MARKET INTELLIGENCE REPORT

Local Manufacturing of Medicines and APIs in Africa

A technical report on cutting import dependence: API synthesis, regulation, economics and investment across the continent.

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SECTION 01

Executive Summary

Africa carries roughly a quarter of the global disease burden yet produces about 3% of the world's pharmaceuticals. This report examines how local manufacturing of generic medicines and medical supplies can cut that dependence, with a technical focus on **active pharmaceutical ingredients (APIs)**: the chemical or biological substances that produce the therapeutic effect in a medicine.

>70%
of medicines used in Africa are imported
IFC, March 2026. WHO has cited a 70-90% range.

>95%
of the APIs used in African production are imported
World Economic Forum, 2026.

60%
African Union goal for locally made medicines, vaccines and diagnostics by 2040
AU leaders / Africa CDC.

~3%
Africa's share of global pharmaceutical production
IFC, 2026; Sagandira, 2025.

3-5
API plants across the whole continent, depending on the source
UNCTAD is cited for 5. Counts vary by date and definition.

10
African regulators at WHO Maturity Level 3
WHO Director-General, Oct 2026.

Key messages

- **Formulation first, API second.** Many African manufacturers already produce finished dosage forms. API synthesis needs far more capital, chemistry talent and quality infrastructure.
- **The dependency is layered.** Many African buyers rely on Indian generics, and India itself sources about 65% of its critical APIs, key starting materials (KSMs) and intermediates from China (NITI Aayog, June 2026). A new African plant that imports its KSMs from the same region moves the dependency instead of removing it.
- **Regulation is turning into an enabler.** The African Medicines Agency (AMA) has been operational since October 2025 and opened two regulatory hubs in Kigali in October 2026.
- **The binding constraints are supply-side:** long-term finance, utilities, pharma-grade solvents and intermediates, and quality-control systems. Demand is not the problem, and pooled procurement is designed to give manufacturers offtake certainty.
- **The first movers are visible:** an antimalarial API plant in Nigeria being completed, an open-access agile API facility in South Africa and a pharma park in the Kenyan PPP pipeline.

BOTTOM LINE

The realistic path is staged: secure formulation capacity, localise a short list of high-volume APIs, map every project down to the KSM level and anchor volumes in pooled procurement.

SECTION 02

The Dependency in Numbers

Import dependence is continental, but its depth varies by country. The table combines the most recent public figures; where sources disagree, the range is shown.

Indicator	Figure	Source and note
Medicines imported (continent)	>70%	IFC (Mar 2026). WHO has estimated 70-90% of medical products.
APIs imported (continent)	>95%	World Economic Forum (2026); Sagandira (2025).
Vaccines produced locally	<1%	WHO figure cited in Kenyan press (2026).
Nigeria: APIs and excipients sourced abroad	>90%	KPMG, *Repositioning Nigeria's Pharmaceutical Industry* (Jul 2026).
Kenya: share of medicines imported	70-80%	WHO figure cited by the Standard (2026), despite 37+ licensed manufacturers.
Tanzania: share of demand met locally	10-20%	2026/27 Health Ministry budget; target is 80% local production by 2030.
Egypt: share of domestic consumption produced locally	>94%	Africa CDC report as reported in the press; treat as indicative.

A layered dependency

Tracing origin only one step back understates the exposure. REPOA research reported in 2026 found that nearly 70% of tracer medicines came from outside East Africa, with India accounting for a major share. India, in turn, sources about 65% of its critical APIs, KSMs and intermediates from China, and China supplies about 86% of its antibiotic imports (NITI Aayog Trade Watch, June 2026).

For African manufacturers, the consequence is twofold: finished goods are exposed to Indian export policy and prices, and the APIs inside them are often exposed to Chinese fermentation and chemical capacity. Foreign-exchange exposure compounds this in import-dependent markets such as Nigeria.

DESIGN RULE

Map every API project to the KSM level. A plant whose starting materials come from the same region as today's imports has relocated the dependency, not reduced it.

SECTION 03

API Manufacturing: Technical Primer

An API is made through a chain of chemical or biological steps. Each stage has distinct equipment, skills and failure modes, which is why API plants cost far more and take longer to qualify than tablet or capsule lines.

