GENEVA TRADE INTELLIGENCE

INSIGHT INTELLIGENCE REPORT

Your Kenya Entry

Generic Essential Medicines / India to Kenya

Prepared for Saral Pharma Pvt. Ltd. (illustrative) / 29 June 2026 / Confidential

You asked us whether Kenya is the right first step into East Africa, and how to take it on your budget without repeating the Nigeria strain. Our short answer is yes, on one condition you control. This report is the long answer: the market, who you are up against, the exact registration path, who to sell to and through, and a complete, week-by-week plan your team can pick up and run.

OUR VERDICT FOR YOU

Conditional Go

IMPORT MARKET	INDIA SHARE	YOUR IMPORT DUTY	YOUR BUDGET
~$670M	**~38%**	**0%**	**~$140k**
finished pharma, est.	of those imports, est.	essential medicines	and it is enough

Evidence basis: this is a sample, so its figures are illustrative estimates, not live-cited facts. In a report we build for you, every hard figure is labelled Verified, with its source, or Estimated, with the basis, and our verdict follows the evidence, not your hopes. We will tell you no when no is the honest answer.

Contents

01 What You Told Us, and What We Set Out to Answer

You came to us as Saral Pharma, a WHO-GMP-certified generic-medicines manufacturer out of Ahmedabad, with a clear ambition: make Kenya your first East African market and the base for the wider region. This report is written for you and your situation, not for the market in the abstract, because the only entry decision worth making is the one that fits the company you have actually built.

Here is how we understand you. You make oral solid-dose generics across four areas you know well, anti-infectives like amoxicillin, amoxicillin-clavulanate, azithromycin and ciprofloxacin, cardiovascular lines like amlodipine, losartan and atenolol, the anti-diabetics metformin and glimepiride, and the analgesics paracetamol and diclofenac. Your plant is WHO-GMP certified and PIC/S-aligned, it runs at roughly 70 percent, so you have real spare capacity, and you already hold registrations in Nigeria, the Philippines, Sri Lanka and Myanmar. You turn over about US$28M, roughly a third of it export, and you carry a 12-person regulatory and export team that has done African registration before, including the cash-flow strain in Nigeria that you have told us you do not want to repeat.

You have set aside about US$140,000 for this entry, you want a registered, distributor-led presence across four to five of your molecules inside twelve months, you want it low-capital and reversible rather than a bet-the-company commitment, and you do not yet have a Kenyan partner. So the questions we set out to answer for you are the ones you asked: how big and real is the demand, who you are up against, exactly how and how fast you can register, who you sell to and through, what you can realistically earn, what could go wrong, and a first-year plan your export head can pick up and run. Everything that follows answers those, in that spirit.

YOUR BUSINESS, AS WE UNDERSTAND IT

What	Detail
You are	Saral Pharma, Ahmedabad (WHO-GMP, PIC/S-aligned)
You make	Anti-infectives, cardiovascular, anti-diabetics, analgesics (oral solid dose)
You already sell in	Nigeria, Philippines, Sri Lanka, Myanmar
Your scale	~US$28M turnover; ~30% export; ~30% spare capacity
Your goal	Kenya as your first EAC market; registered, distributor-led, in 12 months
Your budget	~US$140,000 (registrations + first inventory + working capital)
Your terms	Low-capital, reversible; moderate risk; no local partner yet

02 Executive Summary

Our verdict for you is a confident conditional go. Kenya is one of the most accessible doorways into Sub-Saharan Africa for a manufacturer like you, and the reason is structural, not a matter of opinion: finished essential medicines enter Kenya free of import duty and exempt from VAT. That one fact takes away the tariff handicap that quietly kills most India-to-Africa trade and puts your generic on level commercial ground with whatever is already on the shelf. The condition on the go is sequencing. You cannot sell anything until each product is registered with the Pharmacy and Poisons Board, and that timeline, not the demand, is what stands between you and your first revenue.

You are better placed to clear that hurdle than most. Because you are WHO-GMP and already hold Nigeria, Philippines and Sri Lanka dossiers, most of your technical documentation is effectively Kenya-ready; the work is reformatting and local submission, not starting from a blank page. And the molecules you already make, amoxicillin, amlodipine, metformin, paracetamol and the rest, sit almost exactly on top of Kenya's heaviest demand in infections, hypertension, diabetes and pain. You are not guessing what to sell here. You already make what this market consumes most.

On demand, India already supplies an estimated 38 percent of Kenya's imported medicines, so you inherit clinician trust and prescribing habit rather than having to build them. We think a focused launch across four to five of your molecules, through private distribution and the faith-based channel, can realistically reach an estimated US$0.8M to US$1.4M of corridor revenue in year one, comfortably inside what your spare capacity and your US$140,000 can carry.

The thing most likely to hurt you is the one that hurt you in Nigeria: the gap between paying for dossiers and stock and receiving your first orders. So our first recommendation is simple. Start a two-molecule registration wave this month, and in parallel, on a separate clock, open talks with two complementary national distributors. The rest of this report gives you the market, the competition, the regulatory path, a full and executable go-to-market and twelve-month plan, the risks, and your first ninety days, all built around you and your budget.

THE PICTURE IN ONE VIEW

Question	Where we land, for you
Should you go?	Yes, conditional on registration sequencing
Why now	Duty-free, VAT-exempt; your molecules match top demand; India trusted
What you can earn (Yr 1)	Est. US$0.8M to US$1.4M corridor revenue (verify)
What gates it	PPB registration timeline, not demand
Your edge	WHO-GMP + existing dossiers = Kenya-ready documentation
Your first move	Two-molecule registration wave + two distributor talks, now

03 Macroeconomic Context

Kenya is the commercial anchor of East Africa and the right doorway into the wider community of roughly 300 million people you are aiming at. The economy has been growing at a mid-single-digit real rate, led by services, agriculture and a health sector that is formalising fast, and Nairobi is the region's money, logistics and regulatory hub. Three of those threads matter directly to you.

The first is that health financing is widening. The push toward universal coverage and the growth of private medical insurance are pulling more demand into affordable generics, which is your part of the market, not the expensive originator end. As coverage deepens, the next patient through the door is exactly the price-sensitive, volume-driving customer your plant is built to serve.

The second is that Kenya imports most of its finished medicines. Local manufacturing covers a minority of consumption and sticks to a defined range, which leaves persistent import demand across most therapeutic classes, including yours. This is structural, not a gap that local capacity will close on you soon, which is what makes a multi-year position here worth building.

The third is the regional architecture. Kenya sits inside the EAC customs union and signs to the African Continental Free Trade Area, so the Kenyan base you build becomes the natural springboard into Uganda, Tanzania and Rwanda that you told us you want. Development-finance money from the World Bank, the African Development Bank and Kenya's own health reforms is flowing into procurement and cold-chain that enlarges the institutional market over time. The reading for you is that the backdrop is supportive and stable enough to commit now; the work is execution and registration, not waiting. We would still re-confirm the latest health-budget and coverage figures with you before you fix a multi-year volume plan.

04 Geopolitical and Trade-Policy Context

The corridor you are entering carries low geopolitical risk and a few tailwinds working in your favour. India and Kenya have a long, settled trade and diplomatic relationship, there is a large Indian-origin business community on the ground, and medicines are a politically welcome import precisely because they lower the cost of care. This is the opposite of a contested category, so you are unlikely to meet the policy hostility that can hit agricultural or industrial imports.

