

Kenya Country Profile

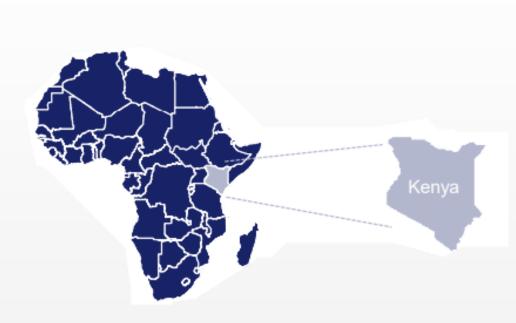
2024



- a. Immunization program overview
- b. Vaccine spending
- c. Product selection and opportunities
- d. Market access



Kenya's Immunization Program - Overview by the numbers



Indicators	Status (2024)
Population	56,203,030
Birth Cohort	1,599,302
Under 5 Mortality Rate (# per 1,000 live births)	37/1000
EPI Coverage	78%
National EPI Manager	Division of Vaccines and Immunization (DVI) at Ministry of Health
GNI per capita (USD)	\$2,170
Government Health Spend (% per GDP) - 2023	5.5-5.7%
Gavi Country Status (Y/N, Year of Transition)	Y, (Accelerated Transition), 2030

Kenya's RI program includes a comprehensive schedule of 10 vaccines to protect children against various infectious diseases from birth through childhood



Vaccine	Abbreviation	Disease prevention	Dosage	Birth	6 weeks	10 weeks	14 weeks	6 month s	7 month s	9 month s	18 month s	24 month s	9-14 yrs girls
Bacillus Calmette- Guérin vaccine	BCG	Prevents Tuberculosis including bloody cough and permanent brain damage	0.05ml										
Oral polio vaccine	OPV	Partially protects against poliomyelitis which causes paralysis and death	2 drops										
Pentavalent (DPT, Hep B and Hib)	Penta	Partially protects against 5 diseases - diphtheria, whooping cough, tetanus, hepatitis B, and influenza	0.5ml										
Rotavirus vaccine	Rota	Diarrhoea disease	1.2ml										
Inactivated polio vaccine	IPV	Prevent poliomyelitis which causes paralysis and death	0.5ml										
Pneumococcal conjugate vaccine	PCV	Protects against most causes of pneumonia and meningitis including blood and lung infections and brain damage	0.5ml										
Measles Rubella	MR	Protects against measles & rubella infections	0.5ml										
Yellow Fever	YF	Prevents yellow fever which causes live diseases and death	0.5ml										
RTS,S vaccine	RTS,S / AS01	prevent malaria caused by the Plasmodium parasite											
Human papillomavirus vaccine	HPV	Protects against HPV types 6,11,16,18 that cause HPV cancers, most commonly cervical cancer											

SOURCE: Kenya's Ministry of Health 4

Vaccine Pipeline: With Malaria & HPV recently introduced, Kenya is expected to now shift gears towards introduction of TCV



