



South Africa Country Profile

2023

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a. Immunization program overview

b. Vaccine spending

c. Product selection and opportunities

d. Market access

South Africa is a fully self-financing, upper middle-income nation in Africa with a strong tender system and regulatory capacity



Indicators	Status (2022)
Population, 2022	59,893,885
GNI per capita (Atlas Method), 2022	\$6,780
Government Health Spend (% per GDP), 2020	8.58%
Gavi Country Status (Y/N, Year of Transition)	Never Gavi-eligible
EPI Budget	<p>South African is a self-procuring MIC. South Africa spending on vaccines:</p> <ul style="list-style-type: none"> • Annual EPI Budget Estimates (Current tender. 2024-2026): ~US\$193 million per year <ul style="list-style-type: none"> – Hexa: ~\$116 million (60%) – DTaP: ~\$28 million (14%) – PCV: ~\$22 million (11%) – RV: ~\$17 million (9%) – HPV: ~\$11 million (6%)
COVAX country (Y/N Note)	Yes/South Africa has received Covid-19 doses through the COVAX vaccine-sharing facility
Birth Cohort (M), 2022	1,127,184
EPI Coverage	The national immunisation under 1 year coverage was 83.5% in 2019/20, an improvement of 1.6% from 2018/19 to 2019/20. Overall, there is an increasing trend in the immunisation under 1 year coverage since 2015/16, except for a drop in the coverage in 2016/17 due to the global hexavalent vaccine stock-out
Under 5 Mortality Rate (# per 1,000 live births)	32 per 1,000 live births in year 2020, dropped from 101 in 1974
National EPI Manager	National Department of Health Expanded Programme Immunisation (EPI)

South Africa's EPI schedule includes 9 vaccines; it is one of 3 countries on the African continent utilizing Hexa (aP) as part of the EPI schedule