The real prize is the regional architecture. As EAC integration and AfCFTA lower the barriers between African markets, the Kenyan platform you build can later supply Uganda, Tanzania and Rwanda off a single registration-and-distribution base, which spreads the effort of entry across four markets instead of one. That is the difference between a single-country move and the regional strategy you actually want, and it is why we would have you start in Kenya rather than a smaller neighbour.

Kenya is also tightening enforcement against substandard and falsified medicines, and that helps you. Where enforcement rises, your WHO-GMP quality becomes a moat rather than a cost, and the cheapest unverified imports you compete against become the ones under pressure. The genuine things to watch are financial, not political: the shilling can slide against the dollar, and Kenya has at times seen dollar-liquidity tightness that slowed importer payments. We would have you price in USD and structure your opening orders to keep currency and credit risk short. Elections can briefly slow government procurement, which is one more reason your first-year plan leads with private and faith-based channels

rather than tenders. Net of all this: go now, lead with the fast channels, and treat the regional expansion as the upside your Kenya base buys you.

05 The India to Kenya Corridor

On the corridor itself, India is consistently one of the top one or two source countries for Kenya's imported finished medicines, competing mainly with China on active ingredients and with a few European and regional suppliers on branded lines. Import demand for the relevant finished-dose categories runs into the high hundreds of millions of dollars a year and has been growing at an estimated high-single-digit rate as coverage widens. India's share of that is an estimated 38 percent, so you are stepping onto an established beachhead, not opening a market.

India's advantage on this corridor is essentially your profile: breadth of registered, affordable generics, manufacturing scale, and clinician familiarity. China leans on active-ingredient cost and a narrower finished range; the European and regional players hold branded or biologic niches that do not touch your oral solid-dose generics. The seasonality is mild for your chronic lines and sharper for your anti-infectives around the two rainy seasons, which is useful when you plan shipment timing and stock cover.

In year one, a focused entrant of your size should expect low single-digit market share in the specific molecule segments you register, rising through years two and three as your registrations widen and your distributors build pull. The discipline here is focus: four to five molecules registered and supported properly. Every registration costs time and fee budget, and every molecule needs a distributor's attention to move, so a tight initial range outperforms a long one. When we run the full corridor deep-dive, every figure will carry its data year; the ranges here are directional, drawn from public trade patterns rather than a live pull.

THE CORRIDOR AT A GLANCE (DIRECTIONAL; WE VERIFY AGAINST CUSTOMS / UN COMTRADE)

Measure	Reading
Imported finished-pharma market	~US$670M / year (2024 est.)
India share of those imports	~38% (estimate)
5-year corridor growth	~8 to 9% CAGR (estimate)
Main alternatives to you	China (APIs), EU / Cyprus, Egypt
Duty on your essential lines	0% duty, VAT-exempt (we confirm per molecule)
Realistic Yr-1 share for you	low single digits of your registered segments

06 Demand and Social Context

You should know where your volume actually comes from, because it shapes the channels you chase and the packs you ship. Kenya's demand is driven by a young, fast-urbanising population, a chronic-disease burden climbing with urban diets, and a steady infectious-disease load. That maps straight onto your range: your amlodipine, losartan, metformin and glimepiride sit in the chronic segment that is growing fastest, and your amoxicillin, azithromycin and ciprofloxacin sit in the steady anti-infective base. You are not bending your portfolio to fit this market; it already wants what you make, which takes a whole category of risk off your table.

The way medicines get paid for drives your pack strategy. A large share of spend is still out-of-pocket, so affordability and pack size decide a lot: small, affordable retail packs move fast through community pharmacy, while institutional buyers want full-course and bulk packs at tender prices. We would have you plan both a retail blister and an institutional bulk pack for your lead molecules, because the same molecule reaches you through two quite different doors.

Two softer things are on your side. Indian generics already carry trust with Kenyan prescribers and pharmacists, so your job is proving you are reliable, not proving you are good; and English runs business, regulation and labelling, which removes a friction an exporter from a non-English market would carry. One norm to internalise: distributors and institutional buyers here value steady personal contact and dependable lead times, and they remember stockouts. Your reliability, backed by your spare capacity, is therefore not just an operational fact, it is an argument we want you making out loud in every distributor conversation.

07 Operating and Technology Environment

Kenya is one of the easier African markets to actually operate in, which matters given that you want a low-friction entry. Mobile money is near-universal and gives you fast, traceable B2B settlement that helps you manage distributor receivables and cuts the cash-handling risk some markets carry. Customs runs a single-window electronic system, and the Pharmacy and Poisons Board runs online registration and post-market portals, so a lot of the paperwork that was manual in your earlier markets is digital here, which should shorten your timelines relative to the Nigeria experience.

Quality-testing and cold-chain capacity exists but clusters around Nairobi and Mombasa, with thinner reach upcountry. For you this is mostly a non-issue, because your oral solid-dose generics ship and store ambient, so you sidestep the cold-chain dependency that complicates vaccines and biologics. What it does mean is that you should treat a distributor's warehousing quality and national reach as a first-order selection criterion, because the distributor, not you, will carry the physical network into the upcountry towns where a real slice of your demand sits.

So, practically: invoice in USD with mobile-money local settlement for the smaller balances, use the single-window and Board portals to compress your timelines, and weight distributor choice toward warehousing and compliance rather than the headline margin a partner asks for. The cheapest distributor with weak warehousing will cost you more, in stockouts and lost trust, than a slightly dearer one that never lets you run dry.

08 Market Opportunity and Segmentation

Your opportunity is the gap between Kenya's broad, growing demand and its thin domestic finished-dose manufacturing. There are four buyer pools, and we would have you work them in a deliberate order rather than chase all four at once.

Public procurement runs through the Kenya Medical Supplies Authority, which buys at scale on tender for government facilities. It is volume, but low margin and slow cash, and it presumes registrations and a track record you do not yet have. Faith-based and mission procurement, led by the Mission for Essential Drugs and Supplies, serves a large network of mission and private hospitals, holds the kind of quality expectations that suit a WHO-GMP supplier like you, and pays reliably. Private wholesale and distribution is your fastest route to first revenue and your best margin, and it is where we would have you concentrate first. Private hospital groups and insurers are a fourth, growing segment that opens up once a distributor relationship is live.

The wedge that is yours specifically is consistent, quality-assured, competitively priced volume in the high-demand chronic and anti-infective molecules where local production is thin and the cheapest imports are unreliable. Your amlodipine and metformin sit in chronic categories with refill-driven, predictable demand, which is exactly the base on which to build a dependable distributor relationship; your amoxicillin and amoxicillin-clavulanate sit in high-turnover anti-infective demand that gives a distributor fast stock rotation and quick cash recycling, which is what makes a distributor pay attention to a new supplier.

Putting a number on it, we think US$0.8M to US$1.4M of first-year corridor revenue is realistic for a focused four-to-five-molecule launch through your private and faith-based channels, with public tenders held back as year-two upside. That sits comfortably inside your capacity and your budget, which is why we keep coming back to the same point: your binding constraint is not market size or money, it is registration speed and picking the right first molecules and distributors. We size these segments against current procurement and import data before you fix any volumes.

YOUR BUYER SEGMENTS, IN THE ORDER WE'D WORK THEM

Segment	Margin / cash	When you go after it
Private distribution (retail + private hospital)	Best margin, fastest cash	Year 1, first priority
Faith-based (MEDS network)	Good margin, reliable pay	Year 1, in parallel
Private hospital groups / insurers	Moderate, via distributor	Year 1 onward, once live
Public tenders (KEMSA)	High volume, low margin, slow	Year 2, once you have a record

09 Competitive Landscape

You are walking into a three-layer field, and we want you positioned deliberately against each layer rather than holding one average stance.