1. The value chain

Stage	What happens	Main technical risk
KSMs and raw materials	Purchased starting chemicals, solvents, reagents and catalysts defined as the regulatory starting point.	Supply concentration, price swings and specification drift.
Intermediates	One or more reaction steps convert KSMs into advanced intermediates.	Yield loss, impurity formation, hazardous reagents.
API synthesis	Final reactions, work-up, crystallisation and purification.	Control of impurities, polymorph form and residual solvents.
Isolation, drying, milling	Filtration, drying and particle-size control.	Particle size and form affect dissolution and bioavailability.
Quality release	Analytical testing against pharmacopoeial and registered specifications.	Method validation, reference standards, QC capacity.
Formulation (FDF)	API is combined with excipients into tablets, capsules, syrups or injectables.	Already established in many African plants.

2. Technology routes

Route	Examples	Implication for Africa
Chemical synthesis	Paracetamol, metformin, lumefantrine, dolutegravir	Most accessible entry point. Needs multi-purpose reactors, solvent recovery and effluent treatment.
Fermentation and semi-synthesis	Penicillins via 6-APA, then amoxicillin	Capital-intensive biology plus chemistry. Beta-lactams need segregated, dedicated facilities.
Plant extraction and semi-synthesis	Artemisinin and derivatives from *Artemisia annua*	Links the API to an agricultural supply chain and extraction capacity.

3. Process technology and quality framework

- **Agile and continuous-flow manufacturing:** modular units, Quality by Design and continuous flow can lower capital outlay and waste (CSIR, South Africa). Biologics such as vaccines follow a separate pathway and are outside this report's scope.
- **GMP for APIs:** ICH Q7 is the reference standard. ICH Q11 covers drug-substance development, and ICH Q3A, Q3C, Q3D and M7 cover impurities, residual solvents, elemental impurities and mutagenic impurities such as nitrosamines.
- **Regulatory dossiers:** API data are filed through a drug master file (DMF/ASMF) or, for WHO prequalification, the API master file procedure.

SECTION 04

Molecule Screening Matrix

Not every API suits an early African plant. The matrix below is a qualitative ProdAfrica screening, based on chemistry and supply-chain structure rather than engineering estimates. Validate with a process-development partner before committing capital.

API	Use	Route and complexity	KSM exposure	Entry rationale
Paracetamol	Analgesic, antipyretic	Short chemical synthesis from phenol-derived intermediates. **Low**	Commodity petrochemical inputs	Very high volume, but sharp price competition.
Metformin HCl	Type 2 diabetes	Condensation of dimethylamine HCl with dicyandiamide. **Low**	Commodity chemicals	Growing non-communicable disease demand.
Lumefantrine	Antimalarial partner drug	Multi-step synthesis. **Medium**	Specialty intermediates	Malaria is a continental priority and procurement is large.
Artemisinin derivatives	Antimalarial	Extraction plus semi-synthesis. **Medium**	Agricultural supply chain	Local farming and extraction link.
Amoxicillin and other beta-lactams	Antibiotic	Fermentation to 6-APA, then coupling. **High**	Highly concentrated globally	High volume, but high barrier. Needs dedicated facilities.
Dolutegravir	HIV	Complex multi-step synthesis. **High**	Specialised intermediates	Access through voluntary licensing. Flow-chemistry research is active.

Complexity ratings are indicative. A specific plant's economics depend on yield, scale, utilisation and input pricing.

SECTION 05

Where Capacity Stands Today

South Africa and Egypt hold the largest concentrations of pharmaceutical facilities on the continent, according to 2026 research. Elsewhere, API activity is mostly projects, pilots and training facilities.

Hub	Country	Evidence and status
North	Egypt	One of Africa's largest manufacturing bases. Africa CDC reports it meets more than 94% of domestic consumption and cut pharma imports by about US$500 million year on year.
North	Morocco, Tunisia	Appear among Africa's leading pharmaceutical exporters in KPMG's July 2026 comparison.
West	Nigeria	Emzor's antimalarial API plant in Sagamu, Ogun State is described as the first full-scale API facility in West Africa and is being completed (Aug 2026). NIPRD runs an API training facility funded with Afreximbank. A presidential order removed duties on pharmaceutical machinery and APIs, benefiting 87 manufacturers (NAFDAC, Apr 2026).
West	Ghana	Exploring API production through public-private partnerships (Sagandira, 2025).
East	Kenya	37+ licensed manufacturers. A 200-acre pharma park at Konza was approved in April 2026 to proceed to feasibility under a PPP. A 2026-2030 local manufacturing strategy is in place.
East	Ethiopia, Tanzania, Rwanda	Sansheng's Addis Ababa plant supplies much of Ethiopia's essential-medicine demand. Tanzania targets 80% local production by 2030. A modular BioNTech mRNA facility is being set up in Kigali, where AMA is also headquartered.
South	South Africa	Aspen Pharmacare and its subsidiary Fine Chemical Corporation produce APIs. CSIR is building the FuturePHARMA open-access agile facility to de-risk investment by local companies.

