

# Nigeria Country Profile

2024



### Contents

#### a. Immunization program overview

b. Vaccine spending

c. Product selection and opportunities

d. Market access



#### **Country Overview**

| 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)    | <ul> <li>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.</li> <li>Nigeria entered the accelerated phase of the Gavi transition in 2018 and will likely remain in this phase until 2030 due to upcoming Gavi policy changes</li> <li>The NSIPSS1, Nigeria's 10-year strategy document (2018 - 2028), defines the country's plan to transition from Gavi support.</li> </ul> |
| Contribution to Gavi                             | <ul> <li>Nigeria committed to invest ~US\$ 2 billion to finance its vaccines from 2018-2028</li> <li>Gavi's financial support of around US\$ 1 billion will include:         <ul> <li>US\$ 773 million for vaccine financing and</li> <li>Up to US\$ 260 million for health system strengthening.</li> </ul> </li> </ul>   |
| COVAX country (Y/N, Note)                        | Yes/Nigeria has received Covid-19 doses through the COVAX vaccine-sharing facility   |

# Nigeria currently has 10 vaccines in its RI portfolio, with Rotavirus and HPV recently being introduced

| <b>CLINTON</b> |
|----------------|
| HEALTH ACCESS  |
| INITIATIVE     |
|                |
|                |

| Vaccine                                | Abbreviation | Disease prevention  | Dosage  | Birth | 6<br>weeks | 10<br>weeks | 14<br>weeks | 9<br>months | 15<br>months | 9-14<br>yrs girls |
|--|--------------|---|---------|-------|------------|-------------|-------------|-------------|--------------|-------------------|
| Bacillus<br>Calmette-Guérin<br>vaccine | BCG          | Prevents Tuberculosis including bloody cough and permanent brain damage                                       | 0.05ml  |       |            |             |             |             |              |                   |
| Hepatitis B<br>vaccine                 | Нер В        | Partially protects against hepatitis B which causes blood infection liver disease, cancer and death           | 0.5ml   |       |            |             |             |             |              |                   |
| Oral polio<br>vaccine                  | OPV          | Partially protects against poliomyelitis which causes paralysis and death                                     | 2 drops |       |            |             |             |             |              |                   |
| Pentavalent<br>(DPT, Hep B and<br>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<br>vaccine           | IPV          | Prevent poliomyelitis which causes paralysis and death  | 0.5ml   |       |            |             |             |             |              |                   |
| Pneumococcal<br>conjugate<br>vaccine   | PCV          | Protects against most causes of pneumonia and meningitis including blood and lung infections and brain damage | 0.5ml   |       |            |             |             |             |              |                   |
| Measles vaccine                        | Measles      | Protects measles  | 0.5ml   |       |            |             |             |             |              |                   |
| Yellow Fever                           | YF           | Prevents yellow fever which causes live diseases and death  | 0.5ml   |       |            |             |             |             |              |                   |
| Meningococcal A<br>vaccine             | Men A        | Protects against strains of the meningococcal bacteria  |         |       |            |             |             |             |              |                   |
| Human<br>papillomavirus<br>vaccine     | HPV          | Protects against HPV types 6,11,16,18 that cause HPV cancers, most commonly cervical cancer                   |         |       |            |             |             |             |              |                   |



#### Nigeria plans to expand routine immunization over the next four years

|                                  |                      |                      |      |                      |      |      |      | Introd | luced        | Planned Switch  |
|----------------------------------|----------------------|----------------------|------|----------------------|------|------|------|--------|--------------|-----------------|
| Vaccine                          | Pre-2018             | 2019                 | 2020 | 2021                 | 2022 | 2023 | 2024 | 2025   | 2026         | Comment         |
| BCG, HepB, bOPV, Penta, YF, MenA |                      |                      |      |                      |      |      |      |        |              |                 |
| IPV                              | 1st dose             |                      |      | 2 <sup>nd</sup> dose |      |      |      |        |              |                 |
| PCV10                            |                      |                      |      |                      |      |      |      |        |              | 2d to 4d switch |
| Measles                          | 1 <sup>st</sup> dose | 2 <sup>nd</sup> dose |      |                      |      |      |      |        | MR<br>switch |                 |
| Rota                             |                      |                      |      |                      |      |      |      |        |              |                 |
| HPV4                             |                      |                      |      |                      |      |      |      |        |              |                 |
| тсч                              |                      |                      |      |                      |      |      |      |        |              |                 |
| 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<sup>1</sup>



