments, crucial to unlock funding Support needed to de-risk investment Non-sustainable financing terms (excessive interest rates, short payback period)	★ **De-risk investments rough advance-purchase commitments** ★ **Incentivise investments through special economic zones, tax credits, land giveaways, etc.**	★ **Develop tailored affordable financial mechanisms with longer payback** Supplement financing with technical assistance where possible Consider partnering with other organisations to distribute and reduce risk
Talent	Lack of practical learning opportunities Insufficient tertiary and vocational programmes relevant for vaccines, and existing programmes' failure to prepare for job market	Develop national strategies to build talent (e.g. scholarships, academic partnerships) Build value proposition for experts living abroad to attract talent back	★ **Support manufacturers to gain practical experience through local and global secondments** Help develop relevant education curriculum and institutions Invest in capacity-building programmes
Technology transfers	Support needed for enhancing value proposition and incentives to attract partners Need for even greater emphasis on capacity building during tech transfers	★ **Provide long-term purchase agreements to attract global partners** ★ **Incentivise partnerships through special economic zones, tax credits, land giveaways, etc.**	★ **Collaborate with African manufacturers on tech transfer, with strong focus on capacity building** ★ **Finance (partly) technology transfers with MNCs / other DCVMs** Help to lower risk and improve capability transfer by partnerships between multiple organisations
Market demand	Despite many announcements, lack of long-term purchase agreements at national or continental level to build business case Insufficient market intelligence to help identify opportunities`	★ **Support manufacturers with long-term purchase agreements** Collaborate with other countries to pool demand to increase market volumes for manufacturers Ensure favourable trade policies	★ **Reform procurement mechanisms and conditions to create space for Africa manufacturers** Consider accelerated prequalification (PQ) pathways to allow faster access to market

★ Highest priority support areas in the short-term to create conditions for a sustainable ecosystem for African vaccine manufacturers

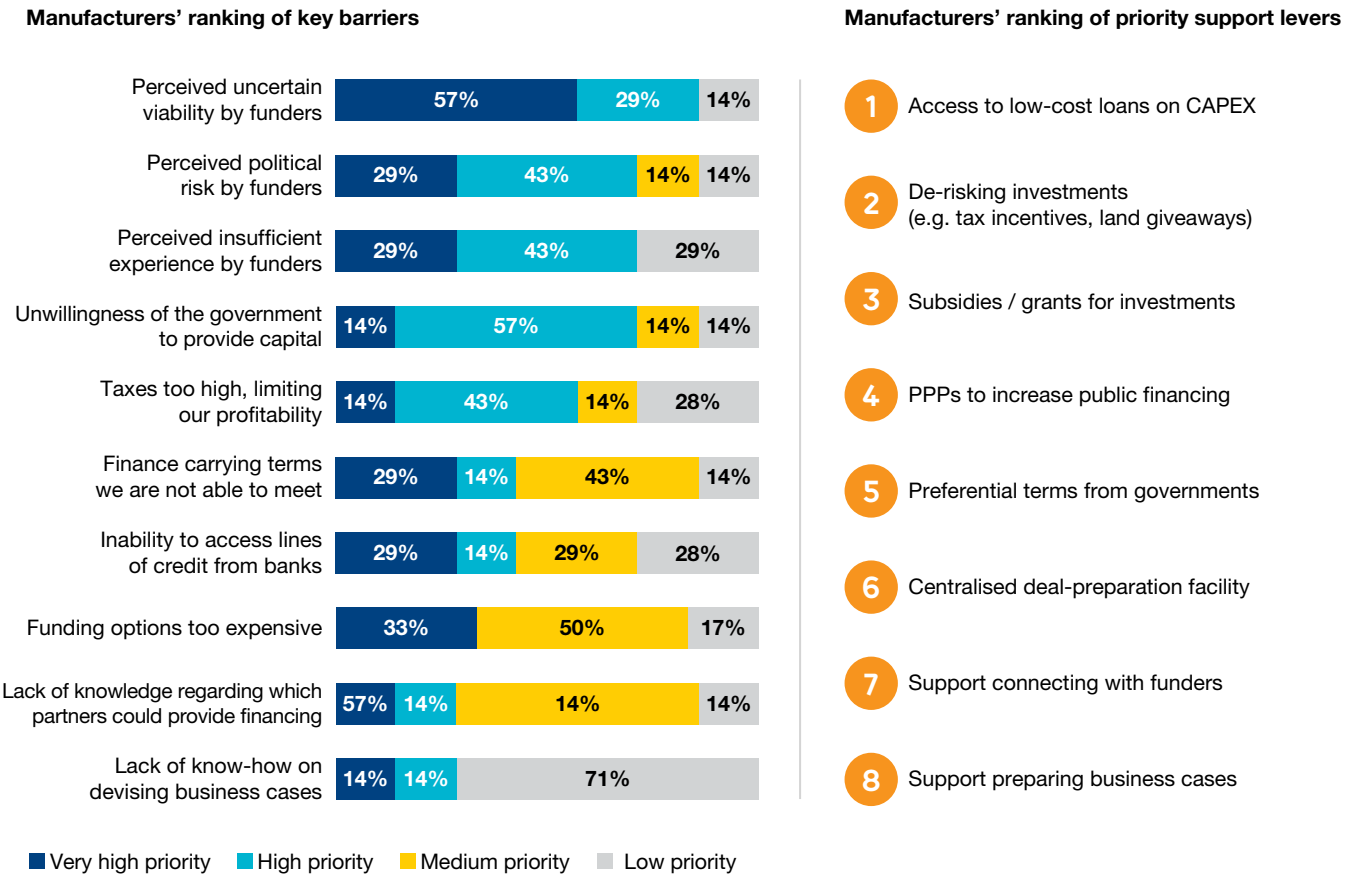
Figure 27: Summary of priority support areas for manufacturers (Cont'd)

Area	Manufacturers' perspectives	Implications for African governments	Implications for Global Health stakeholders
Regulatory	Lack of harmonisation, hence reduced market access and increased complexity Many inefficiencies in facility / product approval processes Insufficient regulatory maturity in some countries, which blocks partnerships with global players	Accelerate efforts to harmonise regulations and strengthen regulators on the continent Support manufacturers and regulators to streamline approval processes	Invest in regulatory capacity around the continent Support manufacturers and regulators to optimise processes
R&D	Insufficient funding for R&D Gaps in critical infrastructure and talent on the continent Insufficient African collaboration	Support R&D ecosystem with economic incentives (e.g., tax relief, tax credits, grants, etc.) Invest in infrastructure and foster Pan-African and global partnerships	Support establishing R&D hubs and networks on the continent Support establishing partnerships with global companies Replicate model of public-health vaccine research organisations (i.e. IVI, Hilleman) in Africa
Infra-structure	Large gaps in transport networks and cold chain Long lead times for machinery	Support manufacturers via duty exemptions to ease imports	Support designing cold-chain strategies and logistics networks
Supply chains	Unduly high costs, owing to current need to import almost all inputs Long lead times and recurring supply shortages, to the detriment of planning	Create incentives to foster creation of local ecosystems for input materials	Provide technical assistance and funding for the establishment of local value chains
Coordination	Need for greater information-sharing through manufacturer forums Openness to coordination of funding and incentives for priority products No need for a centralised supervisory body at regional or continental level	★ **Align national strategy and investment with the continental effort**	★ **Collaborate on funding and support with other organisations to minimise overlaps and build synergies between programmes**

★ Highest priority support areas in the short-term to create conditions for a sustainable ecosystem for African vaccine manufacturers

1. Access to finance

Figure 28: Key challenges and priority support areas related to Access to Finance



Source: BCG survey (number of respondents = 9)

Access to finance is a serious concern for most manufacturers, especially for those still planning to establish capabilities. Three main problems are at issue.

- First of all, financing is difficult to secure, since private investors as well as DFIs tend to perceive many manufacturers as too inexperienced, to question their economic viability, and to worry about political stability. Accordingly, manufacturers have sometimes opted to develop small-scale facilities, which require lower investment, but have then struggled to make them economically viable.
- Second, in the view of many manufacturers, government is under-involved. It could and should play a more active role, either through providing direct financial support or by improving the tax ecosystem.
- Finally, even once capital is made available, it might be with unacceptable strings attached – over-restrictive, perhaps, or excessively expensive to repay. If global health organisations, for instance, offer low-cost funding, they would expect the manufacturer to make the vaccines accessible to the local population, and would require commitments to that effect. The manufacturers would then typically have to compromise on prices, and that would reduce their chance of future viability. So manufacturers have a difficult trade-off to make – secure cheaper financing in the near term, and thereby limit profitability in the long term; or accept financing at more expensive or restrictive terms in near term, in the hope of more attractive business opportunities in the future.

"CAPEX has many conditions; it is hard to just give money without terms. For funders the priority is public benefit, so targeting low-income markets or low ROI. But then it's harder for manufacturers to have sustainable business models."

- Global health organisation

"Attracting the investment to develop manufacturing facilities is difficult. Without other co-funders to share the risk, it might not be achievable."

- Global health organisation

Most of our interviewees agreed that special funding mechanisms need to be put in place to support the industry. The creation of vaccine-manufacturing capabilities is a lengthy process: if technology transfers are very complex, it might take many years before self-sufficient manufacturing can occur, and throughout that time the manufacturer would be incurring high costs. It is no surprise, then, that most manufacturers attach top-priority importance to accessing low-cost loans or grants for investments.

Stakeholders noted the risks in requiring manufacturers to repay funds too soon: the manufacturers would have to take shortcuts (e.g. rushing into manufacturing partnerships for non-strategic products, relying solely on external experts without upskilling local staff) rather than methodically pursue capacity building, and that would endanger their long-term viability and make capital repayments more difficult. But history offers a solution – the pooling of funding, which gives manufacturers stability and cost-efficiency, and at the same time allows funders to mitigate risk.

Case study:
EuBiologics' funding pool[25]

Context

In 2009, EuBiologics set out to develop an affordable cholera vaccine, despite having no prior vaccine-manufacturing expertise. Funding was the immediate challenge. No single organisation was willing to carry the full cost or risk of the endeavour, but a consortium of diverse partners was formed to share the challenge. Project funding of close to $20 million was pooled from various sources of support – philanthropic, private, and governmental – and spread the risk. IVI provided the initial funding, followed by investments from the Korea-Seoul Life Science Fund (KSLSF), Green Cross Corporation, Shinhan-K2 Investment Partners, and the Global Health Investment Fund (GHIF). The Korea Investment Global Frontier Fund (KIGFF) and GHIF provided funds of approximately $5 million for capital equipment, and further funds for the final clinical studies and regulatory preparations. The coalition partners not only contributed to the financing of the project, but also supported the manufacturer more broadly, with expertise and commercial partnerships.

