ONLINE WEBINAR

GO-TO-MARKET (GTM) TOOLBOX LAUNCH: LEVERAGING GLOBAL **HEALTH RESOURCES TO SUPPORT GTM STRATEGY DEVELOPMENT**



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In collaboration with partners CHAI has created a comprehensive toolbox, featuring a range of resources tailored to assist manufacturers in answering common questions encountered during the vaccine development journey, specifically concerning their GTM strategies. Within this toolbox, diverse resources are available, directing manufacturers to pertinent data sources that offer insights and transparency in tender processes addressing information gaps, while concurrently streamlining access to crucial existing resources generated by global partners, including Gavi, UNICEF, WHO, Linksbridge, and PATH.

During this DCVMN webinar, CHAI will provide an overview of this new toolbox, which is now hosted on the DCVMN website. The webinar will also take the audience through several of the resources included in the toolbox that can support DCVM's as they develop their GTM strategies for LMICs.



TIME 11:00 - 12:30 CET



25 January, 2024

REGISTER USING LINK



Go-to-market (GTM) toolbox launch

DCVMN Webinar 2024





We are committed to our mission to save lives and reduce the burden of disease in low- and middle-income countries around the world. We aim to sustainably strengthen government and private health systems in countries where we work.



CHAI creates win-win situations in the interest of health access goals and commercially sustainable business cases for suppliers



1 Suppliers, esp. DCVMs

Aim for sustainably profitable, high-volume business cases in serving LIC and MIC markets















Aim for sustainable supply security and affordability of health commodities meeting LMIC needs



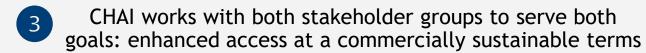














Data Sources Supporting Vaccine Markets Analysis





This module provides an overview of available vaccine market data to empower manufacturers to effectively answer strategic business questions and optimize data use for decision-making.

This module includes:

- Several available data sources DCVMs can use to inform their go-to-market strategies
- Useful tips to leverage these data sources

Several important data sources exist to understand the supply, demand, pricing, usage and coverage dynamics across vaccine markets



			Information & data break-downs							
	Category	Source Name (Source Link) ¹	Antigen	Supply	Demand	Price	Supplier	Country		
	Demand	Linksbridge/GHMH (<u>Login</u>)	•		Ø			⊘ ²		
	Demand	Gavi Demand Forecast (<u>Login</u>)	•		Ø					
	Product Profile	Gavi Detailed Product Profiles - DPP (<u>Link</u>)	•			Ø	Ø			
	Product Profile	WHO PQ List (<u>Link</u>)	•				•			
淡	Intro & Usage	View-hub by IVAC (<u>Link</u>)	•					⊘		
	Coverage	National Immunization Coverage - WUENIC (Link)	•					•		
	Supply	Gavi Shipment Reports (<u>Link</u>)	•	Ø				②		
	Supply	United Nations Global Marketplace (UNGM) (<u>Link</u>)	•	Ø	Ø					
	Supply and Price	WHO MI4A Database (<u>Link</u>)	•			Ø	②			
淡	Price	UNICEF Price Data (<u>Link</u>)	•			Ø	Ø			
	Price	CDC Price List (<u>Link</u>)	•			Ø				
	Price	PAHO Price List (<u>Link</u>)				Ø				



Additional data sources cover market studies and country overviews alongside guidance on epidemiology, financing, R&D and immunization policies (1/2)