Switch

Planned

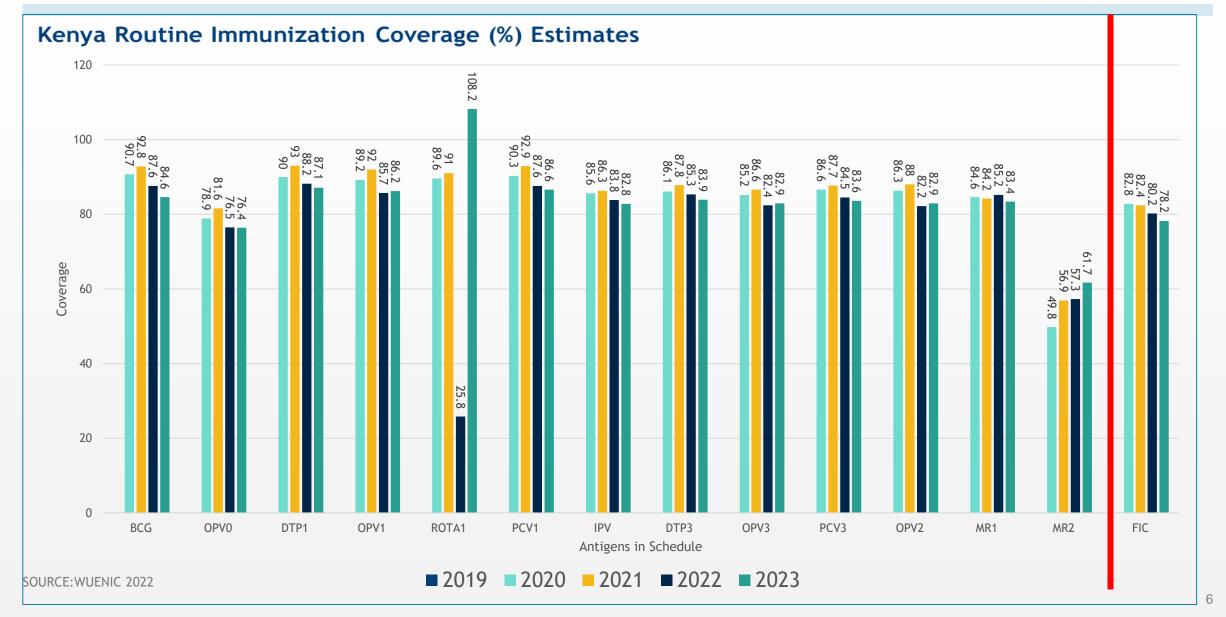
Introduced

Vaccine	Pre-2018	2019	2020	2021	2022	2023	2024	2025	2026
BCG, OPV, Penta, IPV, MR, PCV, Rota, YF									
HPV									
Malaria									
TCV									

- Kenya is one of the three pilot countries (along with Malawi and Ghana) that participated in the Malaria vaccine implementation programme for RTS,S vaccine in 2023 & subsequently introduced the vaccine in RI in 2024
- Kenya's priority is also on introducing second dose of IPV which is expected to be rolled out nationwide by 2025

Vaccine Coverage: Kenya's RI coverage exceeds global and AFRO averages, with higher rates for key vaccines like DTP3 and MCV1, highlighting effective health policies (1/2)





Vaccine Coverage: Kenya's RI coverage exceeds global and AFRO averages, with higher rates for key vaccines like DTP3 and MCV1, highlighting effective health policies (2/2)







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c. Product selection and opportunities

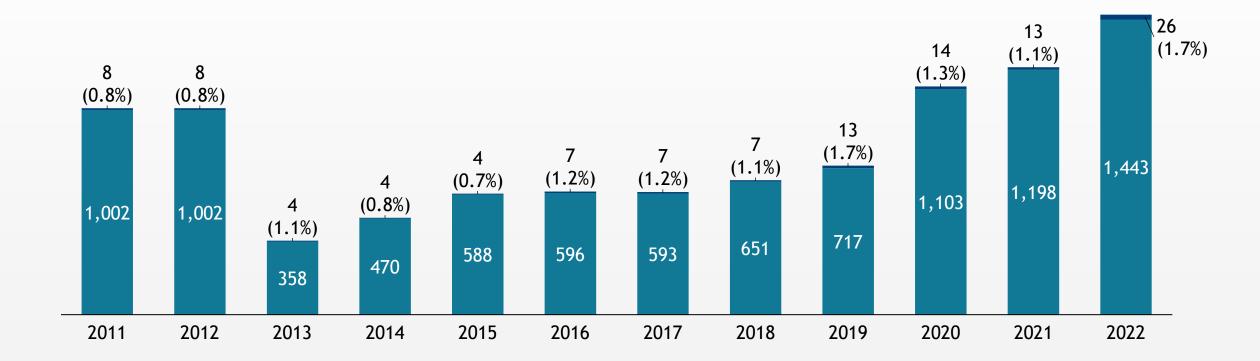
d. Market access

Kenya's allocation for vaccine procurement has been increasing steadily over the years (\$26 Mn; ~1.7% of total health budget)



Vaccine Budget
Other Health Budget

Kenya's YoY Total Health Budget - Vaccines vs Non-Vaccines (\$ Mn)