Impact

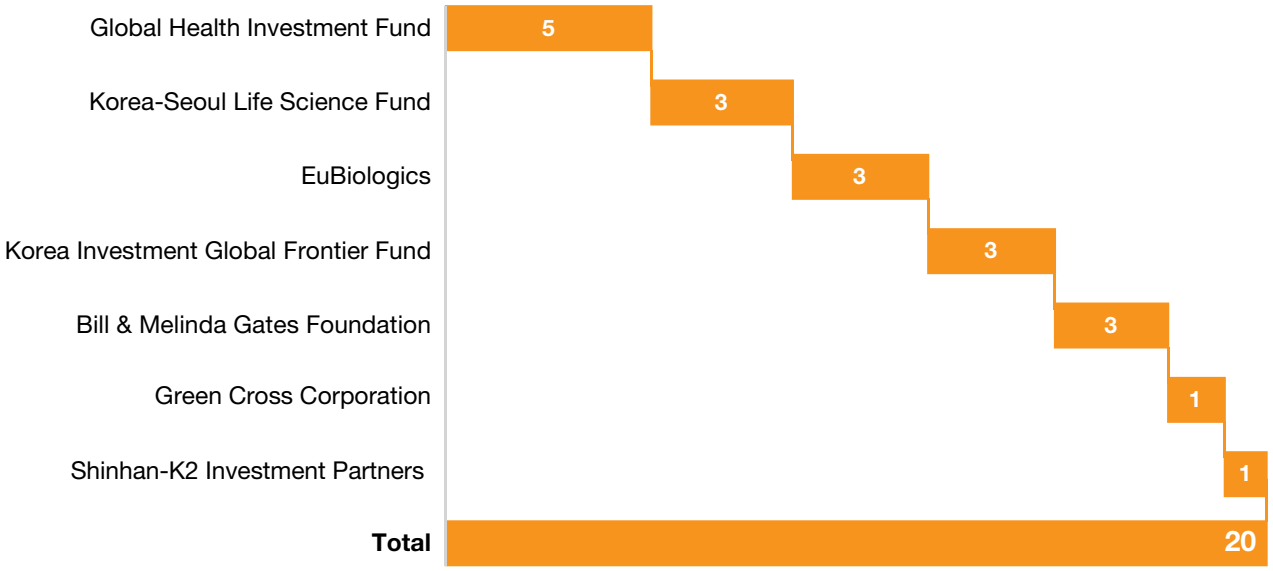
The project was able to use a philanthropically-funded public-private partnership (PPP) to overcome various common obstacles to manufacturing and bring to market a vaccine for a neglected disease. From a starting point of zero vaccine-manufacturing capabilities in 2009, EuBiologics was, within seven years, producing a safe, effective and affordable cholera vaccine with WHO-prequalification. The project produced many other positive effects. In 2018, the price of the vaccine was 32% lower than other available products, greatly to the benefit of the market. IVI facilitated commercial relationships between EuBiologics and Gavi and UNICEF. In due course, EuBiologics signed a long-term agreement with UNICEF to supply their oral cholera vaccine globally. Since 2016, EuBiologics has supplied more than 22 million doses of the vaccine to cholera-endemic and outbreak countries through UNICEF. The company is currently the largest supplier of the oral cholera vaccine, with about 80% of global market share.

Lessons

Vaccine manufacturers do not have to rely on a one-stop shop for their financing solutions. They can secure commitments and support from a wide range of stakeholders and funders, who can provide not only the funding itself but also advice on creating sustainable business models. When funds derive from a variety of sources, and are responsibly coordinated, the risk decreases for all partners involved.

Figure 29: Sources of funding for EuBiologics' cholera-vaccine project (million $)

Project funding was pooled from various sources of philanthropic, private, and government support
(Million $)



Source: Company websites; press releases; desktop research

As mentioned, governments too should do more to unlock financing. A properly supportive business environment would not only improve the economic viability of manufacturers' business models but also create a stable ecosystem – one that would attract additional funders and partners. Global experts in our survey confirmed this view, noting how a conducive business environment has benefited DCVMs elsewhere, notably in India and South Korea. Both of those countries decided against central coordination but put considerable effort into creating the right conditions for local manufacturers to thrive in. India, for example, set up regional hubs that offered preferential terms for local manufacturers and a streamlined regulatory environment.

Another funding approach cited by manufacturers is that of PPPs. The idea is that the public sector should play a much stronger role than it currently does in facilitating financing and underwriting the entire vaccine ecosystem, from market demand to infrastructure improvements. PPPs for vaccine manufacturing have a successful track record elsewhere, as in Brazil (Bio-Manguinhos) and Indonesia (Instituto Butantan) and can provide models for African countries. In fact, it was partly thanks to a PPP that a leading manufacturer in Africa, Biovac, was able to gain such scale.

"There is a notion that the entire effort needs to be private-sector-led. But we should see vaccines as a public good, and we need significant investments from the public sector to support this."

- Global health organisation

Case study:
India's special economic zones to foster the local biopharma industry[26]

Context

The biopharma sector in India has benefited greatly from the implementation of various regional policies that enhance the business environment. An interesting example is the Visakhapatnam Special Economic Zone (VSEZ). It originated in 1989 and is one of the central government's special economic zones. VSEZ is treated as a foreign territory, in respect of trade operations, duties, and tariffs. In other words, any new enterprise can be funded entirely by foreign investors, who can then repatriate the proceeds for free.

Impact

The special economic zone attracted pharmaceutical units from around the world, with companies such as Pfizer and Sanofi establishing facilities there. Lessons for the vaccine industry.

Case study:
Biovac's PPP in South Africa[27] [28]

Context

Biovac was established in 2003 as a PPP by the South African government and private investors. It was given a wide vaccine mandate, covering R&D, manufacturing, and supply. In the absence of a local biotech industry to provide support for new products, the safest and fastest way for Biovac to progress would be through technology transfers, so it sought out large MNCs to undertake technology transfers of leading products. Biovac earns a premium from the government on a wide range of vaccines, which helps to pay for quality control and distribution. For South Africa itself, the arrangement is beneficial: having a local supplier of vaccines ensures a smooth flow of supplies and reduces worries about shortages.

Impact

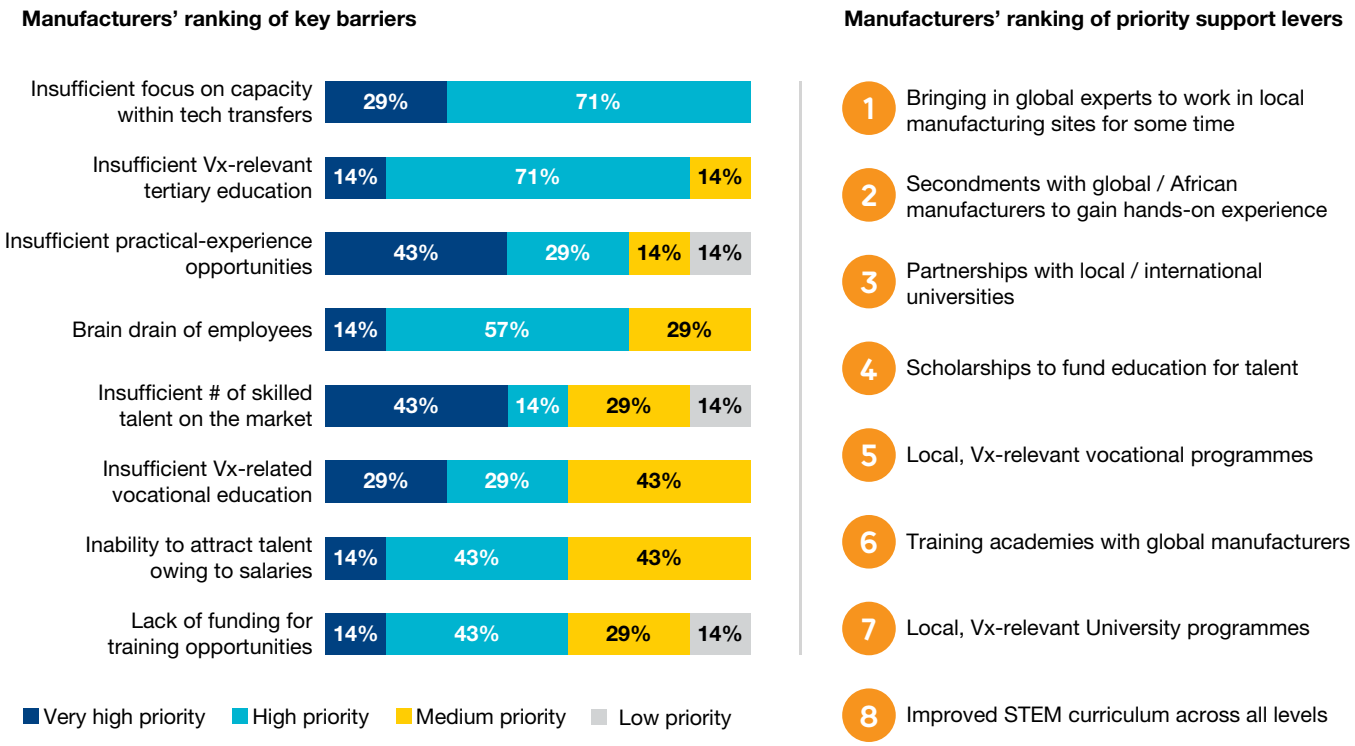
Biovac started out with 24 employees and a revenue of $10 million. It now employs more than 250 people, and its annual revenue exceeds $100 million. It manufactures a broad range of vaccines, distributing over 46 million doses a year in South Africa.

Lessons

PPPs provide a mutually beneficial relationship between vaccine manufacturers and governments. The manufacturers benefit from financing, regulatory support, and reduced risk, while the country improves its security of supply, ensuring the constant availability of essential vaccines for its citizens.

2. Talent

Figure 30: Key challenges and priority support areas related to Talent



Source: BCG survey (number of respondents = 9)

For manufacturers, a top challenge is that of attracting, retaining, and upskilling of talent. And it also represents one of the areas where manufacturers would find support most valuable.

The barriers, according to the manufacturers, can be attributed to various factors; notably, insufficient emphasis on capacity building as part of technology transfers (technology transfers are an opportunity to build capabilities beyond each individual product); gaps in tertiary and vocational education courses relevant for vaccine manufacturing; and a shortage of opportunities for prospective employees to gain practical experience.

To overcome the barriers, two particular areas of support were highlighted by manufacturers: a scheme for bringing in global experts to work onsite with local manufacturers, and a scheme for employees to gain practical experience through secondments to more established manufacturing sites across the globe.

"Technology you can buy. But there are many manufacturers full of good machines, but without scientists to operate them."

- Global biopharmaceutical company

There have in fact been numerous successful secondment programmes globally to support talent enhancement, and they can inform future programme design. One example is that of the Netherlands Vaccine Institute (NVI), which offered LMIC manufacturers the opportunity to gain practical and theoretical vaccine-manufacturing experience on-site in the Netherlands – practical experience that the seconded employees could take back and apply at their home factories.

Another area of support mentioned by most manufacturers was that of improving the education curriculum, whether through establishing academic partnerships, funding scholarships, or refining local tertiary / vocational programmes. Manufacturers stressed that the programmes should not focus solely on theory but should also give the students practical experience that will benefit their current employer or improve their job prospects in the industry.Other industries have led the way in this regard. A case in point, from the Oil & Gas sector, is that of the World Bank's programme of support for Ghana to design a local curriculum to develop local talent.

Throughout discussions, stakeholders stressed the important role that governments should play. Governments needs to treat technical upskilling as strategic priority, and direct resources to the ecosystem that nurtures the relevant capabilities. South Africa is one such example – in 2001, the government developed a national biotechnology strategy to foster expertise in biotechnology. The project made a considerable positive impact, though some ambitions remain unfulfilled.

"Having a PhD is not enough – current education programmes in Africa do not entail much practical training. Manufacturers recruit many postgraduates, but they are not ready for industry, and require another three years of training in a lab or manufacturing facility."

- African academic

Case study:
NVI training academy for DCVMs [29]

Context

In the 1970s, the Dutch government took part in an exchange programme initiated by WHO, inviting students from LMICs to learn how to develop vaccines. Participants were invited to the NVI sites to learn the practical aspects of vaccine manufacturing.

Impact

Following the training they received at NVI, the LMIC participants returned to their home countries with new knowledge and skills to advance local vaccine manufacturing. One notable participant was Dr. Cyrus Poonawalla, who had just a few years previously founded the SII, now the largest vaccine manufacturer in the world. That secondment consolidated the relationship between NVI and SII. SII subsequently acquired the vaccine-producing part of NVI and founded Bilthoven Biologicals (BBio), giving the company a manufacturing base in Europe and greater access to global markets.

Lessons

This case history illustrates the powerful potential of seemingly basic support programmes, such as running training academies and bringing DCVMs into established manufacturing sites. The NVI programme sets an example for global organisations as they design programmes of their own and should encourage manufacturers in Africa to seek such training opportunities whenever possible, to boost the capabilities of local staff.