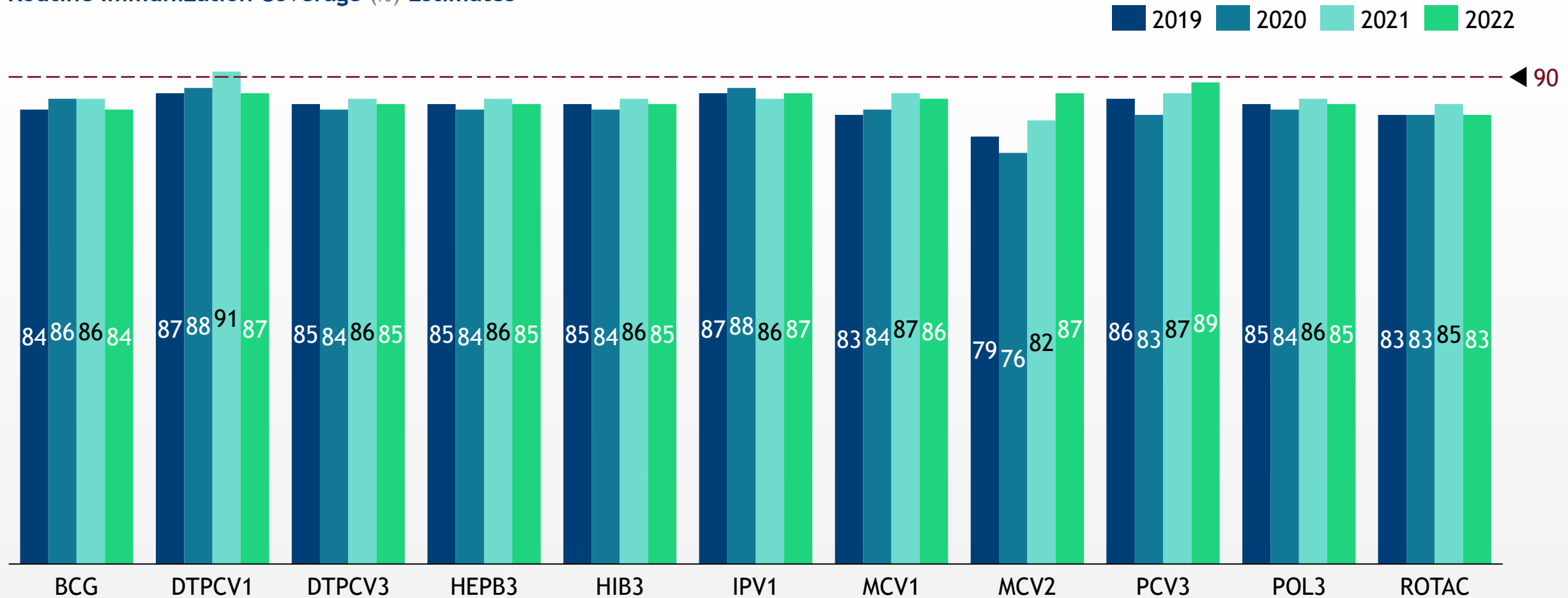


Vaccine	Abbreviation	Disease prevention	Birth	6 weeks	10 weeks	14 weeks	9 months	18 months	6 years	9 years
Bacillus Calmette-Guérin vaccine	BCG	Prevents tuberculosis including bloody cough and permanent brain damage	■							
Oral polio vaccine	OPV	Partially protects against poliomyelitis which causes paralysis and death	■	■						
Rotavirus Vaccine	RV	Diarrhoea disease		■		■				
DTaP/IPV/Hib/HepB	Hexa	Protects against diphtheria, tetanus, pertussis (whooping cough), polio, hepatitis B and Haemophilus influenzae type b (Hib)		■	■	■		■		
Hepatitis B vaccine	Hep B	Partially protects against hepatitis B which causes blood infection liver disease, cancer and death		■	■	■				
Pneumococcal conjugate vaccine	PCV10	Protects against most causes of pneumonia and meningitis including blood and lung infections and brain damage		■		■	■			
Measles vaccine	Measles	Protects against measles					■	■		
Human papillomavirus infection	HPV	Prevents infection of certain types of human papillomavirus							■	
Adult tetanus and diphtheria vaccine	Td	Protects against three potentially life-threatening bacterial diseases: tetanus, diphtheria, and pertussis (whooping cough)						■		■

South Africa's EPI programme aims to fully immunize 90% of children by the age of one; despite progress made to improve coverage, gaps persist



Routine Immunization Coverage (%) Estimates

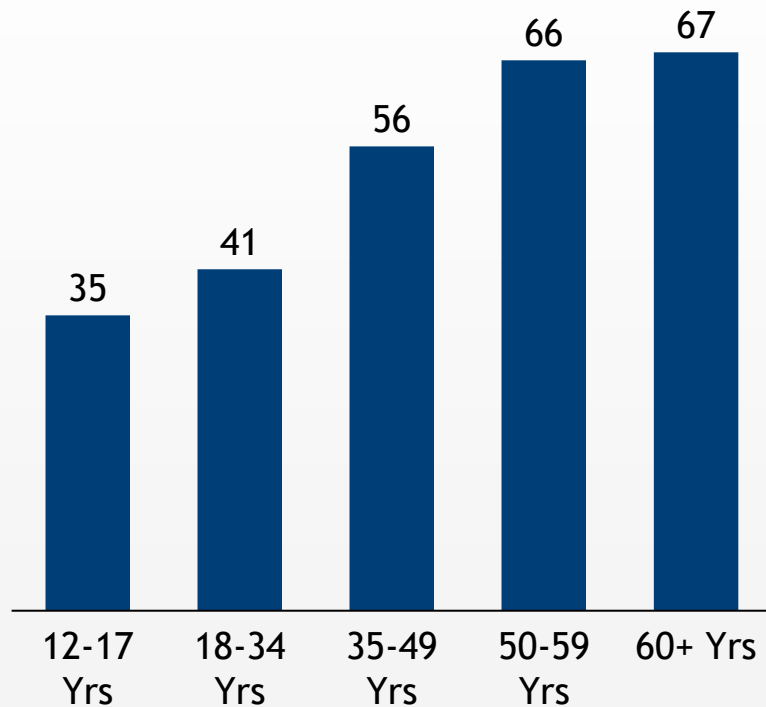


South Africa's preference for a double-shot C-19 vaccine has led to an increased uptake of mRNA vaccines; ~80% of C-19 vaccines delivered so far are mRNA vaccines



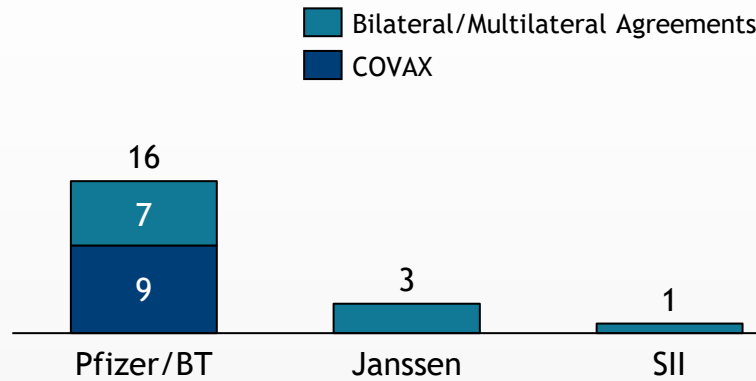
C19 Primary series coverage

% people vaccinated (as of Sep '23)