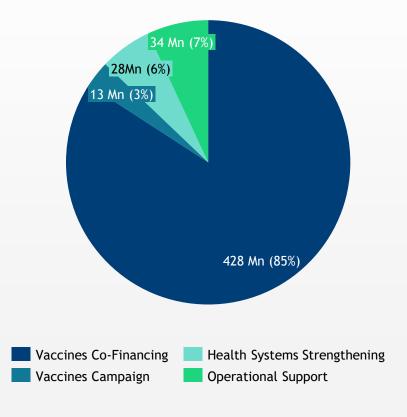


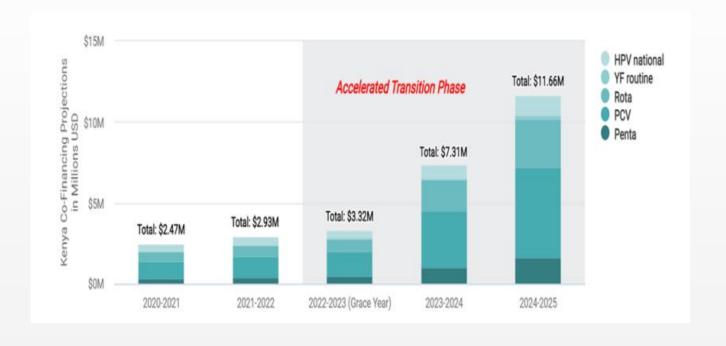


Gavi Financial Commitments to Kenya: 2001-2023

Gavi has committed \$500Mn+ to Kenya b/w 2001-2023 for several immunization priorities

Kenya's co-financing obligation from 2020 to 2025 - expected to increase as it moves to accelerated transition phase



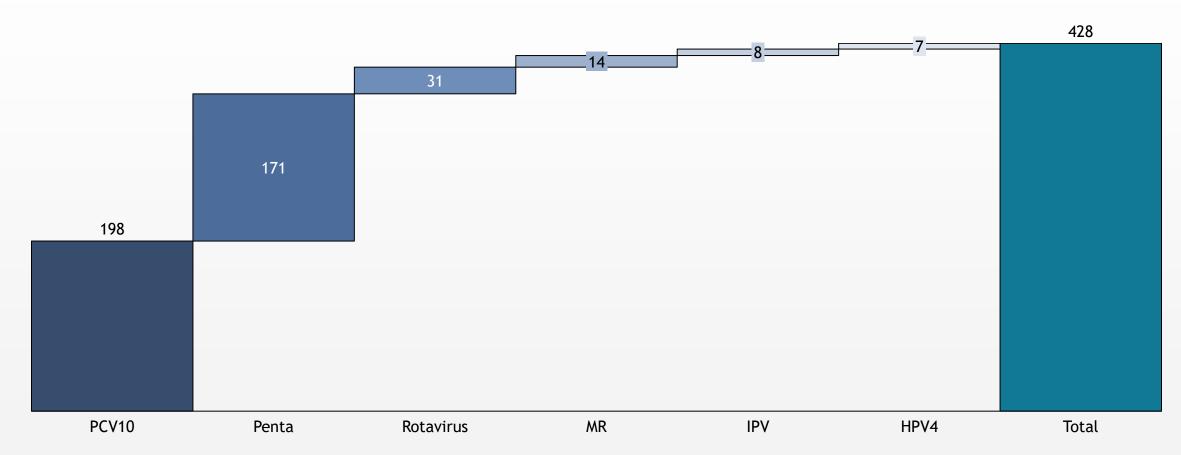


Source: Gavi

Gavi Commitments to Kenya 2001-2023: PCV & Penta alone represent ~86% of vaccine co-financing contribution to Kenya



2001-2023 Gavi's Vaccine Co-financing Contributions (\$ Mn)





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Product use: 7 out 11 vaccines in Kenya are provided by DCVMs with Serum Institute leading the way with 6 products