Case study:

South Africa's government initiative to develop local biotechnology talent [31]

Context

In 2001, South Africa's Department of Science and Technology devised a biotechnology strategy, and set aside approximately $70 million to support and stimulate the development of biotechnology skills, capabilities, and tools in the country. The programme established Regional Innovation Centres (RICs) to identify and develop commercial opportunities in biotech. It set up post-doctoral bursaries, competitive with those offered abroad, to attract and retain local talent. It created career opportunities for experienced and well-trained workers, and facilitated connections between experts from relevant organisations. It also promoted curriculum development, and took steps to improve mathematics and science education at high-school level, with the aim of encouraging more students to enter the field of biotechnology.

Impact

The strategy helped to establish several biotech labs in South Africa, including Lifelab, Biopad, and Biotech – organisations now at the forefront of R&D activities in Africa. South Africa now hosts more than 70% of sub-Saharan Africa's $1 billion annual pharmaceutical capacity, and the country's clinical R&D trials make up 3% of the world's $10 billion clinical-research industry. Despite these successes, however, serious gaps persist in respect of local human capital. Workers with the relevant industrial skills are in short supply. The biotech companies struggle to fill the high-level vacancies in their workforce – whether PhDs, production engineers, quality-control staff, or experts with GMP experience. A further challenge that companies identified is the inability of regulatory bodies to keep pace with industry developments. Interviewees noted, for instance, how the former South African Medicines Control Council (MCC) had lacked the capacity and resources to regulate products within a reasonable timeframe.

Lessons

South Africa's biotechnology strategy succeeded in progressing the country's R&D, clinical trials, and other activities. Serious shortfalls continue, however, in the practical and regulatory skills that would propel the industry further forward. So policymakers should take a holistic approach to developing a vaccine industry strategy, and be sure to invest in developing talent at all skill and structural levels.

"The best scientists are often moved to management, as that is the only upward trajectory. Dedicated career pathways are needed to keep them in R&D and scientific roles, whilst still allowing them to grow."

- Global health organisation

Case study:

World Bank support for education programmes relevant to Oil & Gas in Ghana[30]

Context

The World Bank designed and completed a comprehensive programme supporting education opportunities for the extraction industry in Ghana. The project was approved in December 2010, with funding of approximately $55 million, and ended in December 2017. The support involved two main pillars:

- Vocational Training Centres: The programme expanded capacity at three vocational schools in the country. It included the purchase of relevant machinery (e.g. cranes, hydraulic laboratory equipment) to train people in skills such as welding, pipe fitting, electric circuits, and crane operations.
- Tertiary education: The programme helped the Regional Maritime University to institute relevant degrees, such as petroleum engineering and chemical process engineering.

Impact

The programme proved very successful. At the Kwame Nkrumah University of Science and Technology (KNUST), eight new labs and workshops were set up. As of 2017, over 1000 students had enrolled in petrochemical and petroleum engineering courses at KNUST. More than 530 students completed courses at vocational schools, including courses in mechanical welding and fabrication.

Global donors and health organisations have a fine track record of facilitating capacity building in LMICs. Consider the International Vaccinology Course, run by IVI. It is one of the longest-running vaccinology courses in the Asia-Pacific region, and is open to all applicants working or studying in the field of vaccinology. The training programme reflects IVI's mission to make vaccines available for global health by building capacity in vaccinology and promoting vaccine sustainability in LMICs. Over the 20 years since its launch, the course has trained nearly 5,000 vaccine professionals from LMICs throughout the world,[32] fostering partnerships in research and public health. Vaccine organisations in Africa would benefit greatly if more such programmes took place nearby.

The challenge for manufacturers is not limited to training, however. Experts and trained workers can be tempted away – either into other industries or into vaccine companies abroad. The brain drain is a major issue. So manufacturers need to design and implement mechanisms to retain staff in the long term, or to tempt them back. That would involve creating attractive career pathways and work environments, offering the right salaries and responsibilities, and enabling employees to grow within the organisation and refine their expertise.

Policymakers would do well to support manufacturers to design and implement this value proposition. In doing so, they would help to push the strategy forward for the whole continent.

Technology transfers represent another top priority for manufacturers. The issue resonates particularly strongly with well-established manufacturers, probably because they have already been through the process, and know just how lengthy and complex the transfers can be.

One major challenge is that of finding partners. It seems that MNCs are often wary of partnering with African manufacturers, owing to the perceived inexperience or lack of maturity of the local regulators, or to concerns over the economic viability of such partnerships. Another challenge is that of funding: technology transfers are complex, lengthy, and resource-intensive, as they involve not only the transfer of technology itself but also capability building.

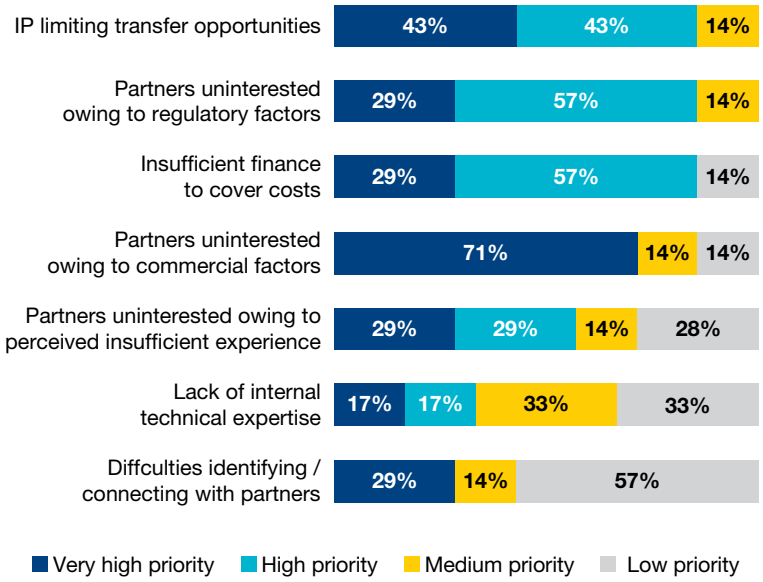
"For technology providers, the limiting factor is often the number of employees they can send to support the technology transfer, as they have day-to-day responsibilities"

- Global biopharmaceutical company

3. Technology transfers

Figure 31: Key challenges and priority support areas related to Technology Transfers

Manufacturers' ranking of key barriers



Manufacturers' ranking of priority support levers

1. Government support, e.g. through tax incentives, funding, market access
2. Financial support to cover costs of transfers
3. Capacity building on relevant platforms to build readiness for transfer
4. Centralised African enablement unit to facilitate transfers (e.g. planning, project management)
5. Identifying / connecting with global partners

Source: BCG survey (number of respondents = 9)

Another concern raised by our interviewees was that of intellectual property (IP) rights, which tend to limit the capabilities that can be transferred. Manufacturers should, as one interviewee noted, be constantly on the lookout for solutions to this problem, such as investigating vaccines whose IP rights are expired or soon to expire.

In regard to priority support areas, manufacturers stressed the need for government help in creating an attractive value proposition for perspective partners. In Africa, as elsewhere in the world, technology transfers have historically been facilitated by special market access for the IP owners. Figure 32 shows how most such partnerships involved a demand agreement.


Photo by Serhii Neznamov via Dreamstime.com

Figure 32: List of technology transfers in Africa

Recipient	Partner	Vaccine	Value chain step	Special market access
Biovac	Sanofi	Hexavalent	F&F	✓
Biovac	Pfizer	Prevnar 13 (pneumonia)	F&F	✓
Biovac	PATH	GBS	E2E	✗
NantSA	ImmunityBio	Covid-19	E2E	✓
Aspen	J&J	Covid-19	F&F	✗
Aspen	Serum Institute	Pneumococcal, Rotavirus, Hexavalent, Meningococcal	F&F	✓
Galenica Minapharm Saidal	RDIF	Covid-19	F&F	✓
Innovative Biotech	Merck / Technovax	Covid-19	DS	✓
Egypt Vacsera Saidal Pharco	Sinovac	Covid-19	F&F	✓
Afrigen	WHO	mRNA	E2E	✗

Note: Non-exhaustive list
Source: Company websites; annual reports; desktop research

"You can't force technology transfers. There is a need to develop win-win commercial partnerships – governments should support with incentives like favourable market access."

- Global biopharmaceutical company

Another invaluable source of support – financial and technical support – is that of global health organisations and global donors. The right support can serve not only to establish capabilities in LMICs, but also to achieve important development milestones (through improving accessibility to vaccines or making them more affordable), and increasingly also to facilitate partnerships. In November 2022, BMGF and the Wellcome Trust announced a seven million USD grant financing to support the first phase of a technology transfer from IVI to Biovac for oral cholera vaccine. BMGF already provided financial support to the GBS-vaccine technology transfer from PATH to Biovac in the past, and has also, together with PATH, provided financial backing for the recently announced partnership between Aspen and SII. Another example is the approach taken by BMGF, PATH, and WHO to make the Meningitis A vaccine more affordable.

Case study:
Successful cooperation on the Meningitis Vaccine Project (MVP)[33]

Context

MVP demonstrates the virtues of a product-development partnership involving a public-sector technology transfer through a technology-transfer platform. MVP was established in June 2001 through a grant from BMGF and a ten-year partnership between WHO and PATH. The goal of the project was to eliminate epidemic meningitis (caused mainly by group A strains of meningococcus) as a public-health problem in sub-Saharan Africa, through the development, testing, licensing, and widespread use of affordable conjugate meningococcal vaccines. When MVP failed to reach an agreement with major vaccine manufacturers, the project created a consortium, with a list of particular ambitions: to identify sources of raw materials (Meningococcus A polysaccharide and Tetanus toxoid); to identify a conjugation method; to try again to find a vaccine manufacturer willing to accept technology transfer (fermentation and conjugation); and to make the vaccine available at a price less than $0.50 per dose. The relevant technology transfer was duly provided to SII from three institutes: polysaccharide development from SynCo BioPartners (the Netherlands), conjugation method from the Center for Biologics Evaluation & Research/United States Food and Drug Administration (United States), and lyophilisation and stabilisation from Aerial (France).

Impact

The vaccine (MenAfriVac) is now licensed and WHO-prequalified and has been rolled out across most African countries. MVP is now Gavi's sole supplier of Meningococcal A vaccines, with more than 400 million doses delivered since 2010.

Lessons

MVP could serve as a model for other fruitful vaccine partnerships. It succeeded admirably in its aims: to develop a technology, transfer it to a DCVM, and manufacture an affordable product for LMICs. If African manufacturers could secure similar support for capacity building, they could achieve similar success. Such support, especially if concentrating on high-priority vaccines, could do so much to improve the continent's market dynamics and the hence the health of its people.

Once financing and value proposition are in place, it is crucial, according to manufacturers, for Global Health partners not to rush things and to remain focused on capability building. The power of properly paced technology transfers is exemplified by the longstanding partnership between GSK and Fiocruz in Brazil.

Technology transfers are highly complex, and typically take many years to complete – a constraint that manufacturers tend to underestimate. In some circumstances, however, transfers can take place much faster, provided that the partners assign the right level of resources to the endeavour. The Covid-19 pandemic gave a strong impetus to such acceleration, and some partnerships managed to achieve the technology transfer from start to finish within a single year.

Case study:
Capacity building partnership between GSK and Fiocruz[18]

Context

The collaboration between GSK and Fiocruz, cultivated over many decades, began with an agreement in 1985 to supply Oral Polio Vaccine (OPV). Since then, the two organisations have formed several strategic alliances to provide key vaccines, including Hib, MMR, and rotavirus vaccines. The first major technology transfer was for the Hib vaccine: the Brazilian government wanted to incorporate it into the national immunisation programme, and agreed to source the products directly from GSK / Fiocruz for years to come. The transfer itself took eight years to implement, with the following phases:

- 1999: years dedicated to building capacity: staff training, secondments, and upgrading facilities and equipment; then Fiocruz's start of bulk import, formulation, fill, freeze-dry, and quality control
- 2003: work on conjugation of polysaccharides and tetanus toxoid using imported materials, and later locally produced materials
- 2006: non-inferiority control to ensure quality parity
- 2007: official licensing of the product in Brazil

Impact

The transfer itself was successful, and contributed strongly to the inclusion of the Hib vaccine into Brazil's national immunisation programme. The initial strategy was to avoid rushing the transfer and instead to focus on building capabilities; the strategy perhaps slowed the product's progress to market, but it created strong foundations in conjugate vaccine technology, and thereby facilitated the partnership's venture into additional products.