C19 Procurement

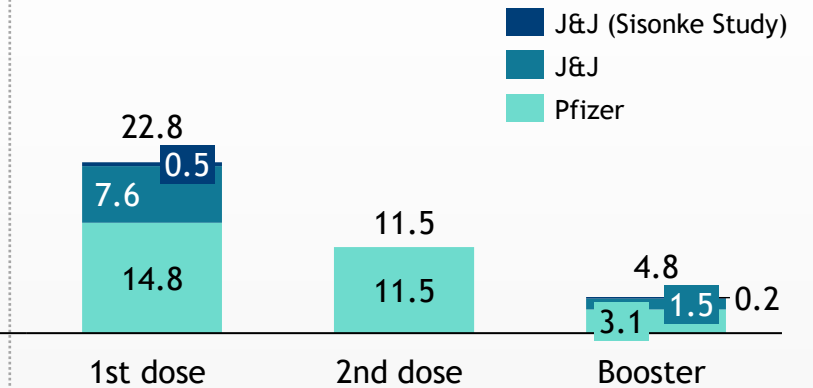
Vaccine Deliveries (Md)² (as of Jul' 23)¹



- ~80% of vaccines delivered so far are mRNA vaccines
- ~54% of vaccines procured have been through Bilateral/Multilateral agreements

C19 Demand

Total vaccinations, Doses (Md) (as of Sep' 23)



- End user preferences indicate that a double shot C-19 vaccine is the most preferred
- South Africa has already rolled out booster shots and these are available to people fully vaccinated with the Pfizer vaccine and those 18+ vaccinated with the J&J vaccine

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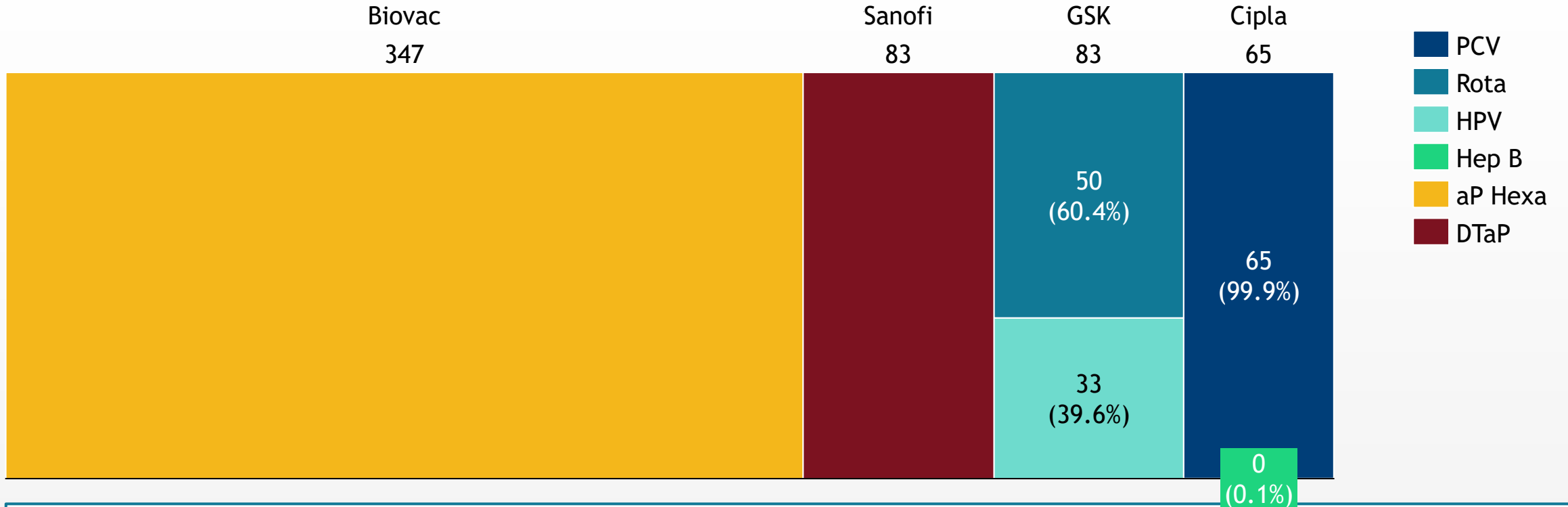
b. Vaccine spending

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Hexa, DTaP, PCV and Rota account for the majority of South Africa's vaccine spend

South Africa EPI Procurement Value Estimates by Supplier, EPI Tender Jan 2024 - Dec 2026 (USD Mn)¹



Takeaways

- NDoH is actively interested in securing better prices as demonstrated by moving from an exclusive supply agreement with BioVac to an open tender and exploration of product-switch opportunities
- Prioritization of domestic manufacturing through BioVac means that Rota and HPV product switches may be most feasible in the short-term

