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Preparing for Next-Generation Antimalarials in Nigeria: A Pre-Introduction Readiness Assessment with Focus on Infant-Friendly Formulations and Emerging Therapies

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Systematic Review

Keywords: Next-generation antimalarials, Nigeria, GanLum, ganaplacide-lumefantrine, infant formulations, malaria preparedness, NAFDAC, supply chain, health systems

Posted Date: March 25th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9201692/v1

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Additional Declarations: The authors declare no competing interests.

RESEARCH PAPER

Preparing for Next-Generation Antimalarials in Nigeria:

A Pre-Introduction Readiness Assessment with Focus on Infant-Friendly Formulations and Emerging Therapies

Secondary Data Review | March 2026

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The views expressed in this paper are the author's own.

ABSTRACT

Nigeria shoulders the world's highest national malaria burden, accounting for approximately 25.9% of global malaria cases and 30.9% of malaria deaths in 2023, with children under five years of age comprising the most vulnerable group. As the global antimalarial pipeline advances notably with GanLum (ganaplacide-lumefantrine), which completed successful Phase 3 trials in November 2025, and new infant-specific formulations for neonates under 5kg. Nigeria's health system readiness to absorb, deploy, and equitably distribute these innovations is critically under-examined. This paper conducts a secondary data review to assess Nigeria's preparedness across five domains: disease burden, regulatory infrastructure, supply chain capacity, health system readiness, and financing. Findings reveal a nation with enormous need but significant structural gaps in regulatory harmonization, last-mile supply chain reliability, healthcare worker training, and domestic financing. The paper concludes with actionable pre-introduction recommendations to position Nigeria to benefit immediately and equitably when next-generation antimalarials receive regulatory approval.

Keywords: *Next-generation antimalarials, Nigeria, GanLum, ganaplacide-lumefantrine, infant formulations, malaria preparedness, NAFDAC, supply chain, health systems*

1. Introduction

Malaria remains one of the most devastating preventable diseases in human history, and no country bears this burden more heavily than Nigeria. According to the 2024 World Malaria Report, Nigeria

accounted for 25.9% of global estimated malaria cases and 30.9% of estimated malaria deaths in 2023, making it the single highest-burden country in the world. Among those deaths, children under five are catastrophically over-represented. WHO data from 2024 confirms that children under five account for approximately 76% of all malaria deaths in the African Region, and Nigeria alone contributes an estimated 31.9% of all malaria deaths on the continent.

The standard of care for uncomplicated falciparum malaria: artemisinin-based combination therapies (ACTs) such as artemether-lumefantrine (AL) is increasingly under pressure. Partial artemisinin resistance has emerged in East Africa and the Horn of Africa, with worrying signs of spread. This makes next-generation antimalarials not just desirable, but urgent.

A landmark development occurred in November 2025 when Medicines for Malaria Venture (MMV) and Novartis announced that GanLum (ganaplacide-lumefantrine, or KLU156) met the primary endpoint of its Phase 3 KALUMA trial, one of the first novel-acting antimalarial combinations in over two decades. Simultaneously, a CALINA Phase II/III study completed evaluation of a new formulation of artemether-lumefantrine for neonates weighing under 5 kilograms, a group for whom no approved malaria treatment previously existed.

Yet pharmaceutical innovation means little without country-level readiness. Regulatory pathways must be pre-aligned, supply chains must be prepared, clinicians must be trained, and financing must be committed. Nigeria's history with new health product introductions i.e. from vaccines to diagnostic technologies, suggests that without deliberate pre-introduction planning, the gap between drug approval and equitable access can span years.

This paper introduces one of the first structured pre-introduction readiness frameworks for next-generation antimalarials in a high-burden country context. It uses secondary data to conduct a pre-introduction readiness assessment, examining what Nigeria must do now before these drugs are approved and available to ensure that when they arrive, they save lives immediately and at scale.

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2. Background: The Malaria Burden in Nigeria

2.1 Epidemiological Overview

Nigeria's malaria burden is staggering in both absolute and relative terms. With 97% of its estimated 220 million population at risk, malaria transmission occurs year-round in the south and for at least three months in the north. The 2024 World Malaria Report estimated 68 million malaria cases and 184,000 malaria deaths in Nigeria in 2024 -the highest estimated national burden worldwide.

Case incidence decreased modestly between 2022 and 2023 from 305 to 299 per 1,000 population at risk and death incidence fell by 6.5%, from 0.86 to 0.8 per 1,000. These marginal gains are encouraging but deeply insufficient given the scale of the problem.