Lessons

- Emphasis on using local talent, equipment, and facilities, as well as on good management
- Building on existing competences in conjugate technology
- Win-win situation, with guaranteed market access and grant support from the government

Case study:
Novavax's speedy Covid-19 technology transfers

Context

In 2020, Novavax announced a Covid-19 vaccine candidate, and in 2021 received regulatory authorisations from around the world. To deliver the vaccine to so many countries, Novavax invested heavily in its manufacturing and distribution capabilities across three continents, leveraging a strong network of partner manufacturers. The company created an internal Global Tech Transfer Team to optimise the transfer process and ensure highest-quality standards.

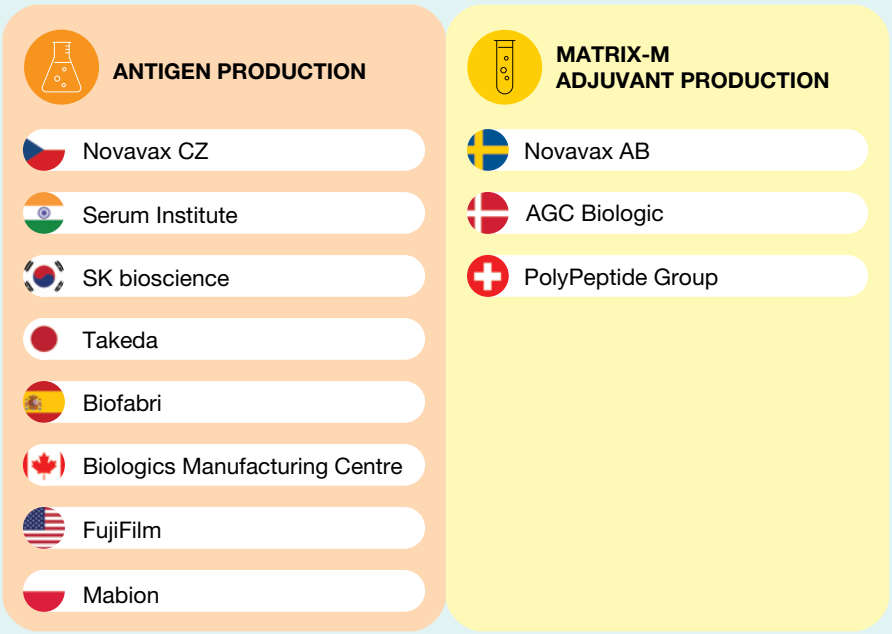
Impact

In just seven months, Novavax managed to scale up its manufacturing and distribution network to extend across the United States and most of the globe. It transferred the technology at record pace: some newly announced partners, such as SK Bioscience, were able to manufacture the Novovax vaccine just six months after the partnership agreement was signed.

Lessons

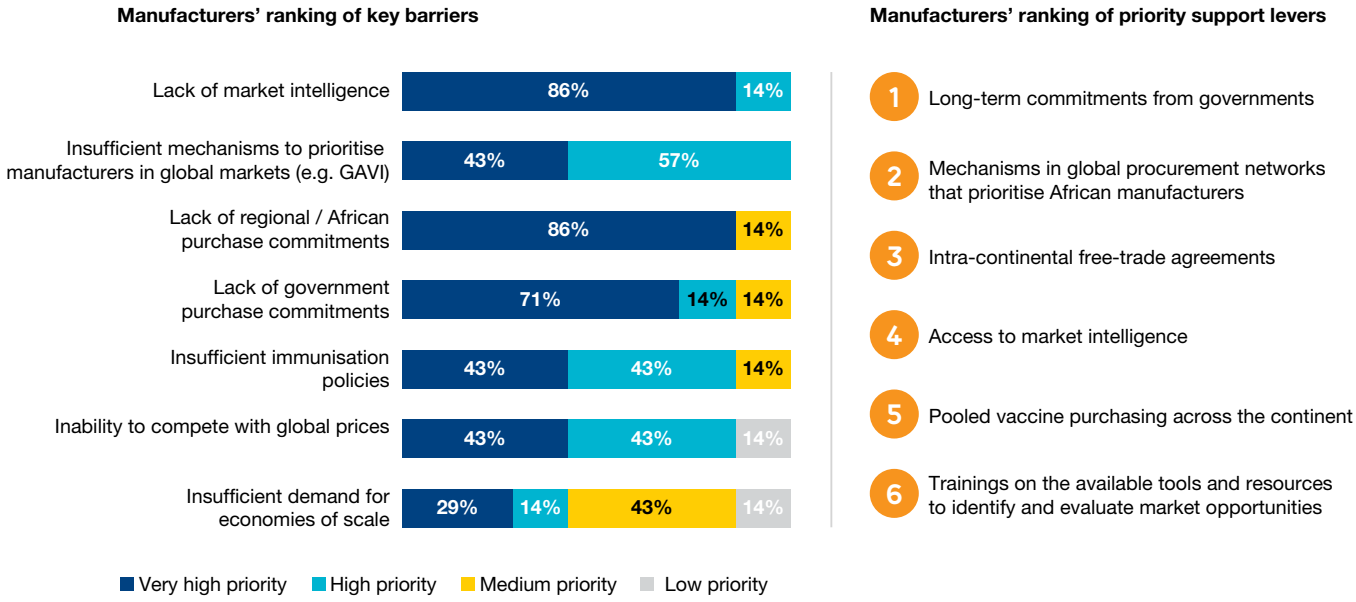
At the moment, tech transfers involving other products and technologies cannot expect to match that pace. But they can increase their speed and improve their efficiency , if they adapt their approach. The Novavax case might offer some useful tips. Among the key success factors for Novavax were the following: establishing strong teams to manage the technology transfer, designing manufacturing processes that would simplify the transfer process as far as possible, and dedicating sufficient resources to ensure that quality requirements are met.

Figure 33: Novavax's vaccine-manufacturing partners across the globe[34]



4. Market demand and intelligence

Figure 34 Key challenges and priority support areas related to Market Demand



Source: BCG survey (number of respondents = 9)

Market demand is another top concern for African manufacturers, who view it as a crucial factor in enabling change and scaling up vaccine production on the continent.

To secure market demand, manufacturers lay great importance on Advance Purchase Commitments from national governments. Advance Purchase Commitments help manufacturers hugely to secure financing (from private investors as well as DFIs) and to attract commercial partners (see section VI.3 on Technology transfers). Advance Purchase Commitments can send a reassuring signal to potential partners, as the case of the PPP involving GSK and BioManguinhos / Fiocruz in Brazil (outlined in section VI.3).

In interviews, manufacturers indicated support for procurement mechanisms that would prioritise African vaccine supply. They would welcome pooled procurement across African countries, but also wanted existing global procurement mechanisms to be adapted to accommodate more African supply, even if that meant higher prices in the short term.

Regarding pooled procurement mechanisms: these have proved their worth in some parts of the world, by helping to aggregate regional demand and lower the cost of vaccines. Many stakeholders cite the Pan American Health Organization (PAHO) mechanism as a case in point.

Case study:
Brazil's ten-year commitment to purchase vaccines from GSK

Context

At the turn of the century, part of GSK's strategy was to do more deals in LMICs, in order to expand distribution and increase revenues there. Hence GSK's $2.4 billion arrangement with the Brazilian government and BioManguinhos / Fiocruz, which involved sales of the GSK pneumococcal vaccine for ten years in Brazil. Initially, GSK would sell its vaccine at a fixed price (about $11.50 per dose), while transferring technology and know-how to Brazil for eventual domestic manufacturing (at which point the price would fall to about $5 per dose). The arrangement also involved GSK's co-sponsoring R&D for a new vaccine for Dengue fever.

Impact

Brazil was able to procure pneumococcal vaccine at a large discount (about $11.50 vs. the standard $30-40). And it gained access to the relevant technology, and today does its own end-to-end manufacturing for the national immunisation programme.

Lessons

If governments are active participants in trade agreements, local manufacturers can more easily get commitments from MNCs for fair technology transfers, and that can eventually enable countries to escape from vaccine dependency.

Source: Press releases; desktop research

Photo by Ivan Ekushenko via Dreamstime.com

Case study:
PAHO's Revolving and Strategic Funds, for pooled procurement of essential medicines, vaccines, and strategic health supplies

Context

PAHO promotes technical cooperation among its 35 member countries, working in partnership with ministries of health, government agencies, international agencies, and other parties. PAHO's Revolving and Strategic Funds are mechanisms for pooled procurement. The Revolving Fund is focused on vaccines, syringes, and cold-chain equipment, while the Strategic Fund is focused on medicines and health supplies. PAHO's work has three main aspects:

- Helping individual countries to estimate their requirements for vaccines and related supplies, to feed into PAHO's annual vaccine-demand forecasting for the region
- Using this demand forecasting to pool demand into a single regional order per product, thereby enabling bulk procurement of vaccines and hence minimising their prices
- Optimising the procurement process, by first evaluating competitive tenders for the consolidated supply of vaccines, then processing the purchase orders, and then coordinating shipments on behalf of member countries

Impact

The Revolving Fund has helped member states in the region in several ways:

- Providing easy access to a sustainable line of credit
- Creating economies of scale that enable bulk purchases at the lowest prices
- Facilitating long-term agreements for the region, and helping national immunisation programmes to achieve financial sustainability
- Helping to reduce or even eliminate vaccine-preventable diseases by maintaining vaccination coverage of over 80%

Lessons

For regional demand forecasting and pooling, collaboration is key. Pooled procurement can help to shape the vaccine market. And they can enhance transparency and market intelligence on regional demand, and thereby stimulate national manufacturing capacities.

Source: PAHO website; desktop research

If global procurement mechanisms remain unchanged, African countries will struggle to market their products more widely. The announced reform of Gavi's procurement mechanism was welcomed by manufacturers, which are hoping for a speedy implementation. The manufacturers, while aware of the complexity of global demand-supply dynamics, would benefit from the introduction of a minimum share of African supply. They indicate that if a vaccine is manufactured locally, then the African supply should be prioritised to some extent, even if it is not the most affordable option. The minimum share still needs to be defined, but it will have to be substantial if the PAVM FFA targets are to be reached.

Another recurring theme in our interviews was the lack of market intelligence – the kind of information flow that helps manufacturers to identify business opportunities. Manufacturers would appreciate greater transparency and better data on manufacturing activities in Africa: such changes would improve local decision-making and also support regional or continental coordination.

This problem has been addressed by Pharmexcil, the Pharmaceutical Export Promotion Council of India. If similar institutional support were available in Africa, it would help to guide priorities, advocate for manufacturers on global markets, and upgrade the regulatory and quality ecosystems.

Case study:

India's government agency for the promotion of national pharmaceutical exports

Context

Pharmexcil is an Indian government agency that promotes external trade by various activities, e.g. organising trade delegations outside India, arranging buyer-seller meetings, and convening international seminars. It also acts as the industry voice to government – for instance, by making suggestions on relevant policy issues. To help boost pharmaceutical exports, Pharmexcil provides information to its member companies on export opportunities, and serves as an intermediary between industry, government, and international agencies. Additionally, it maintains a database of industry-relevant information, such as regulatory procedures in other countries.

Impact

By providing crucial information to its members, Pharmexcil has contributed greatly to the remarkable progress achieved by India's pharmaceutical industry. As a result of Pharmexcil's efforts, Indian manufacturers are now far better informed on opportunities relating to potential clients and trade partners.