SOURCE: 1. EPI 2023 Tender Circular; Bivalent OPV, Td, MR, and BCG price and volumes not available in EPI Tender Circular so excluded currently; Rand to USD currency conversion 1:18.72

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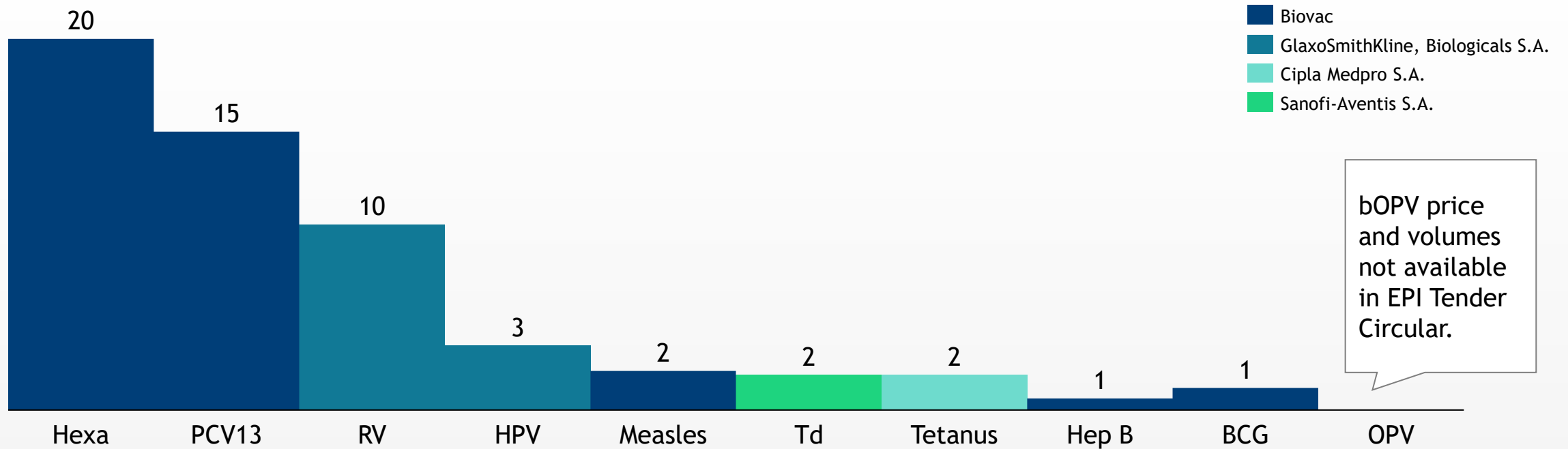
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South Africa's product selection history indicates preference for South Africa based manufacturers



South Africa annual public sector vaccine supply volumes by manufacturer, EPI Tender Jul 2020 - Dec 2023 (Million Doses)¹



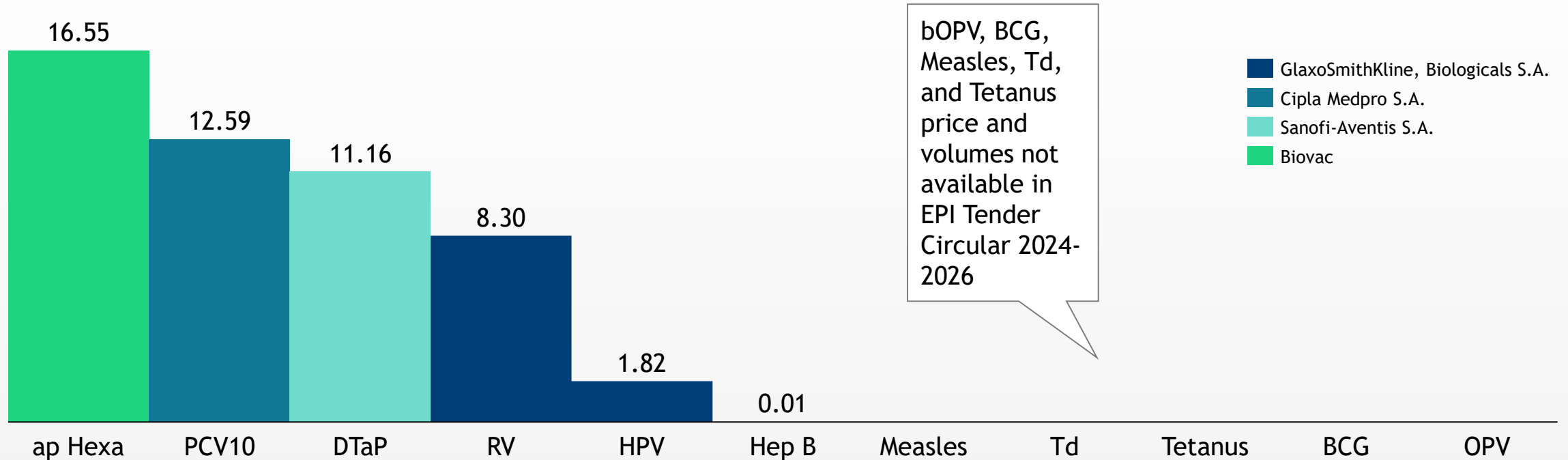
bOPV price and volumes not available in EPI Tender Circular.