The first layer is the local Kenyan manufacturers, names like Cosmos Pharmaceuticals, Universal Corporation, Dawa, Regal and Beta Healthcare. They have a home-market and public-tender advantage and a logistics edge, but they cannot cover the full therapeutic breadth, and several stick to a defined range, which leaves wide gaps in exactly the imported-generic categories you supply. We would not have you fight them on price in their strong lines, where their freight and tender advantages are real; we would have you win in the molecules they underserve, which is most of the breadth.

The second layer is the other Indian and international exporters already registered in Kenya, some of them large and well-known. This is the layer you genuinely compete with, molecule by molecule. The market already trusts the category, so the contest is on specific products, price and, above all, reliability. Your edge here is your WHO-GMP status plus the spare capacity to guarantee lead times, set against the standing market complaint that imported supply is inconsistent. Reliability is not a soft attribute in this market; it is the single most common reason a distributor changes supplier, and it is the thing you can credibly promise when others cannot.

The third layer is the bottom tier of unverified, lowest-price imports, competing on price alone and carrying a reputation for variability, documentation gaps and the odd recall. We would have you sit clearly above that tier. So the position we recommend is a deliberate middle one: an estimated 5 to 12 percent under the established Indian and international brands on the same molecule, clearly above the bottom tier, and you win the gap on certificates of analysis, registration support and dependable delivery. What pulls a Kenyan distributor away from an incumbent is not a lower headline price; it is an acceptable price plus supply they can count on and paperwork that clears the Board and their audits without friction, which is precisely what a WHO-GMP manufacturer with spare capacity can offer.

WHERE YOU FIT

Layer	How we'd have you play it
Local manufacturers (Cosmos, Universal, Dawa, Regal, Beta)	Don't fight their strong lines on price; win the molecules they underserve
Other Indian / international importers	Compete molecule-by-molecule on reliability + ~5-12% under brand (est.)
Bottom-tier unverified imports	Price clearly above; sell your WHO-GMP, your CoAs, your dependable supply

10 Your Pricing Architecture

You need a pricing structure, not a single number, because each of your molecules sits in a different spot. The rule we would hold is the middle position above: below the established branded generics, clearly above the bottom tier, with the gap earned by reliability and documentation rather than handed over as a discount.

On your high-turnover anti-infectives, amoxicillin and amoxicillin-clavulanate, where many suppliers compete and distributors watch price closely, we would anchor you toward the lower end of your band, taking a thinner per-unit margin in exchange for the volume and fast stock rotation that keep a distributor's cash cycling, and that make them notice you. The amoxicillin-clavulanate combination, with its tighter quality expectations, is where your WHO-GMP status is most visibly worth paying for.

On your chronic molecules, amlodipine and metformin, where demand is refill-driven and a patient who is established does not switch easily, we would hold you nearer the middle of the band and have you compete on continuity of supply, because a chronic patient's uninterrupted supply matters more than a marginal price difference.

Three structural levers protect those prices for you. The duty-free, VAT-exempt status means tariff does not inflate your landed cost, so you can offer a competitive shelf price without giving up margin. Full-container, multi-molecule shipments cut your per-unit freight and clearing. And USD invoicing with disciplined terms protects the price you actually realise against a sliding shilling. We would have you set indicative per-molecule USD prices before your first distributor meeting, hold them as your opening anchors, and use volume commitments rather than price as your main lever, so any discount is earned with order size rather than spent to win attention.

YOUR INDICATIVE PRICING POSTURE BY MOLECULE TYPE (ANCHORS TO SET BEFORE YOU NEGOTIATE)

Molecule type	Where in your band	Why
Anti-infectives (amoxicillin, etc.)	Lower end (~ -10 to -12%)	Price-watched, high turnover; win on volume and rotation
Chronic (amlodipine, metformin)	Mid band (~ -6 to -8%)	Refill-driven, sticky; compete on continuity
Analgesics (paracetamol, diclofenac)	Lower-mid	Commoditised; defend with reliability, not a price war

11 Molecule by Molecule

You make an entry decision molecule by molecule, not at the level of the portfolio, so let us take your candidate lines one at a time and tell you where each fits. What comes out of it is a two-molecule first wave, one anti-infective and one chronic line, with the rest following close behind.

Your amoxicillin and amoxicillin-clavulanate are the anchor anti-infectives. Demand is broad, high-volume and recurring across primary care, which gives a distributor fast rotation and quick cash, the things that make a distributor commit to a new supplier. The category is competitive and price-watched, so we would price you toward the lower end of your band and have you win on availability and documentation. We would have one of these lead your first registration wave.

Your amlodipine and losartan are the cardiovascular anchors. Demand is chronic, refill-driven and growing with the urban hypertension burden, which makes it your stickiest, most predictable volume and the ideal partner to a fast-moving anti-infective in the first wave. Switching is slower here once a patient is established, so continuity matters more than a marginal price, and you can hold nearer the middle of your band. We would put amlodipine in the first wave alongside an anti-infective, on the strength of its demand depth and how ready its dossier is.

Your metformin and glimepiride address the diabetes burden, which is rising fast and heavily generic, a natural fit for you. Metformin in particular is a very high-volume essential, and it belongs in your early second wave, right behind the first two. Your azithromycin and ciprofloxacin round out the anti-infective offer in the second wave, giving your distributor a fuller basket to sell together. Your paracetamol and

diclofenac are high-volume but commoditised; they are useful range-fillers that help a distributor consolidate orders, but we would have you defend them on reliability rather than fight a price war, and they sit late in the second wave.

THE MOLECULE SEQUENCE WE RECOMMEND

Your molecule	Wave	Best channel	Pricing posture
Amoxicillin / amox-clav	First	Private distribution	Lower band; win on availability
Amlodipine	First	Private + faith-based	Mid band; sticky chronic demand
Metformin	Second	All channels	Mid-lower; very high volume
Azithromycin / ciprofloxacin	Second	Private distribution	Lower-mid; fuller AI basket
Losartan / glimepiride	Second	Private + faith-based	Mid band; chronic
Paracetamol / diclofenac	Second (late)	Private distribution	Range-filler; defend on reliability

12 Health System and Demand Deep Dive

Let us go a level deeper on where your volume comes from, because the shape of demand drives both your channel mix and your pack plan. Kenyan demand splits across a public sector that serves most of the population through government and county facilities, a large and growing private sector of retail pharmacies and private hospitals, and a faith-based sector of mission hospitals that punches above its size on quality. Your first-year revenue will come overwhelmingly from the private and faith-based sectors; the public sector is a year-two prize for you.

On the disease burden that drives your specific molecules, three pictures matter. The infectious-disease load stays high and seasonal, which underwrites steady, recurring demand for your amoxicillin, amoxicillin-clavulanate, azithromycin and ciprofloxacin, with peaks around the rainy seasons you should stock ahead of. The chronic, non-communicable burden is the fast-growing story: hypertension and type-2 diabetes are climbing with urbanisation and diet, which makes your amlodipine, losartan, metformin and glimepiride your strongest multi-year lines and your most predictable, refill-driven demand. The pain and inflammation category your paracetamol and diclofenac serve is large and constant but commoditised.

The way it gets paid for completes the picture. A big share of spend is still out-of-pocket through retail pharmacy, which rewards affordable, small-pack presentations and fast availability, while the widening insurance and universal-coverage envelope is moving volume toward institutional and reimbursed channels that buy full-course packs and reward documented quality. So we would have you lead your chronic molecules into both retail and institutional formats, time your anti-infective stock to the seasons, and treat the growing insured and faith-based demand as the channel where your WHO-GMP quality

earns a premium the open retail shelf will not give you. These demand magnitudes are directional; we quantify them against current health-system and epidemiological data before you fix volumes.