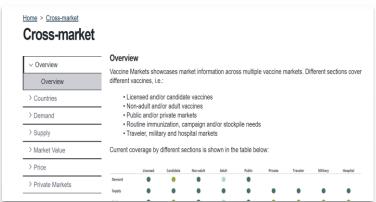


Category	Source name with link ¹	Description
Countries	Gavi country hub	Detailed information on each Gavi-eligible country
Countries	Gavi country support overview	Visual overview of which countries are approved for each type of Gavi support
Countries	Immunization Delivery Cost Catalogue by Immunization Economics	Global evidence base on the cost of delivering vaccines in LMICs
Countries	LNCT member country profiles	High-level overview of transition-related targets and progress for Gavi countries
Epidemiology	GHDx health data	Assesses mortality and disability from hundreds of diseases, injuries, and risk factors
Epidemiology	John Hopkins Lives Saved Tool (LiST)	Impact of coverage change on mortality in low- and middle-income countries
Financing	WHO immunization financing indicators	Immunization expenditure indicators from the WHO-UNICEF Joint Reporting Form
Immunization	SAGE meetings	Documentation from previous SAGE meetings
Market	Gavi market shaping roadmaps	Guide Gavi's market shaping efforts by analysing the dynamics of each vaccine or other immunisation product market
Market	UNICEF market notes and updates	Market and product updates highlighting trends in supply, demand, shortages, surplus and availability of key strategic products procured by UNICEF
Market	UNICEF Tender Calendar	Tentative vaccine tender issuance dates by UNICEF
Market	MI4A market studies by WHO	Vaccine-specific market studies, analyzing global demand and supply prospects

Global Health Markets Hub (GHMH) gives direct access to timely, constantly-updated vaccine demand information







Link	GHMH online portal (access request needs to be placed in accordance with the user guide)					
	GHMH is a data-sharing collaboration using public information on vaccine demand and supply managed and curated by Linksbridge, SPC					
Overview	• Industry partners can receive online access to GHMH, including global demand data by country and World Bank income group for key antigen markets					
	In addition, the Vaccine Almanac is published every 1-2 years and provides a catalogue of available data					
Tips for	 Industry can carry out analyses to answer questions such as forecasted market demand of a vaccine for LMICs over the next 5 years, dollar value of a particular market etc. 					
use	CHAI can support with country level analysis and interpretation of information found in GHMH for use in strategy development and modelling					

VIEW-hub by IVAC provides an online, interactive, map-based platform visualizing data on vaccine use and impact across countries







Link	View-hub online portal
	• Easy-to-use repository for the most relevant and recent vaccine data, covering topics such as vaccine introduction & use, immunization equity, vaccine preventable disease burden, and immunization system strength
Overview	• It also includes country level summary data on the latest academic studies on vaccine impact, as well as the economic burden of disease
	• Provides information on current or planned vaccine product used in a country's national immunization program (including planned and actual introduction dates, planning status, Gavi application status, etc.)
Tips for use	 Data can inform country-specific market access strategies Quick reference point for a country overview and can supplement with GHMH for more detailed demand information



Overview of government decision processes for NVIs and product switches





In select antigen markets, uptake of DCVM products is dependent on country product preference and selection processes.

This module aims to facilitate improved understanding of country product preferences, processes and incentives to introduce/switch to help DCVMs capture demand in these markets.

Suppliers can use this module to register products appropriately, conduct country-specific research to understand product selection processes, engage early with relevant stakeholders and emphasize the product attributes that will support introduction/switches.

In select antigen markets, uptake of DCVM products is dependent on country product preference and selection processes



Gavi-supported countries can state their preferred products for PCV, Rota and HPV:

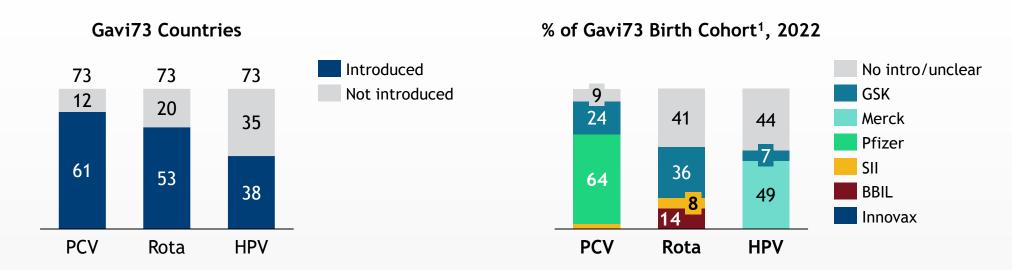
- 1. When applying for Gavi support for introduction, and
- 2. Via applications to switch products¹

As Gavi supports additional vaccines, Gavi-supported countries may also be able to select preferred products for:

- Meningitis (given serotype coverage differences)
- Malaria (e.g., RTS,S vs. R21)
- RSV (maternal vs. mAb)

In these markets, MNCs are incumbents and hold majority of market share; opportunity for new suppliers will be driven by product switches





Implications:

- PCV and Rota: Uptake of new DCVM products depends on countries deciding or being required to switch products (e.g., due to shortages), since minimal demand is associated with countries yet to introduce
- HPV: Significant share of demand comes from countries yet to introduce; however, many countries have conducted HPV
 demos, which may influence their preferred product for full-scale introduction

Over the past 5 years, DCVMs have started to capture market share from MNCs in these markets and further opportunities can be captured with strong go-to-market strategies

Sources: Viewhub 2023; ¹Excluding India

Several product attributes drive country preferences, with importance depending on the market and the country



- Valency tends to be more important where products have different serotype coverage and disease epidemiology varies geographically (e.g., PCV)
- Dose schedules (e.g., 2- vs. 3 dose schedule) and presentations (e.g., 5- vs. 10-dose vial, frozen vs liquid) that help meet immunization targets of higher coverage, lower wastage and cost savings may be favoured
- **Price** is an important driver of product choice in the Gavi market, and countries in later stages of transition tend to be more price sensitive as they bear a higher proportion of procurement costs

Countries may prioritize these factors differently depending on local immunization priorities and challenges (e.g., cold chain space is less likely to be important in a country that recently expanded its cold chain)¹

Non-product attributes also shape country choice, suggesting countries will not always select products that optimally meet their attribute preferences

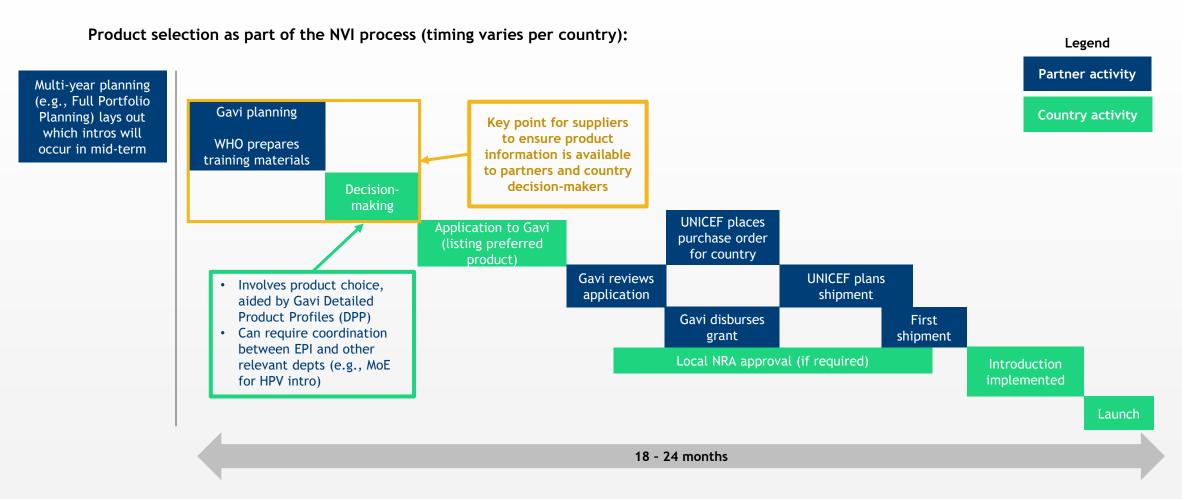


Factor	Insights
Domestic manufacturing	 In countries with domestic vaccine manufacturing capabilities, preference for local manufacturing often overrides other preferences (e.g., for lower price or other product attributes) opportunities for international suppliers tend to be greatest if via tech transfer to a local supplier
Openness to DCVMs	 The extent to which countries have used DCVM products in the past¹ can shed light on openness to new DCVM products; openness to a specific manufacturer is expected to be higher if a country has used their products in the past Further, examining any trends in suppliers across a country's vaccine portfolio can shed light on any company preferences
Country readiness	 Low DTP3 coverage and/or significant drop in DTP3 coverage can indicate likelihood that country will be prioritizing coverage gains before considering NVIs or switches
Other factors	 Country-specific research can help bring to light additional factors that influence product preference, e.g.: Preferences for Halal-certified products by countries with large Muslim population Geopolitical pressure influencing product choices