- South Africa primarily procures from South Africa based manufacturers
- 4 suppliers provide 10 Vxs
- Most of the RI vaccines, including Rota, are supplied by DCVMs
- Biovac supplies 5/10 RI vaccines
- To date, no vaccines from Chinese or Indian manufacturers are used

However current product selection reflects a transition from favoring local manufacturers to prioritizing price, highlighting a growing price sensitivity



South Africa public sector vaccine supply volumes by manufacturer, EPI Tender Jan 2024 - Dec 2026 (Million Doses)¹

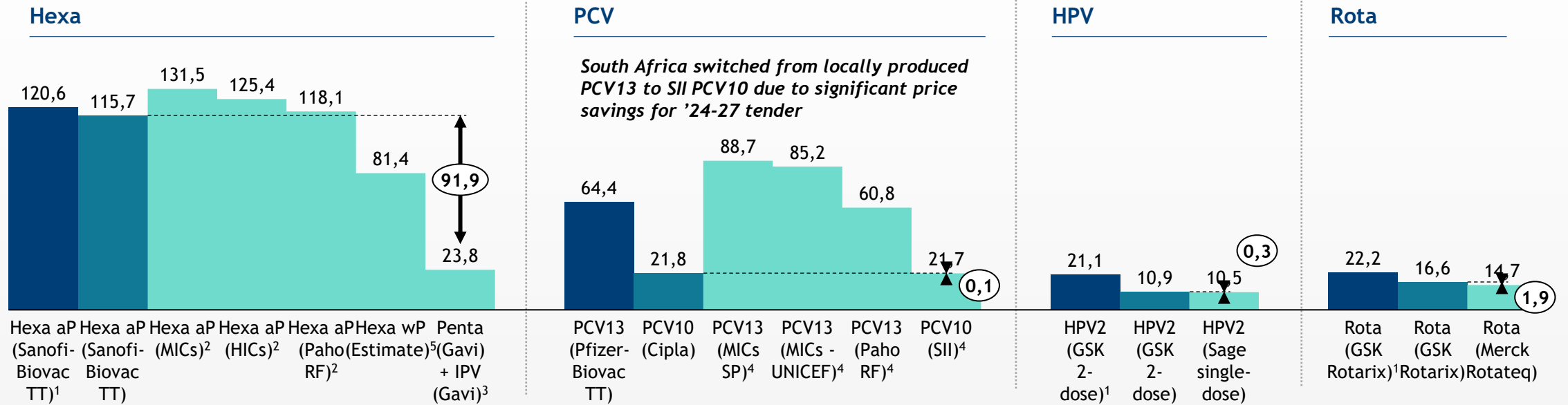


Recent PCV switch saved SA >\$40M; lower-cost alternatives for Hexa and Rota vaccines could save an additional ~\$94M



Total annual savings from price and switch decisions (Million USD)

- South Africa government expenditure at base price (EPI 2020 - 2023 Tender)
- South Africa government expenditure at base price (EPI 2024 - 2026 Tender)
- South Africa government expenditure at reference price



- **Hexa:** South Africa procures the Hexa (aP) product at a price comparable to other self procuring MICs
- **Penta + IPV :** unlikely that South Africa would be able to access Gavi prices
- **PCV:** NDoH recently switched PCV from PCV13 to PCV10 due to issues in Biovac tender bid per the official notification and thus moving from ~\$15 USD/dose to ~\$5 USD/dose.
- **HPV:** South Africa is potentially interested in moving to a 1-dose programme, which would allow to continue using GSK’s product with significant savings. SA tender considers all valancy of HPV equally

SOURCE: 1. EPI 2020 Tender Circular; Bivalent OPV and Td price and volumes not available in EPI Tender Circular so 2021 PAHO price and 2019 EPI Forecast was used as a benchmark; Rand to USD currency conversion 1:14.86 for EPI 2020 Tender and 1: 18.72 for EPI 2024 Tender; Prices available in appendix; 2. WHO 2020 global vaccine market report; 3. Appendix “Gavi revised prices for Penta and IPV” ; 4. Appendix “PCV products with WHO Prequalification - Prices”; 5. Estimated Hexa Wp price for South Africa = South Africa Hexa aP private market price * (India private market Hexa aP to India private market Hexa wP % discount) * (SA Private Sector price to SA Public Sector % discount) = R754*((3900 to 2632 % discount)*(R754 to R320,57 % discount)= R216,34