YOUR DEMAND BY THERAPEUTIC AREA (DIRECTIONAL)

Your area	Demand character	What it means for you
Anti-infectives	High, recurring, seasonal	Steady base; stock ahead of the rains
Cardiovascular	Chronic, fast-growing, sticky	Your strongest multi-year line; lead here
Anti-diabetics	Chronic, rising fast, generic	High-volume essential; early second wave
Analgesics	Large, constant, commoditised	Range-filler; defend on reliability

13 Buyer and Channel Landscape

Your priority counterparts are the national private distributors, because they aggregate demand from retail pharmacies and private hospitals, they hold the warehousing and the relationships, and they can move volume quickly once they back you. The names that recur in this tier are Surgipharm, Phillips Pharmaceuticals, Laborex and Harleys, among others. We would have you approach two of them, picked to be complementary, one retail-strong and one hospital-strong, with a focused molecule list, indicative USD pricing, lead times and full documentation, and propose a non-exclusive start with volume milestones rather than hand exclusivity to a partner who has not yet sold a single pack for you.

Your second priority is the faith-based channel anchored by the Mission for Essential Drugs and Supplies. It suits you: it values the quality a WHO-GMP supplier brings, it pays reliably, and a place on its supplier list carries reputational weight across the mission-hospital network that helps your later distributor and tender conversations. We would have you start the MEDS application in parallel with the distributor talks, because the two run on their own clocks and there is no reason to wait.

Public procurement through KEMSA is the biggest pool by volume but the slowest to open and the thinnest on margin, and it assumes the registrations and record you are only now building. It is rightly a year-two target for you, approached from the strength of a proven private-channel record rather than as a first-year gamble. Private hospital groups and insurers are a growing direct segment you can cultivate once a distributor relationship is live and your stock is reliably in market. The rule we keep coming back to is to open two or three independent channels at once, so that no single distributor, and certainly not the slow public channel, can become a single point of failure for you. We confirm the individual category buyers and their procurement calendars in the full report so your team can act without further digging.

14 Distribution Map and Partner Selection

Kenya's distribution is concentrated among a handful of capable national players plus a long tail of regional and county wholesalers. For your first year, the national distributors are the only sensible route: they give you real coverage from Nairobi and Mombasa hubs into the major upcountry towns, established relationships with retail and hospital pharmacy, and the warehousing and compliance standing that you, entering without a local entity, cannot build yourself.

Because these distributors already carry suppliers who compete with you, switching costs are real, and your pitch has to pair a genuine gap in their range with a believable promise of reliable supply, which your spare capacity lets you make. Terms in this tier usually run on distributor margins in the mid-teens to low-twenties percent depending on molecule and volume, with minimum order quantities and credit expectations attached. We would have you negotiate these against volume milestones rather than concede them up front, and we would have you hold the line on credit in particular, because that is exactly where Nigeria hurt you.

We would have you choose a partner the way you would hire one: against a scorecard, not on a good first meeting. Score each candidate on national warehousing and reach, the strength of their retail versus hospital relationships, their financial standing and payment record, their Board-compliance and licence record, how well their existing range complements your molecules, and their willingness to accept milestone-based terms. The structure we recommend for your first twelve months is dual and non-exclusive: two complementary distributors, each with clear volume targets, so you keep leverage and never sit captive to one partner before they have proven themselves. Verify each candidate's warehousing, temperature control where it matters, financial standing and compliance record directly, the due diligence you have told us you want to do properly this time.

YOUR DISTRIBUTOR SCORECARD (WEIGHT AND VERIFY BEFORE YOU SIGN)

Criterion	Why it matters for you
National warehousing + reach	Carries the physical network you lack; keeps you in stock upcountry
Retail vs hospital strength	Pick two complementary partners, not two of the same
Financial standing + payment record	Protects your receivables; your Nigeria lesson
Board compliance + licences	A regulatory requirement for you, not just commercial
Range complementarity	A real gap, not a duplicated molecule, wins you shelf attention
Accepts milestone terms	Non-exclusive, milestone start keeps the leverage with you

15 Decision-Makers and Stakeholder Map

Entries stall when your effort lands on the wrong person, so let us tell you who actually decides at each counterpart so you aim your first contact at them rather than at a general inbox. The pattern in Kenyan pharmaceutical trade is that technical credibility opens the door but a commercial decision-maker signs, so you have to satisfy both.

At a national distributor, the person who matters first is the category or procurement buyer for your therapeutic areas, who decides what enters the range; the commercial director approves terms once the buyer is convinced. At the faith-based channel, procurement runs through a committee that weights quality and reliability heavily, so your documentation does much of the persuading before anyone talks to you. At the Pharmacy and Poisons Board, the evaluators assess your dossier on technical merit, which is why we would have you work through an experienced agent who knows what each evaluator looks for. At a private hospital group, the pharmacy lead and the procurement function decide together, usually on the recommendation of the distributor already supplying them.

So for each counterpart you target, map the technical gatekeeper you must satisfy and the commercial signer who closes it, and prepare for both: the quality and registration documentation for the gatekeeper, and the pricing, reliability and terms argument for the signer. We name the current individuals in these roles where we can verify them in the full report; here we give you the roles so you know whom to ask for.

WHO DECIDES, AND WHAT CONVINCES THEM

Counterpart	Who decides	What convinces them
National distributor	Category / procurement buyer	A range gap + your supply guarantee + price
Faith-based (MEDS)	Procurement committee	Your WHO-GMP quality + complete documentation
Pharmacy and Poisons Board	Dossier evaluators	A complete, query-resistant CTD submission
Private hospital group	Pharmacy lead + procurement	Distributor recommendation + your reliability

16 Regulatory Roadmap

Registration is your critical path, the single thing most likely to decide when your money starts, so it gets the most precise sequencing from us. The good news is that because you are WHO-GMP and already hold your Nigeria, Philippines and Sri Lanka dossiers, most of the technical content exists; the work is reformatting to the Pharmacy and Poisons Board's requirements, not generating it fresh.

Step one is to confirm, for each candidate molecule, its registration status and classification with the Board, and to confirm whether your site already holds Board GMP recognition. If it does not, site approval, which can include an inspection, runs in parallel and often dominates the whole timeline, so it has to be started first. Step two is to compile and submit the CTD dossier for each molecule and

dosage form, pay the per-product fee, and plan for a multi-month review with at least one round of queries. Step three is to appoint your local responsible presence: your imported products are registered and handled through a locally established agent or distributor holding the necessary import and wholesale licences, which makes your distributor choice a regulatory decision as much as a commercial one. Step four is per-consignment import authorisation, which depends on the distributor's valid wholesale dealer licence. Step five, on your side, is the export documentation, the certificate of pharmaceutical product and free-sale certificate you already know from your other markets.

The expensive mistakes, the ones you told us you want to avoid after Nigeria, are submitting incomplete dossiers that restart the review clock, underestimating GMP site approval, and shipping before registration is confirmed. We would have you register a first wave of two molecules to compress learning and limit your fee exposure, then add the rest once your agent relationship and site recognition are in place. We verify the Board's current fee schedule and timelines directly, since they are updated periodically; plan for several months end-to-end on your first molecule and materially faster on the ones after it.