Lessons

An equivalent initiative in Africa could provide African vaccine manufacturers with information on partnership or funding opportunities. It could create a similarly valuable central database, from information and lessons contributed by existing members. By collating data on regulatory procedures, for instance, the database could help prospective vaccine manufacturers to overcome some of the obstacles to setting up new facilities.

Source: Pharmexcil website; desktop research

This problem has been addressed by Pharmexcil, the Pharmaceutical Export Promotion Council of India. If similar institutional support were available in Africa, it would help to guide priorities, advocate for manufacturers on global markets, and upgrade the regulatory and quality ecosystems.

Most stakeholders resoundingly affirmed the need for a mature, stable, and harmonised regulatory ecosystem. As of today, there are onlyfive National Regulatory Authorities (NRAs) in Africa – Egypt, Ghana, Nigeria, South Africa, and Tanzania – that have reached WHO Maturity Level 3 for vaccines.

Without mature regulatory authorities and harmonised regulations, manufacturers will have trouble marketing their products, accessing broader African markets, and attracting commercial partners. Manufacturers regard the current lack of maturity and lack of harmonisation as key barriers to their efforts to achieve scale.

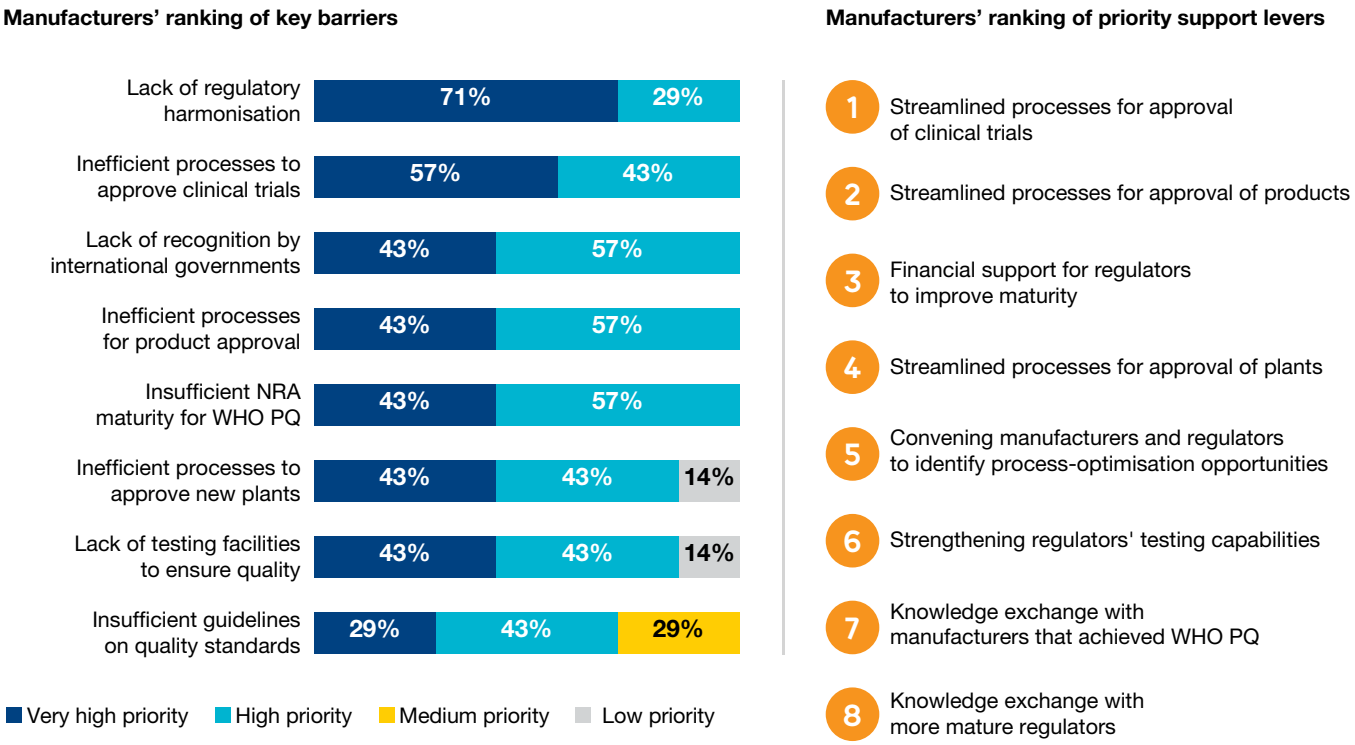
The manufacturers appear optimistic, however, that the many ongoing initiatives on the continent will address those challenges successfully. Three of these initiatives are detailed in Figure 36.

"Until now there has been insufficient market intelligence – manufacturers are unaware of each other's plans, and that can lead to overlaps."

- African manufacturer

5. Regulatory ecosystem

Figure 35: Key challenges and priority support areas related to Regulatory ecosystems



Source: BCG survey (number of respondents = 9)

Manufacturers, while appreciating all of these initiatives, remain concerned about challenges that they face in their national markets, and that receive less regional and global attention. Generally our interviewees felt that more needs to be done to improve and accelerate national regulatory processes for clinical-trial authorisations, manufacturing-site permits, and marketing authorisations. And they put forward several ideas to address these difficulties.

One suggestion was to convene local regulators and manufacturers to identify the main bottlenecks in current processes, and to form joint working groups to propose and test solutions.

Another suggestion was to make better use of existing platforms at regional and continental level to share best practices across countries. For instance, by studying the approval processes taken by different regulators, stakeholders could map out the ideal approach for all regulators to adopt. Such information sharing could help regulators and manufacturers alike to improve overall efficiency.

Figure 36: Select ongoing programmes aiming to strengthen and harmonise Africa's regulatory ecosystem

	African Medicines Agency (AMA)	African Vaccine Regulatory Forum (AVAREF)	African Medicines Regulatory Harmonization (AMRH)
Initiative			
Scope	Aims to strengthen the capacity of AU members to regulate medical products, provide regulatory guidance and harmonise medical regulatory efforts across Africa	Serves as platform to improve access to medical products across the continent by reducing review and approval times for clinical trial applications, by connecting NRAs and National Ethics Committees across Africa	Working in 33 countries in Africa towards creating a collaborative network of partners to create an enabling environment for the pharmaceutical sector
Progress to date	23 countries have ratified the AMA treaty, and 10 others have signed but not ratified yet Rwanda has been selected to host headquarters of the agency	Has been facilitating multiple continental joint-reviews of clinical trial applications Endorsed a set of guidelines to streamline the review process for clinical trials and expedite timelines for review and approvals	Designated 11 regional centres of regulatory excellence to strengthen African regulatory capacity

For more information, please refer to the report commissioned by Wellcome and published in July 2022 on regulatory systems strengthening in LMICs.[35] This report provides an in-depth analysis of the challenges impacting the vaccine regulatory ecosystem in Africa, and details opportunities for investors and development partners to strengthen the regulatory system and improve its sustainability.

Photo by Sergios via Freepik

Case study:
Kyasanur Forest Disease (KFD) vaccine and its regulatory failure[36]

Context

KFD is a lethal disease endemic to the southwestern region of India. It mainly affects agricultural and forest workers. The disease is spread by ticks and involves a viral haemorrhagic fever with a 3-10% mortality rate. No effective treatment is available yet, but a vaccine has been available for over three decades. Yet in October 2022, in Karnataka, an Indian state with a population of 64 million, the rollout of this vital lifesaving product was halted. The background was this: since 2002, the vaccine, manufactured by the Institute of Animal Health and Veterinary Biologicals (IAHVB), had not received formal regulatory review, and during those 20 years, its quality had declined appreciably, and was now registering much lower efficacy. The likely reason for this decline was that the master seed needed for the product had been multiplied more than twice, a violation of GMP, and the virus's genetic sequence was altered as a result.

Impact

The vaccine's efficacy, as measured in 2010, was 0% at one dose vs. 79.3% in 1994, and 62% at two doses vs. 93.5% in 1994. So most recipients of a single dose were entirely unprotected against a deadly disease, and state resources were wasted on an ineffective product.

Lessons

To function effectively, NRAs need the resources to monitor vaccine manufacturing rigorously and ensure compliance with GMP. In the absence of such high-quality NRAs, public trust will falter, and countries or regions will be unable to establish a sustainable vaccine manufacturing industry.

"I believe that quality is the soul of any medicine."

- African manufacturer

Manufacturers also raised concerns about the regulatory timeline. Products need WHO-prequalification if Gavi is to procure them, and only one vaccine currently manufactured in Africa is WHO prequalified. It could take many years before other locally-manufactured products receive prequalification. While stressing the need for quality, safety, and efficacy of vaccines manufactured in Africa, stakeholders would welcome a regulatory process that enables products to get to market more rapidly.

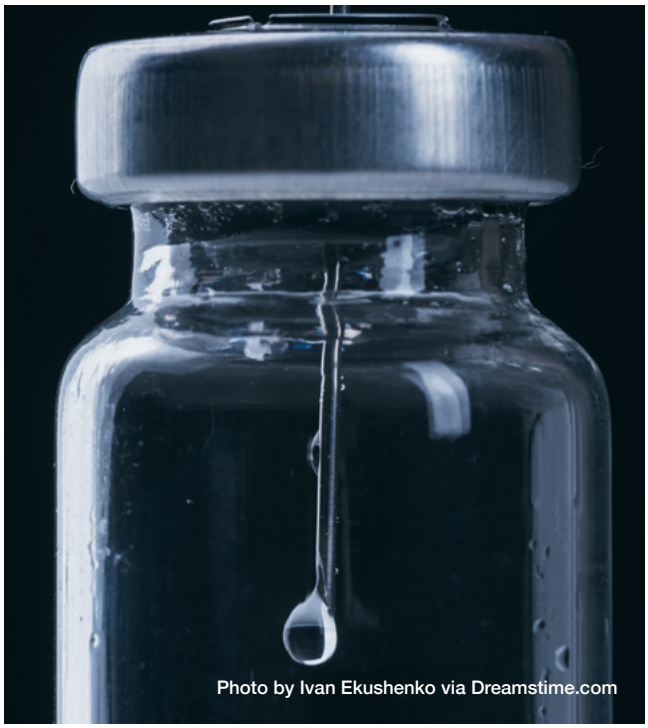
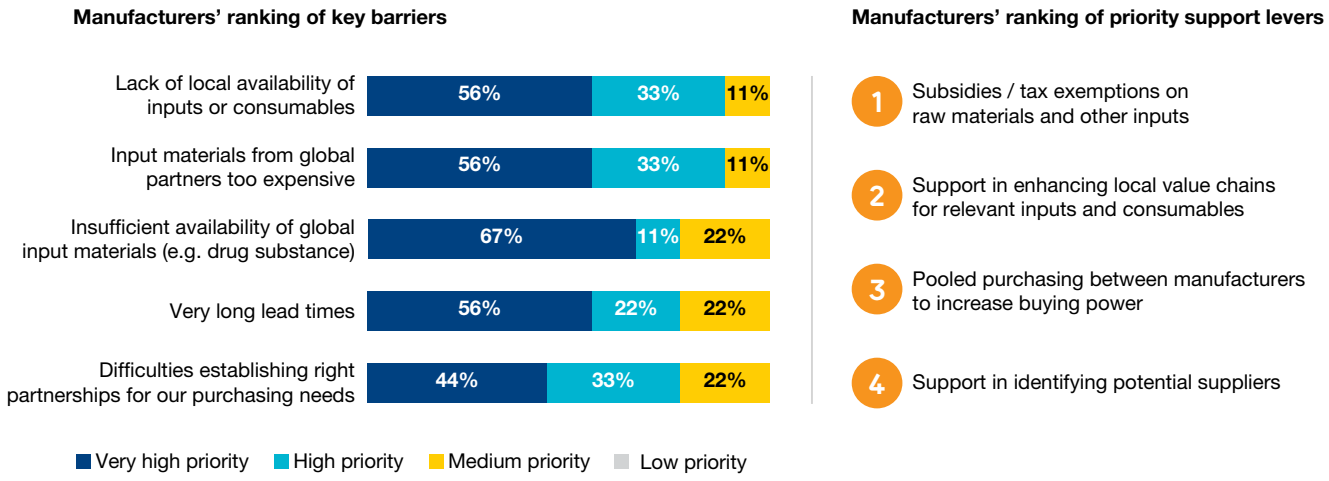


Photo by Ivan Ekushenko via Dreamstime.com

6. Supply chain

Figure 37: Key challenges and priority support areas related to dependence on global Supply Chains



Source: BCG survey (number of respondents = 9)

For many manufacturers, the issue of global Supply chains is a very important one, in view of its impact on the vaccine-manufacturing industry in Africa. African manufacturers are heavily dependent on imports across the value chain, largely owing to the shortage of local suppliers for key consumables (e.g. sterile bottles or glass vials) and inputs such as DS. When manufacturers have to rely so much on imports, that greatly increases costs for them.