Suppliers should research and consider how individual country contexts affect eventual product choice, particularly for high-volume countries where procurement is complex and local production is prominent

The new vaccine introduction (NVI) process can take 18-24 months, and countries' preferred products are usually stipulated upfront in their applications to Gavi





Suppliers should work with Gavi to ensure their products are listed on the <u>Gavi DPP</u> as soon as possible after WHO PQ application is submitted; this step is critical for country stakeholders to become aware of the production option

While the process and stakeholders involved in product selection for switches is expected to be similar to NVIs, some key differences have been observed



- 1. Loss aversion: As there is a product already in use, stakeholders may disproportionately focus on avoiding a loss in certain characteristics
 - **Implication:** The attributes of the product initially introduced, may influence countries' preferences for any future switches (e.g., if countries introduce a high valency product, they may not accept lower valency products in the future)
- 2. Process: Unlike for NVIs, processes are less clear it is not always known when countries will look to switch, and who is involved in the process
- 3. Programmatic interest: In some instances, there is a greater incentive to prioritize NVIs over optimizing current vaccine portfolios through switches
 - **Implication:** New products may see a delay in demand developing if countries have already introduced the product

Examination of past switch behaviour shows four main drivers can enable product switches: strong incentives, ease of switching, country capacity and triggers



- 1. Strong incentives, (e.g. desire to find lower-priced products for self-financing countries or higher valency products) drive switches
- **2. Ease of switching** (e.g. similar products) reduces the 'cost' to switch
 - Countries are more likely to switch to products that are more similar to the product currently in use, because those switches are easier to implement, e.g., same dose schedule or presentation
 - Switches in markets where products are highly differentiated (e.g., Rota) are expected to be more costly

3. Country capacity

- Countries with NVIs planned in the next few years are less likely to have EPI capacity to decide to and execute a switch
- Low DTP3 coverage and/or significant drop in DTP3 coverage can indicate likelihood that country will be prioritizing coverage gains before building switch capacity
- 4. Specific time-bound triggers bring attention to switch options, e.g. tenders, supply shortages





Understanding

- Examine historical trends to understand the context for a product choice
 - For that product, what attributes have been important in product selection and switch previously?
- Conduct in-country engagement to understand product selection processes and registration requirements
 - Which stakeholders require product information?
 - What information do these stakeholders require?
 - When do these stakeholders require information?

Actions

- Register products appropriately according to the target markets
- Ensure key data sources (WHO SAGE recommendations, Gavi detailed product profile (DPP), local and regional data) include the product, and ensure products are listed on the Gavi DPP as soon as possible; this is a critical tool for country stakeholders to become aware of the product option
- Emphasize the product attributes that will provide incentives to countries to select a product these can include valency, presentation or administration, and price savings



Nigeria Country Profile



Contents

a. Immunization program overview

- b. Vaccine spending
- c. Product selection and opportunities
- d. Market access

Nigeria was due to transition out of Gavi support in 2021, but due to its unique circumstances, Gavi approved an exceptional extension until 2029



Indicators	Status (2022)					
Population	216M					
Birth Cohort	8M					
Under 5 Mortality Rate (# per 1,000 live births)	114 in year 2020, dropped from 325.5 in 1964					
EPI Coverage	At first dose, Nigeria's RI vaccines have mostly met the national coverage target of 85%, but low uptake at subsequent doses suggest a need to improve follow up.					
National EPI Manager	NPHCDA					
GNI per capita (USD)	\$2100 (2021)					
Government Health Spend (% per GDP)	3.38% (2020)					
Gavi Country Status (Y/N, Year of Transition)	 Nigeria was due to transition out of Gavi support in 2021, but given the country's low immunization rates, the risks to the sustainability of Nigeria's immunization programme and the health security of the region, the Gavi Board approved an exceptional extension to support the country up to 2028. Nigeria entered the accelerated phase of the Gavi transition in 2018 with the expectation of becoming fully self-financing by 2029 The NSIPSS1, Nigeria's 10-year strategy document (2018 - 2028), defines the country's plan to transition from Gavi support. 					
Contribution to Gavi	 Nigeria committed to invest ~US\$ 2 billion to finance its vaccines from 2018-2028 Gavi's financial support of around US\$ 1 billion will include: US\$ 773 million for vaccine financing and Up to US\$ 260 million for health system strengthening. 					
COVAX country (Y/N, Note)	Yes/Nigeria has received Covid-19 doses through the COVAX vaccine-sharing facility					