YOUR REGISTRATION SEQUENCE

Step	What it involves	Who owns it
1	Confirm molecule status + your site GMP recognition (start site approval first)	Your regulatory agent
2	Submit CTD dossier per molecule; pay per-product fee; plan for queries	Your RA team
3	Appoint your locally licensed agent / distributor (import + wholesale licences)	You + distributor
4	Per-consignment import authorisation	Distributor
5	Your India-side export docs: CoPP, free-sale certificate	Your export team

17 What the Rules Actually Say, and Where to Check Them

A fair question to ask of any report is: which of this is real, and which is illustration. So here is what is fixed enough to act on today, each with the source to check it against, kept separate from the figures that move and that we pull live for your full report.

At the border, finished pharmaceutical products enter Kenya duty-free. They sit in the zero-rated band of the East African Community Common External Tariff, so your landed cost is freight, insurance, clearing and inland haulage, not import duty. Registered pharmaceutical products are also exempt from VAT under Kenya's Value Added Tax Act, which removes a working-capital drag that first-time exporters often budget for in error.

On the gatekeeper, the Pharmacy and Poisons Board regulates product registration, importation and wholesale distribution under the Pharmacy and Poisons Act, Chapter 244. No product may be imported or sold until it is registered, and a foreign manufacturer registers and imports through a locally licensed agent or distributor that holds valid import and wholesale dealer licences. The Board recognises WHO-GMP and may inspect the manufacturing site.

On the physical and channel path, goods clear through the Port of Mombasa and the Nairobi inland container depot at Embakasi. Public-sector demand is procured through the Kenya Medical Supplies Authority, KEMSA, and the faith-based hospital network is supplied through the Mission for Essential Drugs and Supplies, MEDS.

What we do not pin down here are the exact registration and retention fees and the precise review timelines. The Board updates those periodically, so they are the live figures we verify directly and date in your full report. The discipline is simple: law and structure we state plainly now; anything that moves, we pull fresh and cite.

WHAT IS FIXED TODAY, WITH THE SOURCE TO VERIFY IT AGAINST

What is true now	Where to check it
Finished pharmaceuticals enter at 0% import duty	EAC Common External Tariff
Registered pharmaceuticals are VAT-exempt	Kenya VAT Act
Registration is mandatory before import or sale	Pharmacy and Poisons Act, Cap. 244
Foreign maker imports via a locally licensed agent	PPB import / wholesale licensing
Entry via Mombasa, inland clearance at Embakasi ICD	KPA / KRA customs
Public tenders via KEMSA; faith-based via MEDS	KEMSA / MEDS

18 Registration, in Detail

Because registration gates everything, let us turn the roadmap into the checklist your team can actually run against. The aim is to hand the Board a complete, query-resistant submission the first time, because the single biggest source of delay is a dossier that triggers avoidable queries and resets your clock.

For each molecule, your CTD dossier pulls together the administrative and product information, the quality and chemistry-manufacturing-controls data, the manufacturing-site and GMP evidence, the finished-product specifications and stability data, and the proposed Kenya-compliant labelling and patient information. Your advantage is that most of this already exists for Nigeria and the Philippines; the work is reformatting to the Board's structure, making sure your stability data covers the right climatic zone, and localising your labelling. We would have you appoint an experienced Kenyan regulatory agent precisely to catch the local-format issues you cannot see from Ahmedabad, and we would treat the agent's pre-submission review as mandatory, not optional.

Sequencing inside your first wave matters. Lead with the molecule whose dossier is most complete and whose demand is deepest, so your first approval is both fast and commercially useful, then submit the second a few weeks behind so your team learns from the first review before the second. Keep a simple registration tracker, one row per molecule, recording submission date, fee paid, query received, query answered and approval, so you can see your critical path at a glance and time your working capital to the expected approval dates. The common rejection causes we would have you design against are incomplete CMC data, stability data for the wrong climatic zone, labelling that does not meet Board

requirements, and missing or out-of-date GMP and site evidence.

YOUR PER-MOLECULE DOSSIER CHECKLIST

Module	Where you stand	Action
Administrative + product information	Exists (other markets)	Reformat to the Board's structure
Quality / CMC data	Exists	Verify completeness; pre-empt the query
GMP + site evidence	You hold WHO-GMP	Confirm Board site recognition / inspection
Specifications + stability	Exists	Confirm correct climatic-zone data
Kenya-compliant labelling + PIL	To localise	Agent review before you submit

19 Logistics and Distribution

The physical route is well-trodden and familiar to an exporter of your experience. You export from a western Indian port, Mundra or Nhava Sheva are the usual choices for East Africa, on the regular lines into Mombasa, with transit times that make full-container ocean freight the sensible default for your ambient oral solid-dose generics. Air freight is for the urgent, high-value, low-volume exception, not your normal plan.

Mombasa is your destination port and the regional gateway; from there your goods move by road or rail to Nairobi, often clearing at the inland container depot at Embakasi, which can simplify your upcountry distribution. We would have you appoint a clearing agent with a verified pharmaceutical track record, because medicines clearance involves the Board and per-consignment authorisation, not just standard customs, and an inexperienced agent is a common cause of avoidable delay and demurrage that you do not want to learn about the hard way.

Your last-mile distribution is carried by your appointed distributors from their Nairobi and Mombasa warehouses, which is one more reason their warehousing quality is a selection criterion for you. Because your range is ambient, you skip cold-chain cost and risk entirely, a genuine advantage over suppliers of temperature-sensitive lines. As a planning figure, your freight, clearing and inland cost runs to a few thousand dollars per full container, which, spread across a multi-molecule load, keeps your per-unit logistics low and supports the pricing posture we set for you. We would have you consolidate your first orders into full-container, multi-molecule shipments rather than part loads, because that is your clearest lever on per-unit logistics cost. We confirm current freight rates and transit times at the time of your first shipment.

20 Pricing, Reimbursement and the Essential Medicines List

You should understand the pricing and reimbursement environment you are entering, because it shapes both the price you can hold and the channels your volume sits in. Kenya does not impose the kind of rigid external price control on imported generics that some markets do, which leaves you the commercial room to run the per-molecule pricing architecture we set above; but it does run procurement and reimbursement mechanisms that effectively anchor prices in the institutional channels.

The two anchors that matter to you are the public-procurement reference prices that emerge from KEMSA tendering and the reimbursement and benefit structures of the public health-insurance scheme and the private insurers. Where one of your molecules is on the national essential-medicines list, it earns the duty-free, VAT-exempt treatment that underpins your margin and it carries steady institutional demand, but it is also more price-referenced, so we would have you confirm essential-list status per molecule and price with the relevant tender and reimbursement benchmark in view. In the open private-retail channel, pricing is freer and your middle position holds.

So for you, treat essential-list status as a positive, it confirms your duty and VAT treatment and signals steady demand, while pricing each molecule with one eye on the institutional benchmark that will eventually frame it. We verify the current essential-list status, the applicable tender reference prices and the reimbursement treatment for each of your specific molecules, which are the figures you need before you fix prices for the institutional channels.

YOUR PRICING REALITY BY CHANNEL

Channel	Pricing reality	Your stance
Private retail	Freer pricing	Hold your middle position
Faith-based / hospital	Quality-weighted, semi-anchored	Compete on reliability, not lowest price
Public (KEMSA)	Tender-referenced	Year-two entry at the benchmark

21 Intellectual Property and Trademark

As a generics manufacturer your IP exposure runs in two directions, and we would have you confirm both before launch. The first is defensive: making sure the specific molecules and formulations you intend to sell are genuinely off-patent in Kenya and do not infringe a still-protected originator patent. For your mature, long-established molecules, amoxicillin, amlodipine, metformin, paracetamol and the rest, this is almost certainly clear, as these are long off-patent globally, but we confirm patent status per molecule so you proceed with no ambiguity.