# Covid-19: Nigeria's preference for single-shot vaccines has led to an increased uptake of viral vector vaccines

**C19 Procurement** 





- Nigeria likely unable to meet its target of vaccinating 70% of its population by the end of 2023
- Drivers for low vaccination rates include vaccine stockouts, vaccine hesitancy, & ineffective vaccination drives
- Nigeria integrating workplans across multiservice areas to ensure routine immunization is not affected by C-19 vaccination targets shortfalls



- Majority of vaccines procured have been through COVAX
- Nigeria utilized vaccine donations to ensure access
- ~1 million vaccines estimated to have expired in December 2021 without being used.



- End user preferences indicate that a single shot C-19 vaccine is the most preferred
- Nigeria has already rolled out booster shots and these are available to people who have taken the 1st & 2nd dose with the country utilizing mRNA vaccines for boosters



### Contents

a. Immunization program overview

#### b. Vaccine spending

c. Product selection and opportunities

d. Market access

Nigeria will become more price sensitive as it increases its financing contribution from 64% in 2018 to 100% in 2029 - this may change with upcoming Gavi policy shifts

#### Financing for loaded routine immunization vaccines 2018 - 2029 <sup>1</sup>



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.

Nigeria anticipates that it will need Gavi to continue to cover 70% of financing for Supplementary Immunisation Activities (SIA) between 2018 and 2027





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.

## In 2026, ~366M USD will be the total value spent on Nigeria's vaccine procurement, with >60% driven by three vaccines - PCV, IPV and HPV





- 5 vaccines (PCV, IPV, HPV, Penta and Rota) make up approximately 79% of the total value spent by Nigeria on RI vaccines
- The introduction of new vaccines, specifically HPV and Rota, adds to Nigeria's budgetary demands (71M USD)
- CHAI Nigeria forecast differs from NSIPSS forecast due to differences in vaccines included in the forecast

SOURCE: 1 CHAI Nigeria Country Team Forecast; Total Cost of RI procurement = Cost of vaccines + Freight, insurance and inspection (10%) + Handling charges (4.5%) + Buffer (6%); HPV & Rota are forecasted but not yet been introduced

# In 2022, SIA procurement costs was ~50% the size of the RI budget, driven by YF preventative campaigns





- YF makes up ~78% of SIA preventative vaccine costs in 2022
- CHAI Nigeria forecast differs from NSIPSS forecast due to differences in vaccines included in the forecast

SOURCE: 1 CHAI Nigeria Country Team Forecast; Total Cost of RI procurement = Cost of vaccines + Freight, insurance and inspection (10%) + Handling charges (4.5%) + Buffer (6%)

# Gavi co-financing of vaccines varies between 5-60% today; IPV is fully financed by Gavi





#### Key Takeaways

- Gavi extended its support for Nigeria to 2028 instead of the plan to transition in 2021
- The Gavi support is contingent on Nigeria fully meeting its commitments and is based on a robust transition plan which has been jointly developed by the Alliance and the Government of Nigeria
- Based on CHAI Nigeria forecasts, newly introduced vaccines like HPV will be heavily Gavi co-financed (~34%) but older vaccines like Penta will be fully paid by government by 2026
- Unlike the rest of the vaccines, financing for IPV is expected to remain fully covered by GAVI



### Contents

a. Immunization program overview

b. Vaccine spending

c. Product selection and opportunities

d. Market access



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



Vaccine Shipments to Nigeria by Manufacturer, 2021 (Million Doses)

- 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;



### Contents

a. Immunization program overview

b. Vaccine spending

c. Product selection and opportunities

d. Market access

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



| Activity   |         |
|--|---------|
| Drug Product registration processes and timeline |         |
| Submission of Application                        |         |
| Document Verification                            | 2 weeks |
| Facility Inspection/Sampling                     | 4 weeks |
| Laboratory Analysis                              | 8 weeks |
| Final Vetting                                    | 2 weeks |
| Approval /Certificate of registration            | 4 weeks |

• 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.