SOURCE: Gavi; World Bank; Healthnews.ng



Nigeria plans to expand routine immunization over the next four years

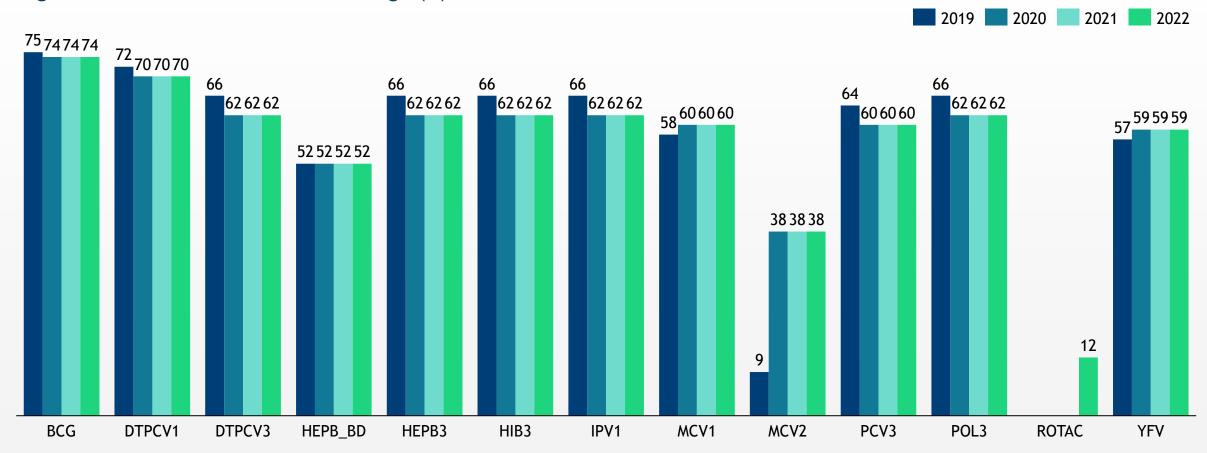
								Introduced		Planned Switch	
Vaccine	Pre-2018	2019	2020	2021	2022	2023	2024	2025	2026	Comment	
BCG, HepB, bOPV, Penta, YF, MenA											
IPV	1st dose			2 nd dose							
PCV10										2d to 4d switch	
Measles	1st dose	2 nd dose							MR switch		
Rota											
HPV4											
TCV											
Malaria											

- Nigeria often plans demos prior to nation wide introductions and suppliers may need to engage stakeholders well in advance of official NVI timelines
- The country has introduced Gardasil 4 on a 1-dose schedule making Nigeria one of the first Gavi countries to introduce with a single dose schedule
- The introduction of the malaria vaccine will be highly dependent on supply availability and country resource to implement amongst other ongoing priorities such as HPV and reaching zero dose children

Nigeria's RI vaccines have not met the national coverage target of 85%; coverages have not recovered to pre-covid levels