2.2 The Child Mortality Crisis

Under-five malaria mortality is the most urgent dimension of this burden. Nigeria accounts for 39% of global malaria deaths in children under five years of age. A 2022 extended cost-effectiveness analysis published in Malaria Journal estimated that under-five malaria accounts for approximately

95,000 annual child deaths in Nigeria alone. More recent 2024 UN data confirms that malaria was the single largest killer of children aged one to 59 months, responsible for 17% of deaths in that age group, with Nigeria among the countries bearing the greatest share.

A particularly urgent gap involves neonates and infants weighing less than 5 kilograms for whom no WHO-approved malaria treatment existed. This population, comprising premature infants and low-birth-weight newborns, represents one of the most vulnerable and underserved groups in global health.

Indicator	Value	Source
Nigeria's share of global malaria cases (2023)	25.9%	WHO World Malaria Report 2024
Nigeria's share of global malaria deaths (2023)	30.9%	WHO World Malaria Report 2024
Children under-5 share of malaria deaths (Africa)	~76%	WHO Fact Sheet 2024
Nigeria's share of under-5 global malaria deaths	39%	Malaria Journal, 2024
Estimated annual malaria cases in Nigeria (2024)	68 million	Nigeria Health Watch, 2026
Estimated malaria deaths in Nigeria (2024)	184,000	Nigeria Health Watch, 2026
Population at risk of malaria in Nigeria	97%	NMEP / Severe Malaria Observatory
Annual child deaths from malaria (under-5)	~95,000	Malaria Journal, 2022

Table 1: Key Nigeria Malaria Burden Indicators

2.3 Geographic and Social Dimensions

Malaria transmission and outcomes are not uniform across Nigeria. The northern states face specific operational challenges including conflict-related disruptions in the Northeast, nomadic populations with poor healthcare-seeking behaviour, and seasonally concentrated transmission windows. In contrast, southern states experience year-round transmission but also benefit from greater proximity to health facilities.

Socioeconomic factors compound vulnerability. High out-of-pocket health expenditure is a documented deterrent to care-seeking, particularly among the poorest quintiles. One analysis found that the poorest 40% of Nigerians would account for 72% of all deaths averted under a cost-subsidisation scenario, underscoring how inequity drives the mortality burden.

3. The Next-Generation Antimalarial Pipeline

3.1 GanLum (Ganaplacide-Lumefantrine)

GanLum represents the most advanced and clinically significant development in the next-generation antimalarial pipeline. It combines ganaplacide a novel imidazolopiperazine compound with an entirely new mechanism of action with a new solid dispersion formulation of lumefantrine optimised for once-daily dosing.

In November 2025, MMV and Novartis announced that the Phase 3 KALUMA trial (NCT05842954), conducted across 34 sites in 12 African countries with 1,688 adult and paediatric participants, met its primary endpoint of non-inferiority to the current standard of care. GanLum achieved a 97.2% cure rate at Day 28 compared to 94% for artemether-lumefantrine. Critically, additional analysis confirmed high efficacy against mutant malaria parasites associated with partial drug resistance a feature that positions GanLum as the frontline option in a post-artemisinin-resistance scenario.

The formulation a sachet of granules administered once daily for three days is clinically significant for paediatric use. The granule/sachet format is appropriate for dissolution and administration to young children, though specific infant dosing formulations for the under-5kg weight band require further regulatory review.

GanLum also demonstrated a rapid response against mature gametocytes, the sexual stage of the parasite responsible for onward mosquito transmission, giving it potential transmission-blocking properties beyond individual treatment. If approved by WHO and national regulators, GanLum would be the first non-artemisinin ACT available since Malarone was launched in 2000.

3.2 Infant Formulations: The CALINA Study

A parallel and equally significant development is the completion of the CALINA Phase II/III study, which evaluated a new dose and ratio of Coartem (artemether-lumefantrine) specifically designed for neonates and infants weighing less than 5 kilograms. The optimised dose accounts for metabolic differences in small babies. As of late 2024, Novartis and MMV had submitted positive data from this study for regulatory review.

If approved, this formulation would close a critical treatment gap the complete absence of any WHO-approved antimalarial for the lowest-weight infants. Given that premature births and low birth weight remain major problems in Nigeria, this formulation is directly relevant to Nigerian clinical practice.