The second is protective: securing your own brand names and trademarks in Kenya. If you sell your molecules under your own brand names rather than purely as international non-proprietary name generics, we would have you register those trademarks in Kenya early, both to stop a local party registering them first and to build the brand equity that supports your pricing above the bottom tier over time. Trademark registration is cheap relative to its protective value, and we would have you start it

alongside your product registrations.

Neither exposure is a barrier for your portfolio; both are confirmations to close so your launch is clean. The instruction is simply to verify freedom-to-operate per molecule and register your own marks early, treating IP as a box to close, not a risk to fear.

22 Risk Matrix

Five risks are material for you, and each has a concrete mitigation we would have you hold from day one. The honest overall reading is that this is a well-understood, manageable-risk corridor whose risks are operational and fundable rather than structural, which is what supports our conditional go. The two biggest, registration delay and the working-capital gap, are exactly the difficulties you met in Nigeria, so you walk in forewarned and can design around them rather than discover them in flight.

The discipline that falls out of the matrix is simple, and we would have you keep it through the whole launch: fund the launch as a single block before you ship, register early and in a tight first wave, price and term in USD, never depend on one distributor or the slow public channel for first-year revenue, and let your WHO-GMP quality be your answer to enforcement risk rather than a cost to be trimmed.

YOUR MATERIAL RISKS AND HOW WE'D MITIGATE THEM

Risk	Severity	Mitigation
Registration / GMP site-approval delay	High	Start site recognition first; reuse your dossiers; register a 2-molecule first wave via an experienced agent.
Working-capital gap before first orders	High	Fund your ~US$140k up front; price in USD; advance or letter-of-credit on opening orders.
Shilling depreciation / USD-liquidity tightness	Medium	Invoice in USD; keep exposure short; watch reserve and rate signals.
A distributor signs but underperforms	Medium	Dual non-exclusive distributors; short initial terms; volume milestones; verify warehousing.
Quality / counterfeit-enforcement exposure	Medium	Lean on your WHO-GMP; CoA per batch; full Board labelling compliance.

23 Go-to-Market: Your Route and Sequence

This is the heart of the report, and we have written it so you could begin on Monday. The route we recommend is a dual-distributor model, not direct operations and not a joint venture, because it gives you the fastest, lowest-capital access to established relationships and warehousing while keeping you from being captive to a single partner, which is exactly the low-capital, reversible entry you asked us for. Direct operations would need a local entity, licences and a sales force you do not have and do not need yet; a joint venture would over-commit you before the market is proven. The dual-distributor model is your reversible, capital-light option.

On molecules, we would have you enter with a first wave of two anchor lines where demand is deep and your documentation is most ready, then widen. The first wave we recommend is one anti-infective, amoxicillin or amoxicillin-clavulanate, for fast distributor rotation and quick cash, and one chronic line, amlodipine or metformin, for predictable, refill-driven volume that builds you a dependable base. The second wave, submitted a few weeks behind, adds two or three more across your remaining areas. This turns your twelve-month goal into a staged, fundable plan rather than one large bet, and it lets your team learn from the first registration before you commit the rest of your fee budget.

Your channels run in parallel, not in series. You open two complementary distributor conversations and your MEDS application at the same time, because each runs on its own clock; you do not wait for registration to approach distributors, because selecting and negotiating them happens during the registration window so that a signed distributor is ready the day approval lands. Public tenders you defer to year two. The result is that by the time your first molecule is approved, you have a distributor signed, terms agreed, pricing set and a first full-container order planned, so your revenue follows approval by weeks, not months.

24 Go-to-Market: How You Approach a Distributor

We would have you run each distributor approach as a defined sequence, not an open-ended chat. The goal of your first contact is not to close terms; it is to earn a serious second meeting by showing you are a credible, low-risk, gap-filling supplier.

In your first contact, reach the category or procurement buyer, not a general inbox, and lead with three things on one page: who you are (a WHO-GMP manufacturer with existing African registrations and the spare capacity to guarantee supply), what you offer (a focused list of named molecules with indicative USD prices and lead times), and why you fit (the specific gap in their current range and the reliability their own customers complain is missing elsewhere). The single most persuasive line you have is a credible guarantee of supply continuity, because stockouts are their recurring pain.

In the negotiation, expect to discuss distributor margin (mid-teens to low-twenties percent), minimum order quantities, credit terms and exclusivity, and we would have you hold a clear position on each. Offer attractive pricing tied to volume milestones rather than an unconditional discount; resist open exclusivity in favour of a non-exclusive start with a volume-based path to exclusivity later; and protect your opening-order cash by proposing advance or letter-of-credit terms on the first orders, easing to short credit only as the relationship proves out. Be willing to give ground on margin for genuine volume commitment, and be willing to walk away from a partner who wants exclusivity and credit before delivering a single order. What you should come out of this phase with is a short, milestone-based, non-exclusive agreement with two complementary distributors, reviewed by a Kenyan-qualified lawyer before you sign.

YOUR OPENING POSITION ON EACH NEGOTIATION LEVER

Lever	Where we'd have you open
Margin	Competitive, but tied to volume milestones, not unconditional
Minimum order quantity	Set to enable full-container, multi-molecule shipping

Lever	Where we'd have you open
Credit terms	Advance / letter-of-credit on opening orders; short credit later
Exclusivity	Non-exclusive start; volume-based path to exclusivity later
Term	Short initial term with a milestone review, not a long lock-in

25 Go-to-Market: Activation and Your First Orders

Activation is where a lot of entries quietly stall, because a signed distributor is not the same as product moving. We would have you treat your first ninety days after approval as a seeding campaign with explicit targets, not a hand-off.

On your private-distribution channel, once your first molecule is approved and your opening order has landed in the distributor's warehouse, agree a joint seeding plan with them: which retail and hospital accounts they will prioritise, what introductory terms or sampling will speed first stocking, and what reorder signal you will watch to confirm genuine pull rather than one-off shelf-filling. Ask for a simple weekly stock-and-sell-through readout for your first quarter so you can see whether your product is moving or just sitting, and intervene early if it is the latter.

On the faith-based channel, once you are on the MEDS list, make sure your lead molecules are quoted into the relevant procurement cycles and that your quality documentation is complete on file, because this channel buys on quality and reliability and rewards a supplier who makes the buyer's compliance job easy. On the direct hospital and insurer segment, let your distributor make the introductions to the larger private hospital groups once your stock is reliably in market, turning their relationships into pull for your molecules specifically.

Your first-orders discipline ties back to your cash and your logistics: consolidate the opening order into a full-container, multi-molecule shipment to minimise per-unit cost; time it to your expected approval so stock is not sitting in a bonded warehouse incurring cost ahead of a licence, nor missing when the distributor is ready to sell; and price and term it in USD with the advance or letter-of-credit you agreed. The measure of a good activation phase is not your first order shipped, it is your first reorder received, because the reorder is the proof of genuine market pull.

26 Your Twelve-Month Operating Plan

We have broken your twelve months into four phases, each with a clear objective and an exit test, so you always know whether you are on track. The plan assumes prompt Board acknowledgement and we re-base the dates to actual regulator response times, but the phase logic holds regardless of the exact calendar.

Months zero to four are your register-and-partner phase: start site GMP recognition, submit your two-molecule first wave, and run your distributor and MEDS conversations to a signed, milestone-based position, so partner readiness leads rather than lags your registration. Your exit test is a first molecule under active review, a second submitted, and at least one distributor signed.

Months three to six are your first-revenue phase: on first approval, authorise import, ship your opening full-container multi-molecule order, and run the seeding campaign to a confirmed reorder. Your exit test is product in market and a first reorder received, which is the real signal that your entry works.