Nigeria Routine Immunization Coverage (%) Estimates





Contents

a. Immunization program overview

b. Vaccine spending

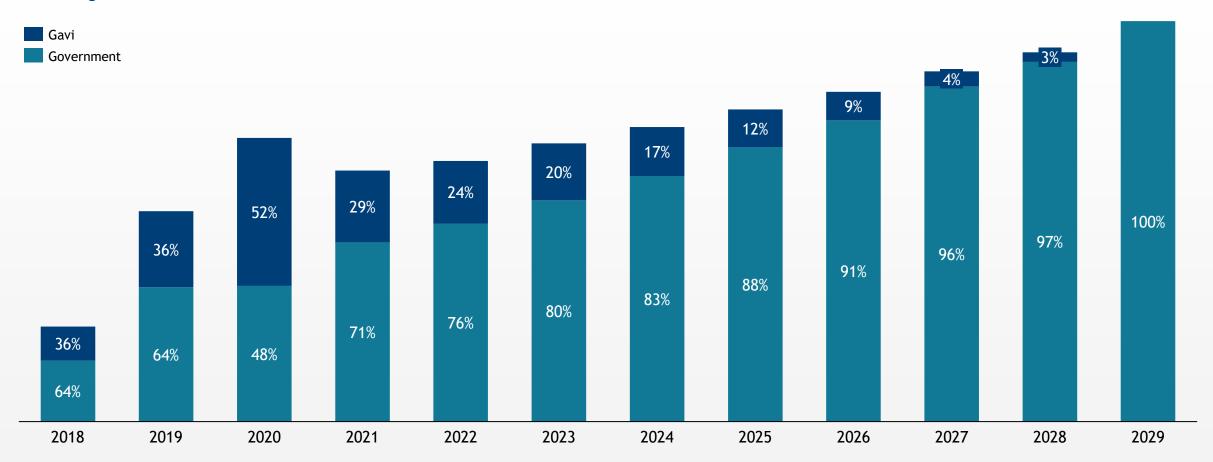
c. Product selection and opportunities

d. Market access

Nigeria will slowly become more price sensitive as it increases its financing contribution from 64% in 2018 to 100% in 2029



Financing for loaded routine immunization vaccines 2018 - 2029 1



SOURCE: 1 Immunization and PHC systems Strengthening [NSIPSS]; includes Penta, IPV & PCV from 2018, Men A & Measles 2nd dose from 2019, Rota & HPV from 2020. BCG, Measles, Yellow Fever, HBV, OPV and Td are not co-financed.