So manufacturers are keen to find ways of ensuring a strong local supply of inputs and consumables, and thereby reduce reliance on overseas imports and compete better with manufacturers from abroad. There are plenty of precedents. In India, many local value chains have been formed close to manufacturers. And South Korea, during the Covid pandemic, quickly expanded the capacity of relevant local suppliers, and thereby improved not only its own supply security but also that of global markets.

African manufacturers and other stakeholders are well aware that upgrading the local supply chain will take time, and that their dependence on imports will persist for a while. In the short- to mid-term, the goals should be to make the imported products more affordable. Manufacturers would like to see more tax exemptions and subsidies on raw materials. In general, they would also welcome a pooled purchasing mechanism, to reinforce their buying power. In short, manufacturers would benefit from supportive government policies aimed at enhancing their sustainability.

"The supply chain of consumables and raw materials needs to be developed in line with vaccine manufacturing. If not, Africa will be just as dependent on external supply during future pandemics."

- DCVM

Case study:
South Korea's rapid and massive increase in production of syringes[37]

Context

During the Covid-19 pandemic, South Korea faced a shortage of syringes, to the potential detriment of the national vaccination programme. The government encouraged Poonglim, a company of 80 employees, to scale up production of their speciality syringes. The type of syringe, known as a low dead space syringe (LDSS), helps to reduce wastage, by minimising the amount of drug remaining in each syringe after use. By using the syringe, healthcare professionals could extract six doses from each BioNTech / Pfizer vial, rather than the standard five. The government helped to arrange financing for Poonglim, and contributed further by drafting in Samsung to help increase the scale of Poonglim's production capabilities and advise on regulatory procedures.

Impact

Within four months, Poonglim was able to increase its syringe production seven-fold, enabling an annual output of 360 million. The company is now one of the largest makers of LDSSs in the world and has more than 400 employees.

Lessons

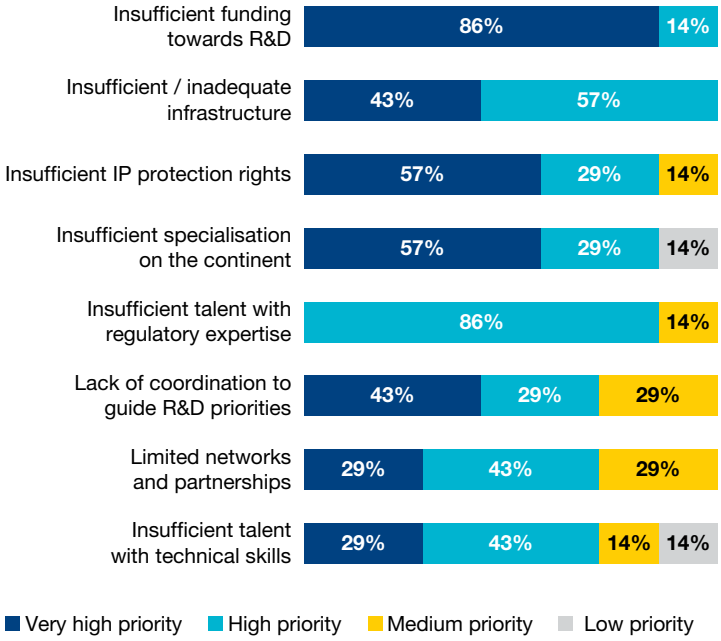
By supporting the scale-up of local manufacturing capacity for consumables such as syringes, countries can enhance supply security and improve access to vaccines for their population.

Photo by reewungjunerr via Freepik

7. R&D

Figure 38: Key challenges and priority support areas related to R&D

Manufacturers' ranking of key barriers



Manufacturers' ranking of priority support levers

1. Establish organisations akin to Hilleman to develop products locally and license to African manufacturer
2. Scale-up of critical infrastructure
3. Setting up of African R&D coordinating platform
4. Facilitating of information sharing and collaboration across regions and countries
5. Financial / tax incentives for R&D activities
6. Connecting with global partners to collaborate on R&D
7. Connecting with potential funders of R&D

Source: BCG survey (number of respondents = 9)

R&D is a central part of the vaccine ecosystem, but in Africa it is probably the most underdeveloped part. Stakeholders cited the limited number of R&D facilities on the continent, and the lack of core upstream capabilities to support vaccine manufacturing.

Unless proper R&D capabilities are established, manufacturers on the continent will remain dependent on technology-transfer partnerships with other DCVMs and with MNCs. The benefits of investing in the quest for novel vaccines or technologies would outweigh the costs, given the likely health improvements for the population. Arguably, if Africa's modest vaccine industry is to expand, it cannot afford not to invest in R&D, at least in the medium to long term. R&D investment will stimulate product innovation and competitiveness, which in turn would help to safeguard future vaccine supply. LMICs elsewhere in the world are already heavily involved: as of October 2019, there were over 180 vaccine projects in the R&D pipeline of the Developing Countries Vaccine Manufacturers Network (DCVMN) members, 24 of which were novel vaccines.[38] Most African stakeholders want Africa likewise to enhance its upstream capabilities, in parallel with expanding the manufacturing side.

"Investing in R&D on the value chain is vital, but it may take decades."

- Global health organisation

"There has to be a pipeline of products – you cannot only look at what you'll produce today, you need a flourishing R&D environment."

- Global biopharmaceutical company

Case study:

The BactiVac Network's seed financing, which unlocked further research funds[39]

Context

The BactiVac Network brings together academics, manufacturers, and other relevant partners from the UK and LMICs. DCVMs can turn to BactiVac for initial catalyst funding, and then to industrial partners for further funding of viable projects. The network consists of more than 1,300 members, half of them from LMICs. The initial funding, usually £50,000, fortifies early bacterial-vaccine projects by enabling researchers to gain proof-of-concept data, which would then facilitate further funding applications.

Impact

BactiVac's smaller-scale grants have proved remarkably successful in generating additional funding from governments, donors, and other organisations. The 50 grants awarded to date have led to the unlocking of more than $18 million of additional funding, and several of the sponsored vaccines have now reached the clinical stage.

Lessons

Vaccine R&D, in Africa as elsewhere, will rely heavily on partnerships and collaboration. Small-scale initial funding, if targeted accurately, can lead to the launch of large-scale projects in the future, which could in turn lead to fully marketable new products.

Local manufacturers expressed various concerns, however. One obvious problem is that upstream development will require massive investment. R&D capabilities need heavy public funding, not only for financing well-defined R&D projects, but at an earlier stage too – seed money that can help prove a concept and unlock further and larger financing from other organisations. One model in this regard is the Bacterial Vaccines Network (BactiVac), which used its modest seed money to great effect.

Photo by alexkich via Freepik

Case study:

CAPRISA's R&D infrastructure, supported by local and international organisations[40]

Context

CAPRISA is a collaborative centre conducting innovative research into HIV pathogenesis, TB-HIV treatment, and HIV prevention. It was established in 2002 as a partnership, under a programme funded by the US National Institutes of Health (NIH), of four South African institutions (University of Kwa-Zulu Natal, University of Cape Town, University of Western Cape, South African National Institute of Communicable Diseases) and Columbia University in New York. One of its three primary goals is to build local research infrastructure and capacity in virology, immunology, clinical infectious disease, bioinformatics, epidemiology, and biostatistics. It has received support and funding from numerous organisations and programmes, including the NIH Fogarty International Center (US NIH), the BMGF, the NRF Research Infrastructure Support Programme, for the expansion of R&D facilities dealing with high-impact endemic diseases.

Impact

Over the years, CAPRISA has built or upgraded infrastructure and acquired state-of-the-art equipment to support its studies. It has also provided specialised training to more than 600 scientists in southern Africa.

Lessons

Collaborations between local and global organisations can prove highly productive for medical R&D in Africa. Following the example of CAPRISA, vaccine R&D could benefit from joint endeavours involving local universities, international universities, and other research institutions.

Many of our interviewees also mentioned the need for investment to upgrade the relevant infrastructure, from labs to animal-testing facilities – though many stakeholders noted that Africa does have a strong clinical-trial capacity. One local initiative, that of the Centre for the Aids Programme of Research in South Africa (CAPRISA), though not directly related to vaccine R&D, has some useful pointers for vaccine-development policymakers.

Almost all manufacturers recognise R&D as a crucial contributor to progressing the continent's vaccine industry, but they are mindful of the complexity, and many of them have no intention of establishing R&D capabilities in-house in the short-term. An alternative approach for them would be to collaborate with a network of dedicated R&D institutions, which would generate a pipeline of products for the manufacturers to produce. Similar models are common in HICs, where MNCs choose not to develop products from scratch but rather to complete clinical trials for de-risked products from specialised research organisations, and then proceed to full-scale manufacturing. The IVI/Hilleman model is one that appealed to African manufacturers and global health organisations alike.

Finally, manufacturers' concerns about Talent (see section VI.2 above) are relevant here too, and any talent-building effort should include an R&D focus. R&D capabilities will also benefit the manufacturing industry with a pipeline of products, and with skilled scientists for the upstream manufacturing activities.

Case study:
IVI and Hilleman Laboratories partnership

Context

IVI and Hilleman Laboratories are two vaccine research organisations researching and developing cost-effective vaccines. IVI, based in South Korea, was launched in 1997 at the initiative of the United Nations Development Programme. Hilleman Laboratories is a joint venture between Merck Sharp & Dohme Corp. and the Wellcome Trust operating mostly from Singapore. In October 2022, IVI and Hilleman Laboratories signed a three-year Memorandum of Understanding to pursue vaccine R&D together. The aim is to broaden the availability of safe, effective, and affordable vaccines in LMICs. Under the agreement, IVI and Hilleman will develop joint funding frameworks for vaccine R&D and manufacturing. The activities will include early development of novel or improved vaccines, candidate selection, design, manufacturing process development, and clinical studies.

Impact

By combining their expertise and complementing each other's strengths, the partners should streamline the vaccine-development process. If things go to plan, the R&D timeline will reduce, and vaccine candidates will advance faster from clinical development through to commercialisation.

Lessons

Collaborative efforts, especially when the partners have complementary strengths, tend to facilitate the transfer of knowledge and skills, and improve the success rate of R&D endeavours. African manufacturers could use the IVI/Hilleman partnership as a template, ideally joining forces with a global R&D partner.