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South Africa has an in-depth registration process managed by SAHPRA which is independent of the National Department of Health



- **Name of regulatory body:** South African Health Products Regulatory Authority (SAPHRA)
- **Expected time for registration:** Highly variable, anywhere from a few months to 3 years
- **Registration fast-track pathways:** WHO PQ or SRA approval may accelerate registration timelines, but its not guaranteed
- **Regulatory Harmonization:** South Africa is part of “Zazibona”, a work sharing initiative in SADC (medicines assessments and GMP inspections) with the objective of reducing timelines for registration of medicines

Requirements	Details
Is local safety or efficacy data required? (e.g., are in-country clinical trials required)	Not required, but local data is preferred.
Is GMP inspection required?	Required
Are product samples required?	Required
Does the country participate in WHO Collaborative Procedure for Accelerated Registration (CRP) ?	No
Does the country require local company registration or an in-country distributor?	A locally registered entity is required to apply for SAPHRA registration. A subsidiary or locally registered distribution partner is required
Is Pricing Regulated?	Yes (National Department of Health regulates both private and public sector prices)

If a supplier would like to participate in a tender, it should register as soon as possible, given potentially lengthy registration timelines



South Africa Tender Process and Timeline

1. Registration

Registration can take over 3 years

- Managed by South African Health Products Regulatory Authority (SAHPRA)
- Timelines highly variable
- SRA/WHO-PQ may enable fast-tracking

2. Tendering

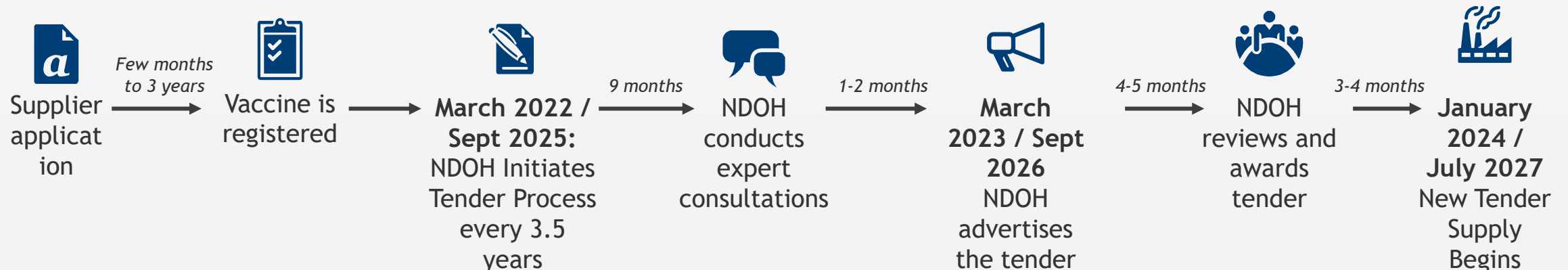
Tender decisions are made by:

- Suitability of Purpose Committee (Essential Medicines List (EML) & EPI teams): Evaluate whether the product is on the EML
- Pricing Evaluation Committee (Heads of MoH, Treasury and EML)
- Price, BEE scores, past performance, local manufacturing are taken into consideration when making tender decisions

3. Procurement

Provinces are the primary buyers

- A supplier needs to coordinate with each of the province to sell and deliver as part of tender requirements
- Suppliers and provinces are responsible for coordinating logistics
- Actual procurement volumes can differ (sometimes significantly) from awards
- Prices are revised every 3-6 months to account for exchange rate fluctuations



South Africa awards tenders based on a preference point system with a maximum allocation of 90 points



In terms of regulation 6 of South Africa's Preferential Procurement Regulations pertaining to the Preferential Procurement Policy Framework Act, 2000 (Act 5 of 2000), responsive Tender bids will be adjudicated by the NDoH on the 90/10 - preference point system in terms of which points are awarded to bidders on the basis of

1. The bid price (maximum 90 points)

- The following formula is used to calculate the points for price:

$$P_s = 90 \left(1 - \frac{P_t - P_{\min}}{P_{\min}} \right)$$

Where:

- P_s = Points scored for comparative price of bid under consideration
- P_t = Comparative price of bid under consideration
- P_{\min} = Comparative price of lowest acceptable bid

2. B-BBEE status level of contributor (maximum 10 points) - This refers to the B-BBEE status of an entity in terms of a code of good practice on black economic empowerment, issued in terms of section 9(1) of the Broad-Based Black Economic Empowerment Act; Sample 1 Sample 2 Sample 3.