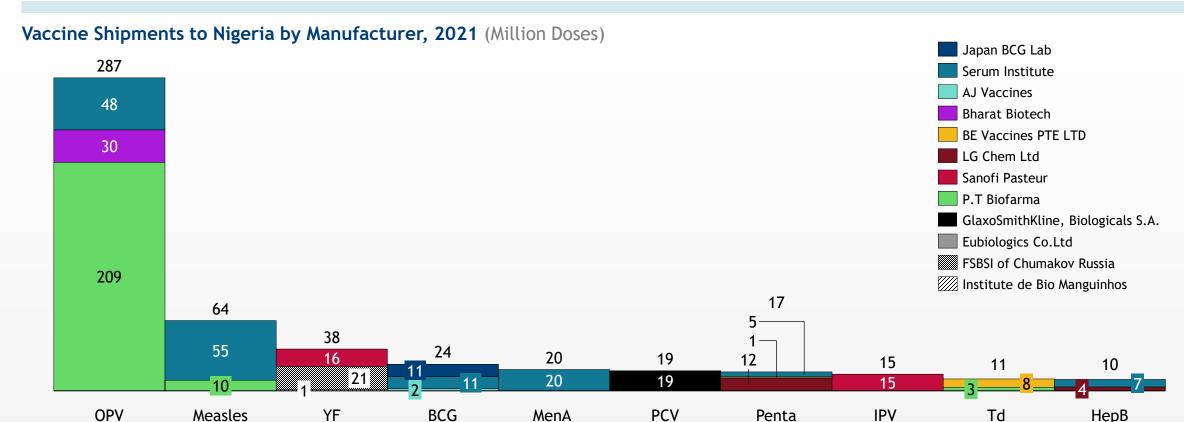


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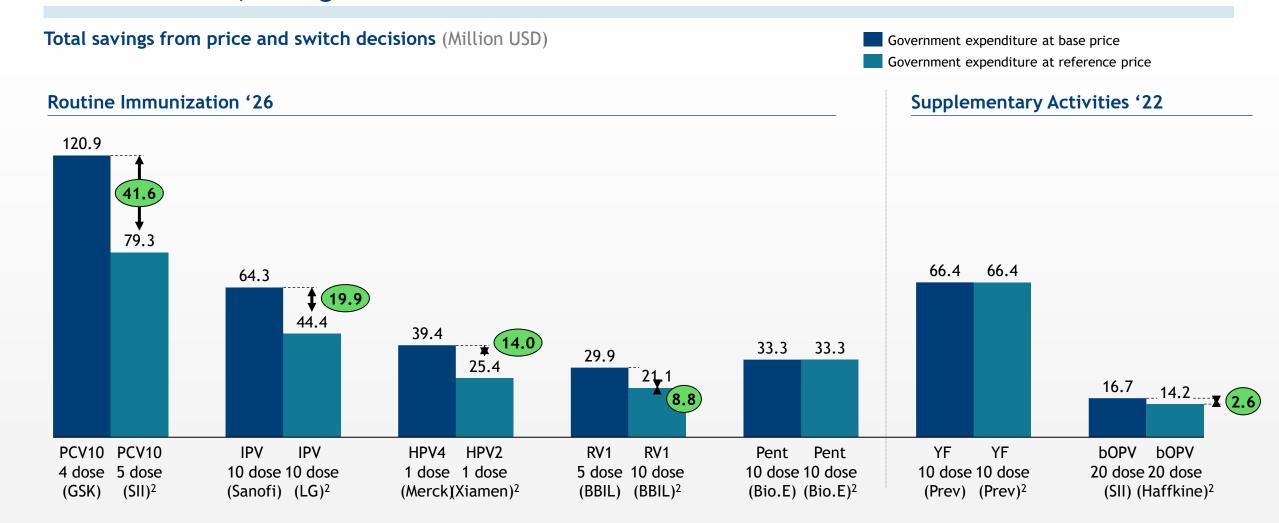
Nigeria's product selection history shows a wide variety of different suppliers



- 12 suppliers provide 10 Vxs; Due to a large birth cohort, Nigeria buys from multiple suppliers for interchangeable Vxs like Penta and Yellow Fever
- Most of the RI vaccines, including Rota, are supplied by DCVMs
- Serum supplies 6 out of 10 RI vaccines
- No Chinese vaccines used to date

In 2026, lower-cost alternatives could save \$88.7M in total, with PCV10 (5 dose) being the main driver, saving \$41.6M





SOURCE: 1 CHAI Nigeria Country Team Forecast 2 UNICEF Price List; Cost to government = ((doses*price) + Freight, insurance and inspection (10%) + Handling charges (4.5%) + Buffer (6%))* Government co-financing %; HPV is forecasted and has not yet been introduced in Nigeria yet; Switch decisions on this document do not consider cold chain and other cold chain requirements;



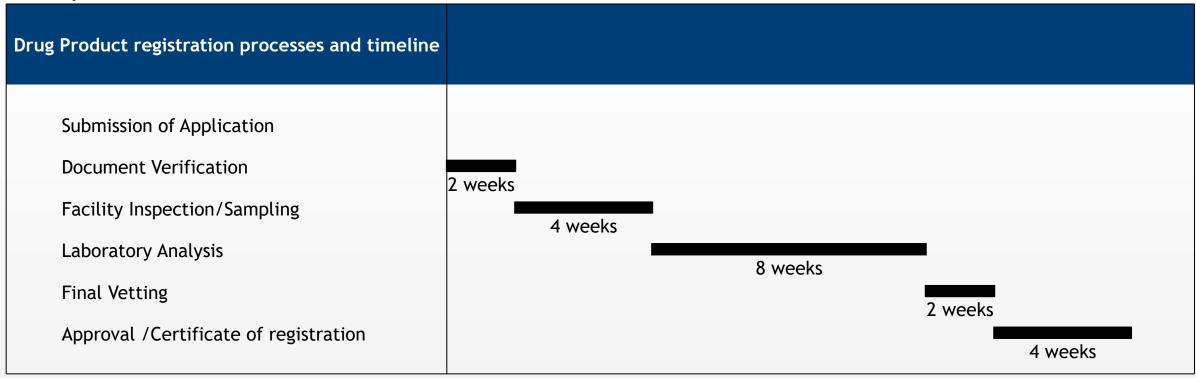
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Nigeria's registration process is managed by the NAFDAC and includes 6 key steps that take approximately 100 working days



Activity



• Depending on the nature of the vaccine, government timelines may be shorter and some steps may be skipped, such as Covid-19 where the process began from laboratory analysis.