3.3 Other Pipeline Candidates

Beyond GanLum and the CALINA formulation, several additional candidates are at various stages:

- Cipargamin (KAE609): In Phase 2 development for severe malaria; relevant to Nigeria's high severe malaria burden. An intravenous formulation is under investigation.
- INE963: In Phase 1 development, under investigation as a potential single-dose cure a formulation that could dramatically improve adherence in resource-limited settings.
- Cabamiquine (M5717): In Phase 2 development; a long-acting candidate with potential for single-dose treatment of uncomplicated malaria.

Candidate	Stage	Formulation	Key Feature	Relevance to Nigeria
GanLum (KLU156)	Phase 3 Complete	Sachet granules, once daily x3	Novel MOA, active vs resistant parasites	Very High – paediatric tested
AL for <5kg (CALINA)	Regulatory Review	Optimised dispersible	First treatment for neonates <5kg	Critical – premature infant gap
Cipargamin IV (KAE609)	Phase 2	IV formulation	Severe malaria; resistance-ready	High – severe malaria burden
INE963	Phase 1	Potential single dose	Improved adherence	Moderate – adherence gap
Cabamiquine (M5717)	Phase 2	Oral	Single-dose, long-acting	Moderate – rural access

Table 2: Next-Generation Antimalarial Pipeline — Nigeria Relevance Assessment

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4. Nigeria's Pre-Introduction Readiness Assessment

4.1 Regulatory Readiness

4.1.1 NAFDAC and the Approval Framework

The National Agency for Food and Drug Administration and Control (NAFDAC) is the primary regulatory authority governing drug approval in Nigeria. Established by Decree No. 15 of 1993 and amended by Decree No. 19 of 1999, NAFDAC is responsible for regulating the manufacture, importation, distribution, and sale of drugs. It operates the NAPAMS (NAFDAC Automated Product Administration and Monitoring System), an e-registration platform for product applications.

For new drugs, NAFDAC mandates demonstration of safety and efficacy through clinical trials. The standard drug registration process from application through laboratory testing, facility inspection, and FDRC committee review to certificate issuance can take several months under optimal conditions. Facility inspections are estimated to require approximately 20 days. Foreign manufacturers must appoint a local agent and hold a Superintendent Pharmacist License, among other requirements.

4.1.2 Regulatory Harmonisation Opportunities

Nigeria participates in the West African Drug Regulatory Authority Network (WADRAN) and is a member of the broader African Medicines Regulatory Harmonisation (AMRH) initiative under AUDA-NEPAD. These frameworks create pathways for joint review and mutual recognition that could significantly accelerate approval of GanLum and infant formulations if pre-approval engagement begins now.

A critical preparedness action is for NAFDAC to initiate early scientific advice engagement with MMV and Novartis ahead of their regulatory dossier submission. Countries that engage regulators during Phase 3 rather than waiting for global approval typically reduce post-WHO-approval national

registration timelines from 18-24 months to 6-9 months. Nigeria should pursue this pathway aggressively for GanLum.

Nigeria has not been included as a trial site in the WANECAM 2 consortium for the KALUMA Phase 3 trial (which covered Burkina Faso, Mali, Gabon, Niger and other sites). This absence has regulatory implications: without local clinical trial data, NAFDAC may require bridging studies before domestic approval, adding time to access.

4.2 Supply Chain Readiness

4.2.1 Documented Deficiencies

Nigeria's pharmaceutical supply chain is among the most critically analysed weaknesses in its health system. A landmark cross-sectional survey published in Global Health: Science and Practice (2024) assessed 1,858 health facilities across seven states in northern Nigeria and found that availability of life-saving malaria commodities was suboptimal across all facilities surveyed. The study identified challenges including poor coordination, human resources capacity gaps, inadequate financial resources, and poor-quality data systems as primary contributors.

A complementary scoping review in BMC Public Health identified difficulty across all stages of the supply chain: selection, procurement, distribution, and inventory management. For vaccines and temperature-sensitive formulations, cold chain infrastructure was highlighted as a particular vulnerability in southeastern Nigeria.

4.2.2 Positive Developments

Despite these challenges, there are meaningful positive developments. In 2023, Nigeria's government contained the impact of supply disruption from flooding in two states by redistributing commodities from other states demonstrating emerging adaptive supply management capacity. Separately, Swiss Pharma Nigeria Ltd, with support from MMV and Unitaid, became the first Nigerian manufacturer of WHO-prequalified sulfadoxine-pyrimethamine, establishing a domestic precedent for local production of antimalarial commodities.