Source: Organisation websites; desktop research

Photo by Drazen Zigic via Freepik

Case study:
WHO's mRNA vaccine technology transfer hub in South Africa[41]

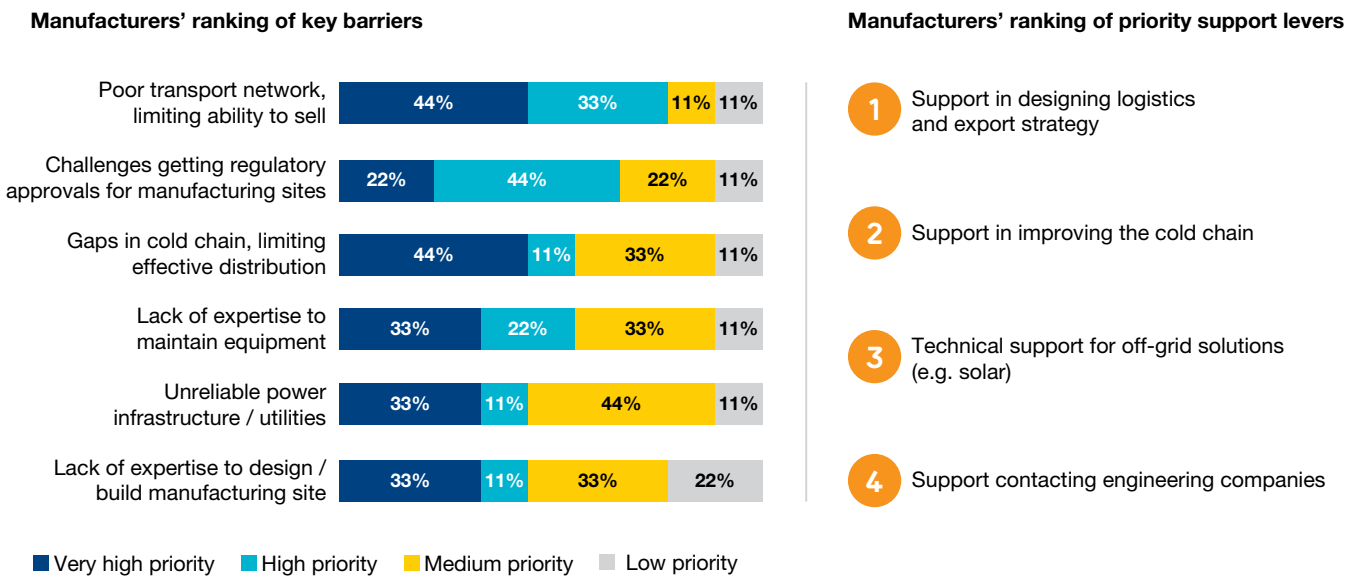
WHO established the mRNA vaccine technology transfer hub-and-spoke model as a means of developing mRNA vaccine capacity in under-served regions. The hub is also supported by the Medicines Patent Pool and the Act-Accelerator/COVAX. The investment in vaccine research, development, and production is expected to be about $100 million over five years. It is run by a consortium of three organisations:

- The South African Medical Research Council (SAMRC) is conducting the research
- The South African company Afrigen serves as the "hub", and is establishing the vaccine-production technology
- Biovac will be the first manufacturing "spoke" to mass-produce the vaccine for national and regional use

Specialised R&D training is given through training centres and by WHO. The initiative provides the opportunity to shorten the timeline normally involved in developing and transferring R&D capabilities.

8. Infrastructure

Figure 39: Key challenges and priority support areas related to Infrastructure



Source: BCG survey (number of respondents = 9)

From the manufacturers' perspective, Infrastructure does not rank as one of the top-priority issues. Nevertheless, it is a key component of any manufacturing strategy and an important limiting factor, particularly for those organisations still working to build capabilities. Some of the most serious challenges cited by manufacturers relate to their ability to transport and sell goods. The transportation network has gaps, as does the cold-chain infrastructure, so delivery to end users is far from optimal.

Manufacturers mentioned several areas where support could be most helpful, particularly in designing logistics and export strategies, and in implementing cold-chain strategies. The Covid-19 pandemic produced many heartening examples of such support.

"Manufacturing doses is one thing, but administering them is another thing. During the pandemic, Africa struggled with the last mile infrastructure and logistics."

- Global biopharmaceutical company

Case study:
UNICEF support to establish ultra-cold chain capacity in Africa[42]

Context

To maintain the cold chain needed in the distribution of vaccines, many countries needed to upgrade local infrastructure during the Covid-19 pandemic. Specifically, mRNA vaccines had to be kept at temperatures of -60°C to -80°C, and in most countries the relevant ultra-cold chain infrastructure was simply unavailable. Initially, more than 45 countries receiving mRNA doses through UNICEF also requested support to develop ultra-cold chain capabilities. UNICEF – in collaboration with Gavi, COVAX partners, and donors – rose to the challenge, and the necessary equipment was procured and delivered within four months, rather than taking a year or more as would happen in normal times.

Impact

UNICEF delivered over 800 ultra-cold-chain freezers, with a capacity of 200 million vaccines, to nearly 70 countries around the world by the end of 2021, and thereby enabled them to weather the pandemic far more effectively.

Lessons

Without adequate infrastructure for vaccine transportation and storage, countries' response to disease is seriously compromised. For many vaccination campaigns, the cold chain is an indispensable component, and needs prompt installing and continuous maintenance.

Case study:

The cold-chain strategy for vaccines in Egypt, with support from Sinovac[43]

Context

Egypt faced serious supply-chain challenges during the Covid-19 pandemic – challenges that needed an efficient and rapid response if the population was to be vaccinated effectively. In early 2020, the Egyptian government launched a major vaccine-distribution effort, providing all parts of the country with storage facilities and vehicles capable of maintaining the cold chain. Sinovac sponsored a high-tech cold-chain complex in Cairo, equipped to store over 150 million doses of vaccines, and capable of automatic loading and unloading, maximising efficiency, and reducing costs. Elsewhere, throughout the country, warehouse infrastructure was upgraded. The government also arranged for staff to receive special training on how to handle the vaccines. The cold chain was strictly monitored during storage and transportation to ensure the safety of the vaccines. The storage availability and usage rates of each region were monitored centrally, and the vaccine sites were supplied with emergency electrical generators.

Impact

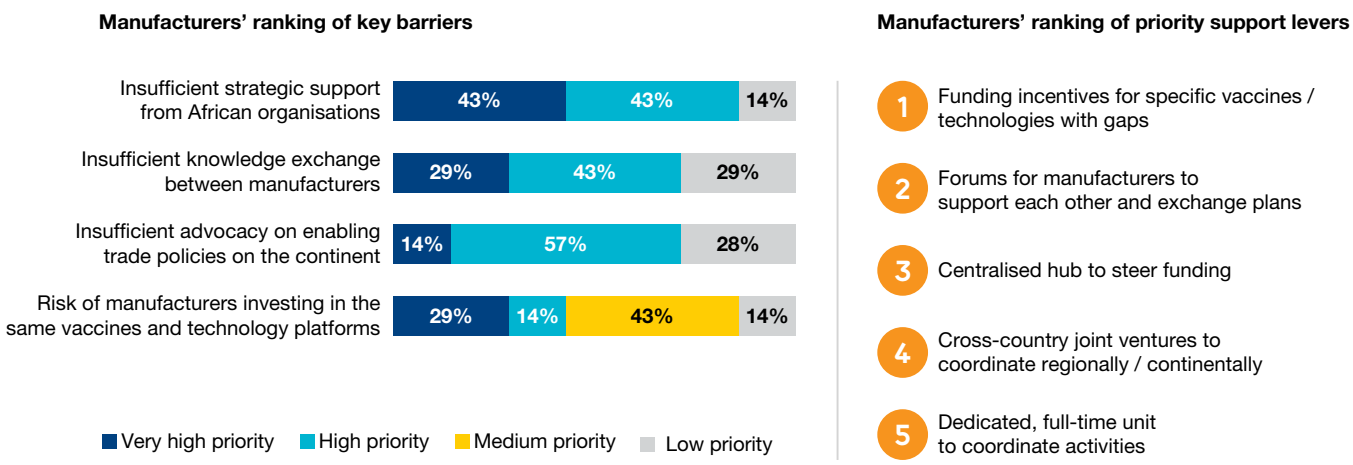
Sinovac's collaboration with the Egyptian government contributed to the efficient rollout of Covid-19 vaccinations in the country. More than 90% of Egyptians have been vaccinated, vs. the average coverage rate in Africa of about 40%.

Lessons

Robust structural support from governments and private organisations can be the backbone of effective vaccine rollouts. Strong central planning and management of infrastructure will enable more cost-effective use of manufacturing capacity and more equitable access to vaccines.

9. Coordination

Figure 40: Key challenges and priority support areas related to Coordination



Source: BCG survey (number of respondents = 9)

Interestingly, Coordination risks do not represent a top-priority concern for African manufacturers. Since the vaccine-manufacturing ecosystem in Africa is still in its early stages, and full of open spaces, manufacturers have limited concerns about overlaps or cannibalisation.

This is not to say that manufacturers are averse to collaborating. They are actually looking for increased cooperation, particularly in information sharing. While many admit to having been wary in the past about sharing details of their strategy, most are now willing to share more. In interviews, the African manufacturers tended to agree that by increasing collaboration with their peers, they could help themselves, as well as the industry as a whole, to make better business decisions and identify market opportunities.

Many manufacturers suggest that the mechanisms would best be developed by a continental organisation like PAVM, which could facilitate coordination by setting up forums, centralising and disseminating information, providing market intelligence, and identifying strategic priorities. African manufacturers, under the umbrella of AVMI, recently joined forces to present a unified voice for the industry in discussions with global health organisations.

"Once the system gets going and funding is there with designated and orchestrated governance, everyone will see the advantage of working together."

- African health organisation

Many global stakeholders favoured the idea of a centralised supervisory body - the type of organisation that would assign products and technology platforms for each manufacturer. But unsurprisingly, the African manufacturers expressed little enthusiasm for it, and clearly prefer to retain their own decision-making powers.

Some manufacturers would also consider the idea of long-term collaborations with counterparts elsewhere on the continent, through strategic partnerships or joint ventures. While opinion is divided, one option was for regional hubs that aggregate capacity among manufacturers. Since vaccine manufacturing is a scale-driven business, it can draw on the experience of other industries that tend to achieve scale through consolidations. Consider the formation of Airbus, when a fragmented European market converged to create a global giant that challenged the US dominance in the field.

Photo by luza studios / E+ via Getty Images

Case study:
The Airbus joint venture, which produced a global champion

Context

As with vaccines, aircraft manufacturing relies very much on economies of scale and R&D-driven innovation. Before 1970, the European aircraft-manufacturing industry was highly fragmented, with many companies attempting end-to-end production but unable to compete with US companies. Many of the European manufacturers accepted this reality, and opted to join forces in a joint venture. Germany, the United Kingdom, and France took equal shares, and all three governments undertook to provide equal financing. Soon after, the Netherlands and Spain signed up too.

Impact

Each founding-member country would contribute components in which it had particular expertise, and these components would then merge into individual aeroplanes at an assembly plant. By 2000, the companies had themselves merged into one entity, though country specialisation still applies. (See Figure 41.) Airbus has subsequently expanded operations into other EU countries, with sites in Italy, Poland, and Portugal.

Figure 41: Airbus case studies – components contributed by member country

Key success factors

- The terms of the joint venture ensured that each country benefited from Airbus's success
- To promote innovation, EU governments offered Airbus substantial tax exemptions and incentives for R&D
- Specialisation allowed each company to focus on innovation in the specific components that they contributed
- Knowledge exchange between companies facilitated learning
- Although supported by governments, the company remained private, and so could ensure sustainability and profitability
- Coordination was simplified, so that each country could adopt the optimal strategy and maximise benefits all round

Lessons

Specialised manufacturing requirements. However, the Airbus model could be applicable to DS and F&F, to this extent: manufacturers could specialise in various value-chain steps and would benefit from large scale. And as with the companies that formed Airbus, African vaccine manufacturers could build on each other's strengths by engaging in knowledge transfer.

Source: Mas Morate, Fernando, et al. "Collaborative Engineering: an Airbus case study." Procedia Engineering. 2013 (63): 336-345

VII. Conclusion

The African ambition for vaccine manufacturing is motivated first and foremost by public-health considerations. Vaccine manufacturers share that motivation, of course, but must also address economic considerations in order to build successful businesses. The public-health vision has to contend with the economic and operational reality, and it is imperative that African and global stakeholders bear that in mind. Manufacturers have a crucial role to play in attaining the public-health objectives, but they need the right conditions if they are to play the role successfully.

While there are no silver bullets, African vaccine manufacturers have indicated various support initiatives that could create the right conditions.