Months six to nine are your widen-and-deepen phase: submit your second-wave molecules, activate the MEDS channel into live procurement cycles, sign your second distributor, and turn distributor relationships into private-hospital pull. Your exit test is four to five molecules registered or in review, two live distributors, and a faith-based channel quoting your products.

Months nine to twelve are your platform phase: build the record and registrations you need to start KEMSA tender qualification, and begin the regulatory groundwork for your first neighbour, Uganda or Tanzania, off your Kenya base. Your exit test is a defensible Kenyan position throwing off repeat revenue and a concrete, costed plan for market two.

YOUR TWELVE MONTHS BY PHASE

Phase / months	Your objective	Your exit test
Register + partner (0-4)	First wave submitted; distributors in negotiation	1 molecule in review, 2nd submitted, 1 distributor signed
First revenue (3-6)	Ship the opening order; seed the market	Product in market; first reorder received
Widen + deepen (6-9)	Second wave; activate MEDS; second distributor	4-5 molecules registered/in review; 2 live distributors
Platform (9-12)	Qualify for KEMSA; prepare market two	Repeat revenue; costed plan for Uganda/Tanzania

27 Your First Ninety Days

Your first ninety days turn the decision into an irreversible head-start on the registration clock and a live distributor relationship. The plan below is specific enough to hand to your export head and run without further interpretation; the dates assume prompt Board acknowledgement and we re-base them to actual response times. The principle we would have you hold is to start the longest-lead items, your site recognition and your first dossier, in week one, because every day you save there is a day earlier to your revenue.

YOUR FIRST 90 DAYS

Weeks	Focus	Who owns it
1 to 2	Appoint your regulatory agent; start site GMP recognition; open lead-molecule dossier; shortlist two distributors	MD / Agent
3 to 4	Submit first-wave molecule 1; open talks with both distributors; begin MEDS application	RA / Export head

Weeks	Focus	Who owns it
5 to 6	Submit molecule 2; agree indicative USD pricing; draft non-exclusive distributor terms with milestones	RA / Export head
7 to 8	Finalise your first distributor; prepare CoPP + free-sale + export docs; ring-fence the working capital	MD / Finance
9 to 10	Answer Board queries fast; sign your second distributor; plan first full-container shipment	RA / Ops
11 to 13	On first approval, authorise import and ship; brief both distributors on availability and seeding	Ops / Export head

28 What You Measure, and How Often

We would have you run this entry against a small set of leading and lagging indicators on a fixed cadence, so drift gets caught early rather than at year-end. The temptation in a new market is to watch only revenue, but revenue is a lagging number that moves too late for you to steer by.

The leading indicators that predict whether you are winning are regulatory and commercial momentum: dossiers submitted against plan, your query turnaround time, distributors signed, and first-stocking accounts opened. The lagging indicators that confirm it are reorders received, sell-through rate, your on-time-in-full delivery performance, and corridor revenue against the US$0.8M to US$1.4M we estimated. We would single out on-time-in-full, because reliability is the differentiator you chose, and it is the metric your distributor will quietly judge you on.

We would have you review weekly through your first ninety days, while the registration critical path and distributor negotiations are live and small delays compound, then monthly through the rest of the year against the phase exit tests. Every review should ask one question above all: is the registration critical path on schedule, and if not, what is the single action that recovers it. Everything else in your plan flexes around that path.

WHAT YOU WATCH

Type	Indicator	Why it matters to you
Leading	Dossiers submitted vs plan; query turnaround	Predicts your time to first revenue
Leading	Distributors signed; first-stocking accounts	Predicts your market activation
Lagging	Reorders; sell-through; on-time-in-full	Confirms genuine pull and your reliability
Lagging	Corridor revenue vs $0.8-1.4M estimate	Confirms the entry thesis

29 Working-Capital Phasing

This is about the timing of the US$140,000 you have already committed, not a financial projection. A bespoke financial model, your margins, break-even and returns, needs your real ex-works costs and belongs to Expert Advisory, where we work through it with you on a call. What we can and should do here is sequence the deployment of the capital you have set aside, so your cash is neither idle nor short at the moment you need it, which is exactly where Nigeria hurt you.

Your capital deploys in three phases. The first and smallest funds your registration wave and your regulatory agent: your per-molecule fees and professional costs, paid up front, well inside your budget, and incurred before any revenue. The second and largest funds your first inventory: a full-container, multi-molecule shipment timed to your expected approval so your stock is not sitting in a bonded warehouse incurring cost ahead of a licence, nor missing when your distributor is ready to sell. The third is the bridge: the working capital that covers the gap between your shipping and your first distributor payment, which we would have you deliberately keep small by pricing in USD and taking advance or letter-of-credit terms on opening orders.

The one discipline that matters most is to time your large inventory draw to your registration critical path, not to the calendar, because committing inventory cash ahead of an uncertain approval is precisely the trap you want to avoid. The registration tracker we recommended is what makes this possible: it tells your finance function when approval is realistically near, so the inventory draw is released against a real date, not a hopeful one. Run this way, your US$140,000 is comfortably enough for your first wave, your first shipment and your bridge, with headroom for your second-wave registrations as your first revenue begins to recycle.

WHEN YOU DEPLOY YOUR BUDGET (TIMING, NOT A PROJECTION)

Phase	What it funds	Timing
1. Registration	Your first-wave fees + regulatory agent	Up front, before revenue (smallest)
2. First inventory	Full-container multi-molecule shipment	Timed to your expected approval (largest)
3. Bridge	Gap to your first distributor payment	Kept small via USD + advance/LC terms

30 Turning Your Quality Into a Commercial Weapon

Your WHO-GMP status is not just a regulatory ticket; it is your strongest commercial weapon in a market where the recurring complaint about imported supply is inconsistency, and where enforcement against substandard medicines is rising. We would have you make your quality visible and turn it into the reason a distributor, a faith-based buyer and a hospital choose you over a cheaper, less reliable line.

In practice that is three things. First, lead every commercial conversation with the documentation that de-risks the buyer: your WHO-GMP certificate, a certificate of analysis on every batch, and clear registration status per molecule. A buyer who can show clean paperwork to their own auditor or to the

Board will favour the supplier who makes that easy, and that is you. Second, build and show post-market readiness, a pharmacovigilance contact, a complaints process and a defined recall procedure, because the faith-based and hospital channels in particular reward a supplier who is audit-ready and penalise one who is not. Third, treat consistency as a promise you keep rather than a claim you make: on-time-in-full delivery, batch consistency and no stockouts are what turn your first order into a standing relationship, and your spare capacity is what lets you keep that promise where others cannot.

The defensive value matches the commercial value. Rising enforcement against falsified and substandard medicines is a risk to the bottom tier and an opportunity for you; by holding strict WHO-GMP discipline and complete documentation, you turn an industry-wide risk into a position of relative strength. In this market, documented quality is what keeps you in the buyer's catalogue when cheaper but riskier suppliers are dropped.

YOUR QUALITY, AS COMMERCIAL ADVANTAGE

What you do	What it buys you
WHO-GMP cert + per-batch CoA up front	De-risks the buyer; eases their own audits
Pharmacovigilance + recall readiness	Wins the faith-based and hospital channels
On-time-in-full + no stockouts	Turns your first orders into standing relationships
Strict GMP discipline	Turns enforcement risk into your relative strength

31 Delivering on the Promise: Your Supply Assurance

Your whole commercial argument rests on reliability, so you have to be able to deliver the supply promise you make, and this is what that asks of your own operations. The good news is that your profile, an established manufacturer at roughly 70 percent utilisation with around 30 percent spare capacity, is exactly the profile that can credibly guarantee continuity to a Kenyan distributor; the discipline is to protect that capability on purpose rather than assume it.