- Businesses are awarded points which they can claim on a BBEE certificate which entitles them to a greater chance of obtaining government contracts.

3. Localization of manufacturing and past performance is also taken into consideration

In 2019, South Africa replaced Biovac's role in managing the procurement and distribution of vaccine to a competitive tender process managed by the NDoH



Key Stakeholders in the Procurement Process

Stakeholder	Priorities	Unmet Needs	Role in Product Selection
Pricing Evaluation Committee¹ (PEC)	<ul style="list-style-type: none"> Affordability and Access of Vaccines 		<ul style="list-style-type: none"> Final Decision Makers on Tender Outcomes
EPI Programme	<ul style="list-style-type: none"> Affordability and Access of Vaccines High Coverage Rates Clinically Effective Vaccines 	Low Coverage Rates	<ul style="list-style-type: none"> Provides recommendations to PEC
National Essential Medicines List Team	<ul style="list-style-type: none"> Affordability and Access of all Medicines High Coverage Rates Clinically Effective Vaccines 		<ul style="list-style-type: none"> Provides recommendations to PEC
NITAG (National Advisory Group on Immunization - NAGI)	<ul style="list-style-type: none"> Affordability and Access of Vaccines High Coverage Rates Clinically Effective Vaccines 		<ul style="list-style-type: none"> Makes recommendations on vaccine schedules and formulations

¹ A separate committee that includes Head of EML team at the MoH, Treasury Representative, Deputy Director General of the MoH and representatives from the different provinces.

A partnership with BioVac or Aspen can increase likelihood of success in accessing the South Africa market



BioVac engages in different types of vaccine partnerships with suppliers, and some have evolved over time

- **Packaging and Labeling:** At least 5 vaccines including Measles, BCG, Hexa, and PCV13
- **Fill & Finish:** PCV13, Hexa
- **Local Formulation:** PCV13 (TBD)

Aspen manufactures branded and generic pharmaceutical products and has recently entered the vaccines space

- **Packaging and Labeling:** n/a
- **Fill & Finish:** Covid-19 vaccine
- **Local Formulation:** PCV, Rota, MenACWY, Hexa (planned for end 2023 through SII tech-transfer)

Advantages

- There is strong domestic political support for tech transfers
- BioVac has significant tech transfer experience and experience manufacturing APIs (HepB)
- Partnership would fulfill South Africa's requirements for local partners
- Largest African based pharmaceutical company, with distribution to 120 countries around the world
- Very strong distribution capabilities through integration with alliance partners
- A wide portfolio of products
- Partnership would fulfill South Africa's requirements for local partners

Challenges

- More sophisticated tech transfers take time to execute
- In the past, BioVac has underestimated the financial and human-resource requirements for tech transfer
- Relatively new vaccines tech transfer and vaccine manufacturing experience

South Africa's procurement and industrial policies support preferential treatment of locally manufactured vaccines (1/2)



Procurement Policy	Current	<ul style="list-style-type: none"> • South Africa self-procures vaccines through bilateral deals with vaccine manufacturers.¹ • All public procurement is governed by the South African Procurement Act. Vaccines procurement like other public goods work by competitive bidding processes, which include allowances for preferential procurement of locally, and to some extent regionally, manufactured products (see Regional Preference below).² • On local manufacturing, the Preferential Procurement Policy Framework Act establishes a preference for procurement from local manufacturers and suppliers via a point system.² <ul style="list-style-type: none"> – Tenders' bid price and the source of goods/services used in product manufacturing are awarded a maximum of 100 points based on defined criteria and calculations. In the Point System, for a tender of value over R50 000 000 (US\$ 2 725 700), 90 points are awarded based on price and 10 points are allocated based on locally manufactured goods or goods/services manufactured by historically disadvantaged South Africans (HDSAs). <ul style="list-style-type: none"> • <i>The implementation of this policy to support local manufacturing has been called into question by pharmaceutical and vaccine manufacturers, particularly given the tender document includes no mention of point allocation for local manufacturing in the score calculation. Ministry of Health informally maintains that, despite not being clearly listed on the tender documents, local manufacturing is considered appropriately.</i>⁷ • Regional Preference: Article 19 of the Southern African Development Community (SADC) Procurement Protocol stipulates regional preference in SADC members' procurement.^{3,4} <ul style="list-style-type: none"> – Article 19 states that a “margin of preference in the evaluation of bids” is offered to “services, goods, and works originating from SADC countries when compared to bids offering services, goods, and works originating from elsewhere.” The South African Procurement Act aligns with the SADC Procurement Protocol.⁴ – Although the SADC Procurement Policy has no established guidelines for regional collaboration on local vaccine manufacturing, neighboring SADC member states (i.e., eSwatini) have used it to procure vaccines from the Biovac Institute.^{5,6}
	Future	<ul style="list-style-type: none"> • Whilst guidelines allow for the preferential procurement of vaccines (and other health products) from local manufacturers, a consultation is ongoing between the Ministry of Health, the Department of Treasury, the Department of Science and Innovation (DSI), and the Department of Trade, Industry and Competition (DTIC) to discuss the future scale and nature of this support.