The needed changes involve procurement policies, financial mechanisms, and coordination processes, and such changes take time to implement, especially since they have to take account of global demand-supply dynamics. And even the "must-have" changes that need immediate implementation will, once implemented, also need regular revisiting and adaptation.

The mood among stakeholders is one of optimism – that the current and forthcoming efforts will succeed in scaling up Africa's vaccine-manufacturing capacity. Recent encouraging announcements, flurry of activity ongoing at the local, regional and global levels, as well the outpouring of support and interest in this report gives us confidence that these efforts if well directed can achieve the desired and needed impact.

Photo by tayhifi5 via Freepik

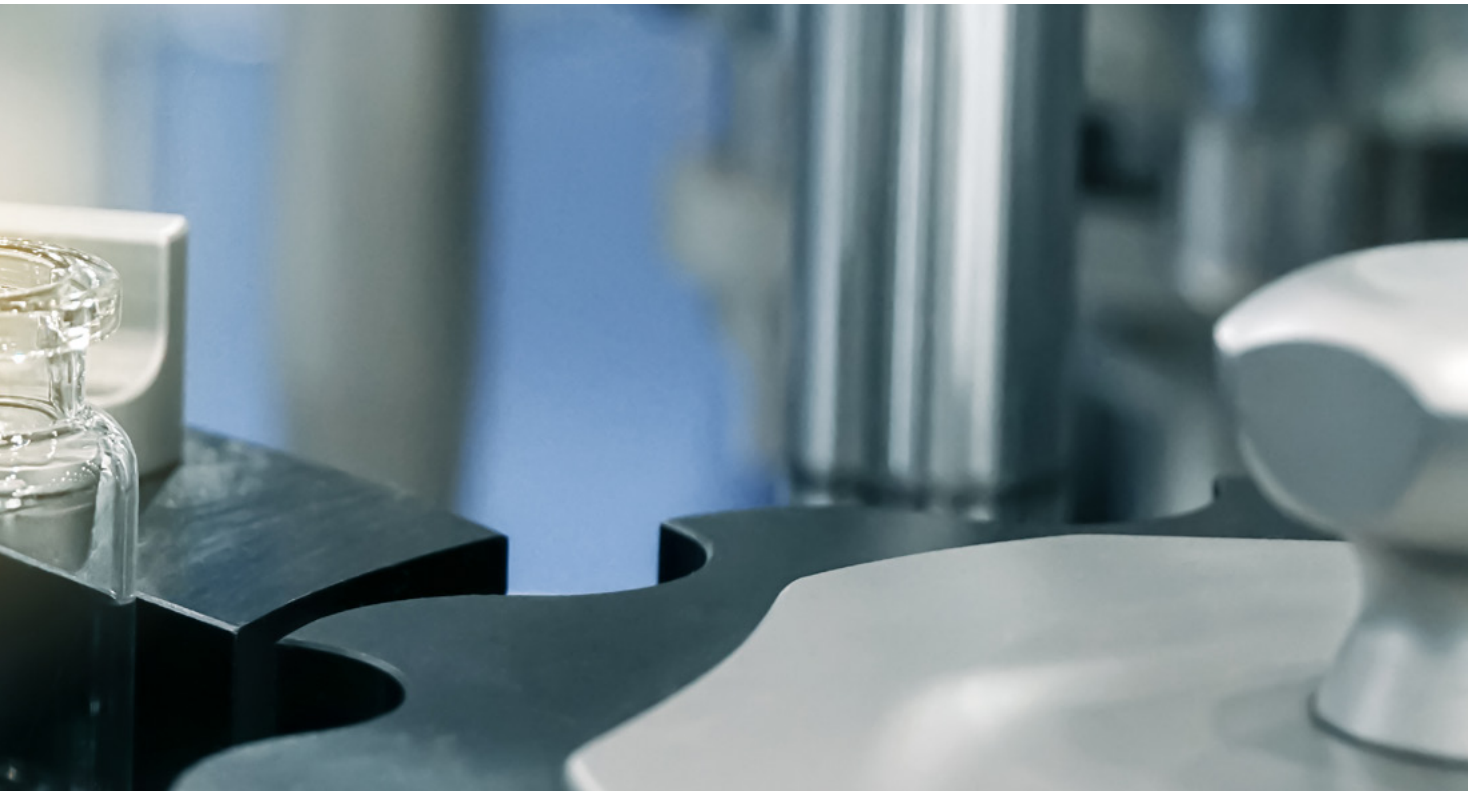
Figure 42: Summary of risks and required support per stakeholder group

Three major risks to the economic viability of African vaccine manufacturers

Sustainability risk	Strategic risk	Support risk
Uncoordinated efforts, creating risk of overcapacity No concrete announcements made yet to break the historical dynamic	Current strategy and set of possible initiatives are fairly broad Need for further prioritisation (antigens, vaccines, technology platforms)	As the Covid-19 pandemic recedes, risk of loss in attention and effort of stakeholders to support African manufacturers

Priority support areas per stakeholder group from manufacturers' perspectives

African governments	• Prioritise African supply (even if more expensive) through national or continental advance purchase commitments • Ensure a conducive economic and regulatory environment for the manufacturers
Global health organisations	• Review procurement mechanism(s) to facilitate market access and offer predictable demand to African supply • Set up financial mechanism(s) to counterbalance the lack of price-competitiveness
Donors	• Offer sustained support to manufacturers to help them overcome the obstacles to scaling up capacity • In particular, support manufacturers with three priority areas: Access to finance, Talent and Technology transfers
Continental organisations	• Coordinate information sharing, provide market intelligence, and dynamically revisit strategic ambitions and priorities to create a sustainable vaccine manufacturing industry



VIII. Appendix

Appendix A: Table of Figures

Appendix B: Acknowledgements

The views and opinions expressed in this report represent those of the joint Wellcome, Biovac and Boston Consulting Group project team, and do not necessarily reflect those of the individuals and organisations named below.

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Local manufacturers and manufacturing organisations:

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- Afrigen Biologics & Vaccines - Petro Terblanche, CEO
- Aspen Pharmacare - Stavros Nicolaou, Group Senior Executive: Strategic Trade Development
- Biovac - Morena Makhoana, CEO; Mark MacNaughton, Chief Operations Officer; Patrick Tippoo, Head: Science & Innovation, and founding member of AVMI; Ebrahim Mohammed, Group Leader: Downstream Processing
- Biovaccines - Oyewale Tomori, Chairman
- Brentec Investments - Vinand Nantulya, Founder & Managing Director
- Cooper Pharma - Ayman Cheikh Lahlou, CEO
- DEI BioPharma - Hitesh Upreti, former CEO
- Ethiopian Public Health Institute - Birhanu Hurisa, Director: Vaccine & Diagnostic Production Directorate
- Eva Pharma - Riad Armanious, CEO
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- Institut Pasteur Tunis - Nizar Laabadi, Director: Manufacturing of Vaccines & Serums
- Kenya BioVax Institute - Michael Lusiola, CEO
- Minapharm/ProBioGen - Lutz Hilbrich, CEO ProBioGen

HIC biopharmaceutical companies and manufacturing organisations:

- BIO - Phyllis Arthur, VP: Infectious Diseases & Diagnostics Policy
- BioNTech - Pedro Alonso, former Director of Global Malaria Programme at WHO
- GSK - Francesco Berlanda Scorza, Global Health R&D Vaccines Head, and GSK Vaccines for Global

Photo by Maskot / DigitalVision via Getty Images

Health (GVGH) Institute Director

- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) - Thomas Cueni, Director General
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LMIC biopharmaceutical companies:

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Global health organisations and research organisations:

- Aga Khan Foundation - Galeb Gulam, CEO Industrial Promotion Services Kenya
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- Coalition for Epidemic Preparedness Innovations (CEPI) - Matthew Downham, Director: Manufacturing & Supply Chain Networks
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- International Finance Corporation (IFC) - Farid Fezoua, Director: Health & Education
- International Vaccine Institute (IVI) - Jerome Kim, Director General
- PATH - David Kaslow, Chief Scientific Officer: Essential Medicines and Head: PATH's Center for Vaccine Innovation and Access
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Regional health organisations:

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- African Union (AU) - Lwazi Manzi, Head of Secretariat: AU Commission on COVID-19
- African Vaccine Regulatory Forum (AVAREF) - Dicky Akanmori, Regional Adviser for Vaccine Research and Regulation
- Partnership for African Vaccine Manufacturing (PAVM) - Niteen Wairagkar, Lead: R&D and Regulation

Local regulators:

- Ghana Food & Drugs Authority (FDA) - Eric Karikari Boateng, Head of Laboratory
- South African Health Products Regulatory Authority (SAHPRA) - Boitumelo Semete, CEO
- Tanzania Medicines & Medical Devices Authority (TMDA) - Adam Mitangu Fimbo, Director General

Academia:

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Independent experts:

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- Kristopher Howard, Global Vaccine & Pharmaceutical Manufacturing Consultant, Managing Director at NRL Enterprise, Former Emerging Markets Vaccines & Biologics Business Operations Lead at Merck
- Luc Debruyne, Strategy advisor to CEO CEPI, Professor at KULeuven Belgium, Scientific Advisor to Biovac, Former President of Vaccines at GSK

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IX. Abbreviations

A

Africa CDC

Africa Centres for Disease Control and Prevention

AMA

Africa Medicines Agency

AMR

Antimicrobial Resistance

AMRH

African Medicines Regulatory Harmonization

AU

African Union

AVATT

Africa Vaccine Acquisition Task Team

AVAREF

African Vaccine Regulatory Forum

AVMI

African Vaccine Manufacturing Initiative

B

BCG

Bacillus Calmette-Guerin

BMGF

Bill & Melinda Gates Foundation

C

CAPRISA

Centre for the Aids Programme of Research in South Africa

CAPEX

Capital Expenditures

CEPI

Coalition for Epidemic Preparedness Innovations

COGS

Cost of Goods Sold

COVAX

Covid-19 Vaccines Global Access

D

DALYs

Disability-Adjusted Life Years

DCVM

Developing Country Vaccine Manufacturer

DFI

Development Finance Institution

ds

Dose

DS

Drug Substance

DT

Diphtheria-Tetanus

DTP

Diphtheria-Tetanus-Pertussis

E

E2E

End-to-end

F

F&F
Fill-and-Finish

G

GBS

Group B Streptococcus

GMP

Good Manufacturing Practice

H

HepB

Hepatitis B

Hib

Haemophilus Influenzae Type B

HIC

High-Income Country

HIV

Human Immunodeficiency Virus

HPV

Human Papillomavirus

I

IPV

Inactivated Poliovirus Vaccine

IVI

International Vaccine Institute

J

J.ENC.
Japanese Encephalitis

K

KFD

Kyasanur Forest Disease

L

LDSS

Low Dead Space Syringe

LMICs

Low- and Middle-Income Countries

M

MMR

Measles-Mumps-Rubella

MNC

Multinational Corporation

MR

Measles-Rubella

mRNA

messenger ribonucleic acid

MVP

Meningitis Vaccine Project

N

NPV

Net Present Value

NRA

National Regulatory Authority

NVI

Netherlands Vaccine Institute

O

OCV

Oral Cholera Vaccine

OPV

Oral Poliovirus Vaccine

P

PAHO

Pan American Health Organization

PAVM

Partnerships for African Vaccine Manufacturing

PAVM FFA

Partnerships for African Vaccine Manufacturing Framework For Action

PCV

Pneumococcal Conjugate Vaccine

PPP

Public-Private Partnership

PQ

Prequalification

R

R&D

Research and Development

RECs

Regional Economic Communities

S

SII

Serum Institute of India

sIPV

Sabin Inactivated Polio Vaccine

STEM

Science, Technology, Engineering, and Mathematics

T

TB

Tuberculosis

Td

Tetanus and Diphtheria

TCV

Typhoid Conjugate Vaccine

W

WHO

World Health Organisation

Photo by Serhii Neznamov via Dreamstime.com

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