#### As part of the new vaccine introductions (NVI), Nigeria generally has a defined process to select products for introduction



• Some variation is expected from product to product

| Decision-making   | Product selecti  | ion  | Approvals  | Planning                               |
|---|--|--|--|--|
| NPHCDA selects<br>antigens and sets<br>timelines in strategy<br>documents, for<br>example as part of<br>FPP process | NGI-TAG sets up<br>disease working<br>group to<br>synthesize<br>evidence | NGI-TAG<br>selects<br>preferred<br>product | Approvals by NPHCDA,<br>Core Group, ICC,<br>followed by Gavi<br>application submission<br>and approval | NPHCDA<br>plans and<br>executes<br>NVI |

Triggered by NVI timelines, with partner support (e.g., WHO, CHAI)

Understanding these processes can help shed light on *which* stakeholders require product information



#### Multiple stakeholders are involved in the Nigeria product selection process

|   | Stakeholde  | er group                               |         |        |               |     |    | Stakeholder                      |
|---|---|--|---------|--------|---------------|-----|----|----------------------------------|
| Step in product selection process   | Partners<br>(e.g., CDC,<br>CHAI, WHO<br>, UNICEF) | NGI-TAG<br>disease<br>working<br>group | NGI-TAG | NPHCDA | Core<br>Group | ICC |    | Supports<br>Decides<br>Signs-off |
| Antigens selected and timelines set for NVIs<br>in multi-year strategy documents (e.g., cMYP<br>includes planning to 2020, NSIPPS includes<br>planning to 2028) |   |  |         |        |               |     |    |                                  |
| Disease working group set up by NGI-TAG to<br>synthesize evidence on product options, with<br>support of partners as members of<br>Secretariat                  |   |  | -       |        |               |     |    | No history of                    |
| Preferred product selected by NGI-TAG   |   |  |         |        |               | -   | i– | product                          |
| Gavi application submitted and approved   |   |  | -       |        |               |     | 1  | recommended<br>by NITAG          |
| NVI planned and executed  |   |  |         |        |               |     |    |                                  |

# While Nigeria does not yet have a systematic product switch process, its approach to PCV presentation switch shows parallels to its NVI process



| NPHCDA selects<br>antigens and sets<br>NGI-TAG (est.<br>2015) sets up<br>NGI-TA   |   |
|---|---|
| NVI<br>processtimelines in multi-<br>year strategy<br>documentsdisease working<br>group to<br>synthesize<br>evidenceselects<br>preferre<br>product  | Approvals by NPHCDA,<br>Core Group, ICC,<br>followed by Gavi<br>application submission<br>and approval<br>NVI   |
| <b>Triggered by NVI timelines</b> , with  | partner support (e.g., WHO, CHAI)   |
| Switch :<br>PCV<br>presen-<br>tationNPHCDA prepared<br>proposal for how<br>switch would be<br>executedNigeria did not identify a need<br>to revisit product options, since<br>PCV10 had previously been<br>selected as the preferred<br>product | Approvals by Core<br>Group and ICC, followed<br>by Gavi switch<br>application submission<br>and approval<br>NPHCDA<br>plans and<br>executes<br>switch |