Note: US Dollar to South African Rand rate, US\$ 1 = R18.34, as of February 23, 2023

SOURCE: [Department of Health](#), Republic of South Africa, July 2022; [Preferential Procurement Policy Framework Act \(PPPFA\)](#) ; [Southern African Development Community](#) ; [SADC Procurement Policy 2019](#) ; [Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa: With a focus on the Role of Finance](#), FSU Libraries, March 2021 ; [Biovac](#), Partners; CHAI discussion with South African government officials and South African manufacturers

South Africa's procurement and industrial policies support preferential treatment of locally manufactured vaccines (2/2)



Industrial & Related Policies	Current	<ul style="list-style-type: none"> • A public-private partnership (PPP) signed in 2003 between the South African govt. and the Biovac Consortium, a local private entity, to develop local vaccine R&D, manufacturing, and supply. The PPP was a private ownership/public finance initiative. Biovac had a controlling share of 52.5%, and the govt. had the remaining shares via the Department of Science and Innovation (DSI) 35%, and the Technology Innovation Agency 12.5%. The partnership assured local vaccine procurement from Biovac and guaranteed the Biovac Institute as the sole public-sector vaccine supplier. In addition to the purchase cost of vaccines, Biovac was permitted to charge the Provincial Departments of Health an extra fee between 10 - 20% in order to raise capital to build vaccine manufacturing and distribution infrastructure.¹ • The South African Health Products Regulatory Agency (SAHPRA) is the South African NRA. For product registration, separate registration by a locally registered supplier is required.² <ul style="list-style-type: none"> – South Africa is a member of the WHO Collaborative Procedure for Accelerated Registration, however, SAHPRA does not recognize WHO PQ and a separate registration is required. • Technical/regulatory support: National Regulatory Authority at Maturity Level 3 (ML3) for vaccines regulation, including vaccines manufactured in the country, allows local vaccine manufacturers to apply for WHO prequalification.³ • The Department of Trade, Industry and Competition (DTIC) manages the South African industrial incentive program. There are financial & non-financial programs aimed at funding/ incentivizing manufacturing generally in South Africa.⁴ <ul style="list-style-type: none"> – Support Programme for Industrial Innovation (SPII): Provides “financial assistance for the development of innovative products and/or processes” up to two million South African Rand (R2 million; ~ US\$ 109 000). – Manufacturing Competitiveness Enhancement Programme (MCEP) Loan Facility: Provides working capital loans at a preferential fixed rate of 4% per annum. The loan is capped at R50 million (~ US\$ 2 730 000). – Strategic Partnership Programme (SPP) provides cost-sharing grants for the manufacturing industry “capped at a maximum of R15 million (~ US\$ 820 000) (VAT inclusive) per financial year over a three-year period”. <ul style="list-style-type: none"> • <i>The above are non-specific manufacturing incentives that possibly apply to the vaccines manufacturing industry.</i>
	Future	<ul style="list-style-type: none"> • DTIC is also working on the development of a new trade policy framework, which will include provisions that will enable South Africa to effectively participate in the African Continental Free Trade Area (AfCFTA). This new policy may lead to changes in procurement laws and regulations.⁵ • The African Medicine Agency (AMA) treaty was ratified in South Africa, but with SAHPRA playing a supportive role. Unclear whether there would be any conflict between South Africa's membership of AMA and their Pharmaceutical Inspection Co-operation Scheme (PIC/S) membership. <ul style="list-style-type: none"> – PIC/S was established in 1995 as an int'l organization, with 53 member countries, including the European Union and the United States. PIC/S aims to promote & harmonize GMP for medicinal products through mutual acceptance of inspection results between member countries, thus reducing duplication.

Note: US Dollar to South African Rand rate, US\$ 1 = R18.34, as of February 23, 2023

SOURCE: [Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa: With a focus on the Role of Finance](#), FSU Libraries, March 2021; [SAHPRA](#), September 2022; [World Health Organization](#), October 2022; [Department of Trade, Industry and Competition \(DTIC\)](#), A Guide to the DTIC Incentive Schemes 2020/21; CHAI discussion with the South African govt. officials



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