Multiple stakeholders are involved in the Nigeria product selection process

	Stakeholde	er group						Stakeholder role
Step in product selection process	Partners (e.g., CDC, CHAI, WHO , UNICEF)		NGI-TAG	NPHCDA	Core Group	ICC		Supports Decides Signs-off
Antigens selected and timelines set for NVIs in multi-year strategy documents (e.g., cMYP includes planning to 2020, NSIPPS includes planning to 2028)								
Disease working group set up by NGI-TAG to synthesize evidence on product options, with support of partners as members of Secretariat			_					No history of dissent on
Preferred product selected by NGI-TAG			 			_	<u>i</u> –	product
Gavi application submitted and approved			•					recommended by NITAG
NVI planned and executed								·

Whilst there is limited current support for locally manufactured vaccines in Nigeria, there are strong indications of Govt. support moving forwards



		 Nigeria procures through UNICEF SD and is in the Gavi accelerated transition phase and will graduate from Gavi support in 2028. The country was due to graduate out of Gavi but renegotiated an extension. The framework for the extension requires that the govt. must provide incremental funds from budgetary sources every year culminating in 100% funding for vaccine procurement by 2028.^{1,2}
	Current	• Public procurement in Nigeria is governed by the Public Procurement Act.¹ The Act established the Bureau for Public Procurement (BPP) to oversee public procurement and ensure fair, competitive, and transparent standards and practices for the procurement of public goods and services.³
		 Since Nigeria is still Gavi-supported, the country has opted for vaccine procurement through UNICEF SD. However, govt. funded vaccines procurement is by open competitive bidding.
Policy		 As there is no vaccine manufacturing in Nigeria presently, there is no current policy in place for preferential consideration of locally /regionally /continentally manufactured vaccines. Govt. support for local vaccine manufacturing is geared mostly towards industrial support for the planned vaccine manufacturers, especially, Biovaccines Nigeria Limited, BVNL.
		 Whilst there is no formal process for preference of locally manufactured products, Nigeria's recent decision to introduce BBIL's Rotavirus product, which has a local partnership with Innovative Biotech to localize production of the antigen in Nigeria, may signal support for local manufacturing.
Procurement		• The govt. signed an MoU with BVNL for the latter to supply vaccines to the govt. and engage in contract manufacturing. The Nigerian govt. also developed the Nigeria Vaccine Policy (NVP) which sets out the targets and strategies to "achieve vaccine availability and sufficiency and consequently vaccine security in the country" after transitioning from Gavi support. It also set out guidelines for vaccine management across the vaccine value chain. 1,4
	ıre	 Supply services: The NVP specifies that BVNL will engage in supply services of vaccines and injection devices upon request by the govt and preference for vaccine procurement is "accorded to locally manufactured vaccines" in accordance with the Public Procurement Act. Under the terms of the agreement, the govt. makes advance payment and BVNL will deliver the vaccines to the approved warehouses.¹
	Future	— Local vaccine manufacturing: To produce local vaccines through BVNL, "30% of vaccines dossiers developed & registered for local production."4
		• ECOWAS Regional Procurement: The Economic Committee of West African States (ECOWAS) is working on ECOWAS Procurement. This regional procurement will be a revolving fund, like the PAHO RF. Unlike the PAHO RF, however, it will include medicines and medical devices, and not just vaccines. When available, the Fund will preferentially procure from regional, then continental sources. Pooled procurement and volume guarantees to local manufacturers are among the tools intended to encourage end-to-end pharmaceutical manufacturing in the region and continent. The revolving funds will be coordinated by the West African Health Organization (WAHO). ⁴

Thank you!



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