Data conflict: reports on Emzor's plant differ on investment (US$23 million in most outlets, US$230 million in one) and capacity (20 to 400 tonnes a year). Verify with the company before citing figures.

SECTION 06

Regulation and Quality Systems

A locally made API only creates value if regulators and buyers accept it. Regulatory capacity is improving, but the pathway is still fragmented.

African Medicines Agency (AMA)

Operational in Kigali since October 2025 under Director General Dr Delese Mimi Darko. It coordinates national regulators and cannot yet act as a single approval channel for all countries. In October 2026 it launched two hubs, including a Regulatory Innovation and Manufacturing Readiness Hub that engages manufacturers earlier in development.

WHO Global Benchmarking Tool

Regulators at Maturity Level 3 are the backbone of AMA's work. Counts differ by scope and date: 7 to 9 in 2025 depending on source, and 10 cited by the WHO Director-General in October 2026.

WHO prequalification

Prequalification opens UN and donor procurement and gives manufacturers the scale to compete. Two Nigerian products have reached it, per NAFDAC (April 2026).

Regional harmonisation

Joint assessments under the East African Community fell from a median of 553 days in 2015 to 259 days in 2023. WHO ministers adopted a 2026-2035 regional strategy for medical products regulation.

What an API project must show a regulator

- ICH Q7-compliant GMP, with validated processes, analytical methods and data-integrity controls.
- A defined regulatory starting material and a full impurity profile, including nitrosamine risk assessment.
- Dedicated or segregated facilities where required, such as beta-lactams and highly potent compounds.
- An API dossier (DMF/ASMF or WHO API master file) aligned with the target finished-dose products.
- Substandard and falsified products remain a risk: WHO issued 36 alerts on antimicrobials and cough syrups in the African region between 2020 and 2022.

SECTION 07

Economics and Financing

The USP assessment for Nigeria and the Sagandira review point to the same short list of constraints. They are mostly about capital and infrastructure, not demand.

Constraint	Evidence	Implication
Capital and tenor	High CAPEX and limited long-term financing are critical barriers (USP, Dec 2025).	Blended finance and DFI-backed long tenors are essential.
Cost of capital	Emzor raised a US$19.8 million (N26.7 billion) bond at a 19% coupon over five years (Aug 2026).	Local-currency debt at this cost makes thin-margin APIs hard to finance.
Energy and utilities	High energy tariffs and a lack of industrial utilities in Nigeria (USP).	Shared-utility industrial parks and captive power reduce cost per kilogram.
Inputs	Limited local supply of pharma-grade solvents and intermediates (USP).	Solvent recovery and regional chemical supply chains are part of the business case.
Quality systems	Most Nigerian plants have QC set up for finished products, not upstream synthesis (USP).	Budget for analytical upgrades from day one.
Demand certainty	Africa CDC's pooled procurement mechanism and its first maternal and child health tender cover 10 products across 10 countries.	Long-term offtake can underwrite plant utilisation.

Who is financing

- **Development finance:** European Investment Bank (EUR 50 million African pharmaceutical manufacturing initiative from 2020, with EUR 14 million reported for Emzor), US DFC, World Bank (Nigeria's PVAC programme), IFC and Afreximbank.
- **Technical programmes:** USP's MedSuRe Africa, funded by Unitaid and the EU, is developing commercially viable processes for two essential-medicine APIs for transfer to African manufacturers.
- **Policy levers:** import-duty exemptions, local preference in procurement and the AfCFTA single market to build scale.

MODEL DRIVERS TO TEST

Capacity utilisation, yield and solvent recovery, KSM price versus imported finished API, energy cost per batch, regulatory approval timeline and offtake volume. These matter more than headline plant size.