The granule/sachet format of GanLum offers some supply chain advantages compared with ACT tablets: the sachet format is shelf-stable and does not require cold chain storage, potentially simplifying distribution logistics compared with vaccines.

4.2.3 Key Supply Chain Gaps for Next-Gen Introduction

- Last-mile delivery to hard-to-reach communities, particularly in Northern Nigeria where insurgency and nomadic populations impede routine service
- Data systems: reliance on manual/paper-based stock tracking remains widespread at primary health care level, as documented in Ekiti State before the 2023 IMPACT project
- Quantification of drug demand for new products: Nigeria's current quantification frameworks are calibrated to existing ACTs and would need recalibration for GanLum and the infant formulation
- Health facility storage capacity and product management training for novel dosage forms (granule sachets for GanLum vs existing dispersible tablets)

4.3 Health System and Clinical Readiness

4.3.1 Treatment-Seeking and Diagnostics Gap

The 2021 Nigeria Malaria Indicator Survey (NMIS) revealed that while 56% of households own at least one insecticide-treated net, only 41% of under-fives slept under a net the night before the survey revealing an ownership-to-use gap. More critically for drug introductions, the same survey found that among under-fives with fever, only approximately one in four had blood taken for malaria testing. Without scaling diagnostic coverage, new drugs will be administered without confirmed diagnoses, undermining both their impact and the evidence base for monitoring.

4.3.2 Healthcare Worker Awareness and Prescribing Practices

A 2023 Severe Malaria Stakeholders Workshop attended by representatives from all 36 Nigerian states identified a key challenge: limited awareness of updated guidelines and strategic documents among frontline health workers, leading to the misuse of non-recommended medications. This finding is directly relevant to new drug introduction: if health workers are not adequately trained before GanLum's approval, the drug risks being used incorrectly, sub-therapeutically, or displaced by entrenched prescribing habits.

4.3.3 Malaria Vaccine Integration

Nigeria began piloting the R21 malaria vaccine in Kebbi and Bayelsa states in October 2024, with support from Gavi and UNICEF. This represents an important operational parallel for next-generation drug introduction: the systems, community engagement strategies, and cold chain experience developed for vaccine rollout can inform and accelerate the introduction of new therapeutics. However, Nigeria faces financing constraints, with a total health budget of approximately $10 per capita this is well below what is required for comprehensive malaria prevention and treatment at scale.

4.4 Financing Readiness

Nigeria's financing landscape for malaria control is characterised by heavy external dependence and systemic underfunding. Global malaria funding reached only $4 billion in 2023 against a target of $8.3 billion, creating coverage gaps in insecticide-treated nets, medicines, and other life-saving tools. For Nigeria specifically, middle-income classification creates a paradox: high burden with reduced access to concessional financing even though it carries a third of global malaria deaths.

On the domestic side, Nigeria's House Committee on HIV, TB and Malaria has introduced legislation calling for increased funding for malaria and universal accessibility of malaria commodities a legislative signal of political will that has not yet translated into commensurate resource mobilisation. The country's 2021-2025 National Malaria Strategic Plan (NMSP) targets reductions in parasite prevalence and mortality, but the plan is heavily donor-financed.

For next-generation antimalarials, the financing question is particularly acute. New drugs especially GanLum, which represents a novel mechanism and is likely to carry a premium price in early post-launch years will require either domestic government subsidies, donor procurement support, or negotiated access agreements through MMV's not-for-profit pricing models.

5. Pre-Introduction Readiness Framework for Nigeria

Drawing from the readiness assessment above, this section proposes a structured pre-introduction framework organised across five domains. This framework should be operationalised by the National Malaria Elimination Programme (NMEP), NAFDAC, and Federal Ministry of Health in partnership with MMV, WHO, and key implementing partners — ideally beginning in 2026, in anticipation of GanLum's expected regulatory timeline.