# Whilst there is limited current support for locally manufactured vaccines in Nigeria, there are strong indications of Govt. support moving forwards (1/2)



| icy      |        | <ul> <li>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<br/>Gavi but renegotiated an extension. The framework for the extension requires that the govt. must provide incremental funds from budgetary sources every year<br/>culminating in 100% funding for vaccine procurement by 2028.<sup>1,2</sup></li> </ul>   |
|----------|--------|--|
|          | Ŀ      | • Public procurement in Nigeria is governed by the Public Procurement Act. <sup>1</sup> 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. <sup>3</sup>   |
|          | Curren | <ul> <li>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.</li> </ul>   |
|          | 0      | <ul> <li>As there is no vaccine manufacturing in Nigeria presently, there is no current policy in place for preferential consideration of locally / regionally / continentally<br/>manufactured vaccines. Govt. support for local vaccine manufacturing is geared mostly towards industrial support for the planned vaccine manufacturers,<br/>especially, Biovaccines Nigeria Limited, BVNL.</li> </ul>   |
| ent Po   |        | <ul> <li>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.</li> </ul>  |
| Procurem |        | • 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. <sup>1,4</sup>   |
|          | ure    | <ul> <li>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.<sup>1</sup></li> </ul>   |
|          | Fut    | - Local vaccine manufacturing: To produce local vaccines through BVNL, "30% of vaccines dossiers developed & registered for local production." <sup>4</sup>  |
|          |        | • 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). <sup>4</sup> |

SOURCE: Federal Ministry of Health, FG Signs MOU For Locally Made Vaccines, June 2020; Nigeria Vaccine Policy, 1st Edition, September 2021; Federal Ministry of Information and Culture, Nigeria; NAFDAC, Vaccines & Biologics; NMRA's Participating in the WHO Collaborative Procedure, November 2022; Nigerian Investment Promotion Commission, Pioneer Status Incentive; Nigerian Investment Promotion Commission, List of Pioneer Industries and Products; Health Policy Watch, African Medicines Agency Multimedia



|           |        | Nigerian vaccine manufacturing plan  |
|-----------|--------|--|
|           |        | <ul> <li>In November 2020, the govt. signed an MOU for a joint venture with May &amp; Baker Nigeria Plc, an indigenous pharmaceutical company. The purpose of the joint venture is "to achieve local production and uptake of vaccines". This public-private partnership birthed Biovaccines Nigeria Limited (BVNL) <sup>1,2</sup></li> </ul>  |
| 10        |        | <ul> <li>Nigeria develops the Nigeria Vaccine Policy document in September 2021 to encourage local production and self-sufficiency of vaccines <sup>2</sup></li> </ul>   |
| Policies  | ent    | — In June 2022, the Nigerian govt. inaugurated the Inter-ministerial Steering Committee (IMSC) and Technical Working Group (TWG) on Local Vaccines. This was in line with the strategies and timeline for local vaccine production as developed in the Nigeria Vaccine Policy (NVP) document. The committee and TWC oversee Nigeria's vaccine production plan according to the timeline specified in the NVP. <sup>3</sup> |
| ated      | Curr   | <ul> <li>The National Agency for Food and Drug Administration and Control (NAFDAC) is the national regulatory agency. NAFDAC is WHO ML3 certified for the regulation of<br/>imported vaccines.<sup>4</sup></li> </ul>  |
| Rel       |        | - NAFDAC participates in the WHO Collaborative Registration Procedure for products that are WHO-prequalified and adopts WHO PQ'd products. <sup>5</sup>  |
| ıstrial & |        | Nigeria has some industrial policies to incentivize local vaccine manufacturing:   |
|           |        | — Tax holiday: It is granted to a select list of pioneer industries and products. Tax holiday "grants qualifying industries and products relief from payment of corporate income tax for an initial period of three years, extendable for one or two additional years". The vaccine industry is included in the list. <sup>6,7</sup>   |
| ndı       |        | <ul> <li>The govt. intends to fund vaccine manufacturing through the joint venture with May &amp; Baker Nigeria Plc as mentioned above.<sup>1,2</sup></li> </ul>   |
|           | Future | • Nigeria has ratified AfCFTA, however, the govt. is yet to sign or ratify AMA. <sup>8</sup>   |



www.clintonhealthaccess.org