Vaccine	Intro Timeline	Product	Brand	Supplier type		
Rota 2014		Rotarix	GSK	MNC		
		Rotavac	BBIL	DCVM		
Malaria	2024	Mosquirix	Serum Institute	DCVM		
PCV10	2011	Pneumosil	Serum Institute	DCVM		
		Synflorix	GSK	MNC		
MenA	2018	MenAfriVac	Serum Institute	DCVM		
HPV4	2023	Gardasil	MSD, SSI	MNC		
BCG	2000	Vaccin BCG SSI	SSI	MNC		
OPV	2016	Sanofi, BioFarma, Serum Institute	Sanofi, GSK, Serum Institute			
DTwP-HepB-Hib (Penta)	2001	Easyfive-TT	Serum Institute,	DCVM		
IPV	2015	Imovax	Sanofi , LG Chem	MNC		
MR	2017	MR-Vac	Serum Institute, BE ltd,	DCVM		
YF	2001	YF-Vax	Sanofi	MNC		

Source: GVMM Database, Press Research



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Comprehensive Framework for New Vaccine Introductions in Kenya involves multiple steps from evidence gathering all the way up to monitoring & evaluation



Evidence Gathering & Policy Formulation

MoH conducts disease burden assessments and gathers evidence on Vx safety, efficacy, and costeffectiveness

National Immunization Technical Advisory Group (KENITAG) evaluates data and provides recommendations to MoH.

Regulatory Approval

Obtain approval from Pharmacy and Poisons Board (PPB) which oversees Vx registration, requiring clinical trial data and potentially accepting international approvals for new products

Vx Procurement & Program Implementation

MoH's special arm National Vaccine and Immunization Program (NVIP) with support from partners works on Vx procurement & integration of NVIs in NIP, strengthening cold chain systems and workforce training

Conduct pilot introductions in select regions to identify and address challenges

Scale up to a nationwide rollout based on pilot results and readiness assessments

Monitoring & Evaluation

MoH and partners monitor Vx coverage through routine health information systems and surveys to ensure target population is being reached

Safety of the new Vx is continuously monitored through Pharmacovigilance program & over time impact assessment analysis is conducted to ensure intended outcomes being achieved



Vaccine Procurement Process in Kenya

- Procurement of vaccines is led by National Vaccines & Immunization Program (NVIP) within MoH, and supported by UNICEF, CHAI, Gavi, WHO, & MoF. The National Forecast group provides a vaccine forecast annually
- Procurement of both traditional and Gavi supported vaccines through UNICEF, whilst non-EPI vaccines and antisera are procured through local tendering.
- The national level maintains a maximum and minimum stock level at the regional level and plans procurements in relation to the maximum and minimum national stock levels. i.e. once the minimum is reached, the procurement mechanism is triggered.

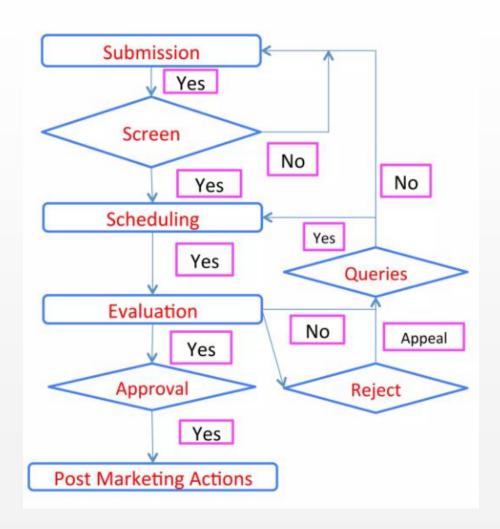
NVIP declares intent (usually with support from development partners)

NVIP evaluates products based on the following criteria (with technical support from partners): i) Serotypes, ii) Presentation, iii) Ease of Use

NVIP makes a final decision Inter-Agency
Coordinating
Committee
(ICC) Rubber
stamps
decision



Market Authorization Process for Vaccines in Kenya involves 6 broad steps



- Scheduling of Dossiers on First in First Out (FIFO) basis
- Timeline for review within ~12 months (~3 months in case of priority Vx)
- Evaluation & Responses to Queries by NVIP
- Post Marketing Actions
 - Annual Retention
 - Post market variations
 - Pharmacovigilance

Source: Pharmacy & Poisons Board Kenya 17



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