Domain	Current Gap	Pre-Introduction Action	Lead Actor	Timeline
Regulatory	No early engagement with MMV/Novartis; absent from Phase 3 trial sites	Initiate early scientific advice engagement with MMV; explore Article 58 or WHO pre-approval pathway	NAFDAC, FMOH	Q2 2026
Regulatory	No bridging data for Nigeria population	Negotiate inclusion of Nigerian sites in future Phase 3 extension or post-approval studies	NAFDAC, Academic Centers	Q3 2026
Supply Chain	Suboptimal commodity availability, poor data systems	Integrate GanLum into LMIS demand forecasting models; establish national stock buffer planning	NMEP, SCMS partners	Q3 2026
Supply Chain	Last-mile delivery failures in North	Pilot drone/community distributor model for granule sachet delivery in high-burden LGAs	NMEP, NGO partners	Q4 2026
Clinical Readiness	Low diagnostic coverage (25% of febrile under-5s tested)	Scale rapid diagnostic testing with new drug awareness campaigns integrated	NMEP, PHC system	Ongoing
Clinical Readiness	Frontline HCW unaware of updated guidelines	Develop national orientation curriculum specific to GanLum and infant formulation ahead of launch	NMEP, NPHCDA	Q1 2027
Financing	High donor dependence; budget gap	Advocate for domestic line-item budget for next-gen antimalarials in 2027 appropriation	FMOH, End Malaria Council	Q4 2026
Financing	Gavi eligibility gap for vaccines/drugs	Negotiate MMV not-for-profit pricing agreement with facility for Nigerian procurement	FMOH, MMV	Q2 2026
Monitoring	Weak post-market surveillance	Establish pharmacovigilance sentinel sites specific to new formulations in 6 geopolitical zones	NAFDAC, WHO	Q1 2027

Table 3: Nigeria Pre-Introduction Readiness Framework

6. Discussion

Nigeria's position in this moment is one of profound paradox: it carries the world's highest malaria burden yet risks being among the last countries to benefit from next-generation therapeutics unless deliberate preparatory action is taken now. The lessons of COVID-19 vaccine access, where high-burden African nations waited months after initial approvals while lower-burden countries drew down global supply, must not be repeated for antimalarials.

GanLum's Phase 3 success creates a narrow but real window. The likely 12-24 month regulatory review timeline at WHO and NAFDAC if initiated promptly gives Nigeria the opportunity to prepare its health system in parallel with global regulatory processes rather than sequentially. The key insight is that preparation should not wait for approval; it should run concurrently.

The infant formulation gap is particularly urgent. Nigeria's high rates of preterm birth and low birth weight, combined with the previously complete absence of any approved antimalarial for infants under 5kg, means that the CALINA formulation addresses a life-threatening treatment void. NAFDAC should treat this product as a priority review item, analogous to an unmet medical need designation, given the clear vulnerability of the target population.

The supply chain challenge is structural and will not be resolved by any single intervention. What is needed is a pre-introduction supply chain readiness assessment similar to those conducted for malaria vaccine introduction that maps distribution pathways, identifies facility-level readiness, plans forecasting models, and establishes accountability for last-mile delivery. The experience of Project IMPACT in Ekiti State demonstrates that targeted interventions can dramatically improve commodity availability; this model should be adapted and scaled as part of a national new drug introduction strategy.

Finally, the financing constraint demands a political response. Nigeria cannot rely indefinitely on donor financing for medicines that address conditions killing hundreds of thousands of its citizens annually. The existing parliamentary advocacy, MMV's not-for-profit pricing model, and the precedent set by Swiss Pharma Nigeria Ltd's domestic manufacturing of WHO-prequalified sulfadoxine-pyrimethamine together point toward a viable pathway: domestic production partnerships, government subsidy frameworks, and negotiated access pricing.

7. Conclusion

The arrival of next-generation antimalarials particularly GanLum and the new infant formulation of artemether-lumefantrine represents a potentially transformative moment for malaria control in Nigeria. With Phase 3 data confirmed and regulatory review underway, the window for preparatory action is now open.

This paper has demonstrated that Nigeria's readiness is mixed. The epidemiological justification for prioritising access is overwhelming no country needs these drugs more urgently. Yet the regulatory,

supply chain, clinical, and financing infrastructure to operationalise access at scale requires intentional and immediate strengthening.

The recommendations presented in this paper are not aspirational; they are operationally achievable within existing institutional structures and existing partnerships. What they require is coordinated will from NAFDAC, NMEP, the Federal Ministry of Health, academic institutions, MMV, WHO, and the community of malaria advocates who understand that Nigeria's success or failure on next-generation antimalarials will significantly determine global malaria outcomes through this decade.

A child in Nigeria should not die from a disease for which a cure exists and the work of ensuring that a better cure reaches that child before it is needed begins today.

Without immediate pre-introduction planning, Nigeria risks delayed and inequitable access to next-generation antimalarials, despite carrying the world’s highest malaria burden.

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