SECTION 08

Risk Register

Risk	Why it matters	Mitigation
KSM concentration	Starting materials mostly come from China and India.	Dual-source KSMs. Map to KSM level. Back-integrate in stages.
Foreign exchange	Imported inputs and equipment priced in hard currency.	Hard-currency offtake, hedging and DFI financing.
Regulatory delay	Approval and prequalification can take years.	Engage AMA hubs and national regulators early. Choose WHO-listed reference products.
Utilities and energy	Unreliable or costly power and water.	Industrial parks with shared utilities and captive power.
Offtake shortfall	Low utilisation destroys margins.	Long-term purchase agreements and pooled procurement.
Talent	Process chemists and QA specialists are scarce.	University partnerships and technology-transfer training.
Environment and safety	Solvent, effluent and hazardous-reagent handling.	Effluent treatment, solvent recovery and EHS design from the start.

SECTION 09

Recommendations by Stakeholder

Investors

- Back staged projects with a defined KSM strategy and signed offtake.
- Favour sites in industrial parks with shared utilities.
- Pair equity with DFI debt to lower cost of capital.

Manufacturers and technology suppliers

- Start with low-complexity, high-volume APIs.
- Design modular, multi-purpose lines with solvent recovery.
- Plan quality systems for ICH Q7 before construction.

Governments and regulators

- Provide predictable procurement and local preference.
- Remove duties on machinery, APIs and key inputs.
- Fund shared utilities and analytical labs.

Buyers and distributors

- Commit to multi-year volumes for African-made, quality-assured products.
- Require WHO-PQ or equivalent assurance.
- Track API origin down to the KSM.

SECTION 10

Technical Due Diligence Checklist

Process and IP

- [ ] Process route and yield validated at pilot scale
- [ ] KSMs defined with at least two qualified suppliers
- [ ] Licence or freedom to operate confirmed
- [ ] Impurity and nitrosamine risk assessed

Quality and regulatory

- [ ] ICH Q7 gap assessment completed
- [ ] DMF/ASMF or WHO API master file strategy
- [ ] Analytical methods validated
- [ ] Target regulators and approval timeline mapped

Infrastructure and EHS

- [ ] Power, steam and purified-water supply secured
- [ ] Solvent recovery and effluent treatment designed
- [ ] Segregation for beta-lactams or potent compounds
- [ ] Environmental permits in place

Commercial and finance

- [ ] Offtake or pooled-procurement route identified
- [ ] Delivered-cost comparison against imported API
- [ ] FX exposure and financing tenor modelled
- [ ] Talent plan and technology-transfer partner

VERIFY FIRST, THEN COMMIT

Use the ProdAfrica B2B Directory to identify and verify African manufacturers, equipment suppliers and service providers before engaging.

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SECTION 11

Sources and Notes

- IFC, Mkandawire, *Improving Access to Essential Medicines Through Local Manufacturing in Africa* (March 2026).
- World Economic Forum, Africa medicines and pharmaceuticals (2026). WHO and Africa CDC statements as reported by the Standard (Kenya), the Guardian (Tanzania) and AllAfrica (2026).
- KPMG, *Repositioning Nigeria's Pharmaceutical Industry* (July 2026). USP Quality Matters, *Nigeria's drive to become an API manufacturing hub* (Dec 2025).
- Sagandira, C. R., *Agile local manufacturing of APIs in Africa*, Communications Medicine (2025).
- African Medicines Agency coverage: Health Policy Watch (July 2026), New Times and AllAfrica (October 2026). WHO AFRO RC75 progress report (2025). Lancet Regional Health Africa (August 2026).
- Emzor project coverage: Nairametrics, BusinessDay, AllAfrica, Guardian Nigeria (2024-2026). NAFDAC statement (April 2026). Khusoko on the Konza pharma park (2026).
- NITI Aayog Trade Watch Quarterly (June 2026) via ETV Bharat and Deccan Chronicle. USP Medicine Supply Map via Pharma Now.
- Counts of API plants on the continent (3 to 5) come from secondary sources (UNCTAD as cited by trade press, WEF 2023) and vary by date and definition. Details on the Konza pharma park and the Sansheng plant come from trade press and should be confirmed with the project owners.

This report is provided for business intelligence purposes and does not constitute legal, regulatory, tax or investment advice. Figures come from public sources as of November 2026 and some conflict between sources, as flagged in the text. Complexity ratings are qualitative. Confirm specifics with qualified advisers and the relevant regulators.