Three commitments underwrite the promise. First, ring-fence a defined slice of your spare capacity for the Kenya programme, so a domestic or existing-export surge cannot crowd out a Kenyan reorder at the moment a distributor needs it; a stockout in your first year, while trust is still being earned, hurts you far more than a marginal opportunity cost elsewhere. Second, hold safety stock of your first-wave molecules and their key active ingredients sufficient to cover the ocean-freight lead time plus a buffer, so a reorder ships promptly rather than waiting on a production cycle. Third, plan your shipment timing around the anti-infective seasonality, building stock ahead of the rainy-season peaks rather than chasing them.

The number that matters, and the one your distributor will judge you on, is on-time-in-full delivery. Track it from your first order and treat any miss as a priority incident, because in a market where the universal complaint is inconsistent imported supply, near-perfect reliability is not a hygiene factor for you, it is the core of your competitive position. Your spare capacity is the asset; turning it into a kept promise is the work, and it is well within what you have.

32 What We'd Have You Do: Recommendations

1. Start a two-molecule registration wave this month. Registration, not demand, gates your first revenue, so the clock has to start now; start your site GMP recognition first, then submit an anti-infective and a chronic molecule whose dossiers are most ready, through an experienced Kenyan agent who reviews your submission before it is filed.

2. Sign two complementary national distributors, non-exclusive, with volume milestones, one retail-strong and one hospital-strong, scoring each on warehousing, financial standing and compliance before you commit.

3. Start focused. Concentrate the first wave on two anchor molecules, then widen to four or five once they move. Registering the whole catalogue at once thins out the fee budget and the attention each product needs to sell.

4. Apply to the MEDS faith-based channel in parallel; it rewards your WHO-GMP quality, pays reliably, and builds your reputation for the later tender and distributor conversations.

5. Set a per-molecule pricing architecture, not one number: lower in your band for the price-watched anti-infectives, mid-band for the sticky chronic lines, and sell the gap to the incumbents on reliability and documentation rather than on discount.

6. Run activation as a seeding campaign with a weekly sell-through readout, and treat your first reorder, not your first order, as the proof your entry works.

7. Defer KEMSA tenders to year two, going after government volume only once your registrations and private-channel record are in place.

8. Fund the launch as a single working-capital block. Treat the registration-to-first-order cash gap, your Nigeria lesson, as the core of your plan and secure your US$140,000 before you ship, priced and termed in USD to protect it.

33 When the Plan Meets Reality: Your Decision Gates

A good plan survives contact with reality because you have decided your responses in advance, so let us set the decision gates that turn a setback into a prepared move rather than a scramble.

If your site recognition or first dossier stalls beyond the planned review window, the move is not to wait but to escalate through your agent, confirm the precise query, and, if the delay is structural rather than a fixable query, re-base your working-capital draw and your distributor expectations rather than letting your cash sit committed against an uncertain date. If a lead distributor demands exclusivity and extended credit before any order, the move is to hold your non-exclusive, milestone-based position and proceed with the complementary partner, because a partner who front-loads their demands rarely back-loads their performance.

If your first sell-through is weak despite product being in market, the move is to diagnose, using the weekly readout, whether it is price, availability or distributor effort, and act on the specific cause rather than discounting on reflex. If the shilling slides sharply or dollar liquidity tightens, your USD pricing and

advance terms already absorb most of the shock, but slow your credit extension until conditions settle. And if, by the end of your first-revenue phase, no reorder has come, that is the honest signal to pause widening, fix the activation problem, and protect your capital rather than register more molecules into a channel that is not yet pulling. These gates are what make your entry genuinely reversible, which is what you asked us for.

34 Who to Reach, and What to Say

Let us put the people you need in one place, organised by what you need from each, with how we'd have you open. For regulation, the Pharmacy and Poisons Board handles your product registration, GMP recognition and import authorisation; engage it only through your appointed local agent and always lead with a complete dossier, because incomplete submissions are your main cause of delay. Your opening aim is a clean acknowledgement and a clear query list, not a fast yes.

For the faith-based channel, the Mission for Essential Drugs and Supplies serves mission and private hospitals and rewards your WHO-GMP quality; apply to its supplier list early with full documentation, and lead your message with your quality credentials and your supply reliability. For distribution, the national distributors, Surgipharm, Phillips Pharmaceuticals, Laborex, Harleys and their peers, are your fastest route to revenue; ask for the category buyer and lead with your molecule list, your indicative pricing, your lead times and a credible supply guarantee.

For public procurement, the Kenya Medical Supplies Authority is your year-two target; register as a supplier now even while you defer active tendering, so the qualification is in place when you choose to compete. For trade facilitation, the High Commission of India in Nairobi and the Indian pharmaceutical export-promotion bodies, alongside Kenyan industry associations, can open doors and help you validate counterparts. For logistics, appoint a clearing agent with a verified pharmaceutical clearance record at Mombasa. Here we give you the organisations and roles; in the full report we confirm the current named contacts, their procurement calendars, and the specific person and opening message for each, so your team can act without further research.

WHO TO REACH, AND HOW WE'D OPEN

What you need	Who	How we'd have you open
Regulation	Pharmacy and Poisons Board (via your agent)	A complete dossier; aim for a clean acknowledgement
Faith-based	MEDS	Apply early; lead with your WHO-GMP quality + reliability
Distribution	Surgipharm / Phillips / Laborex / Harleys	Your molecule list, USD pricing, supply guarantee
Public	KEMSA	Register as a supplier now; tender in year two
Logistics	A pharma-experienced Mombasa clearing agent	Verify their track record before you appoint

35 Legal Considerations

Three legal requirements sit between you and your first shipment. First, product registration and import authorisation under the Pharmacy and Poisons Board: selling or importing an unregistered medicine is an offence and your stock can be seized, so this is a hard gate, not a formality. Second, a locally licensed importer and wholesale dealer: your imported medicines have to move through a partner holding valid Board import and wholesale licences, which is exactly why your distributor due diligence is a legal matter as well as a commercial one. Third, labelling, GMP and quality compliance: your products have to meet Board labelling and good-manufacturing standards, and falsified or substandard medicines attract serious penalties, an area where your WHO-GMP discipline is an asset rather than a risk.

On your contracts with distributors, specify a clear governing law and a workable dispute-resolution mechanism, with arbitration under a recognised institution common for this kind of cross-border trade; insist on payment terms that protect your opening-order cash, namely advance or letter-of-credit on first orders; and define quality, recall and indemnity obligations explicitly so responsibility is unambiguous if a batch issue ever arises. There are no unusual sanctions or dual-use concerns for your standard generic medicines, but confirm that none of your specific molecules sits on a controlled-substance schedule needing extra licensing. This is operational guidance, not formal legal advice; have a Kenyan-qualified lawyer review your distributor agreement before you sign.

36 Where We Land

Our verdict for you is a confident conditional go. Kenya gives you a duty-free, VAT-exempt, trust-established way into East Africa; your WHO-GMP plant and your existing dossiers make you unusually ready; and your core molecules sit on top of the market's deepest demand. The only thing between you and your first revenue is registration sequencing, which is squarely in your hands.

In your next thirty days, appoint your regulatory agent and start site GMP recognition, submit your two-molecule first-wave dossiers, open talks with two complementary national distributors, begin your MEDS application, and ring-fence your working capital in USD. The risks, registration delay, the working-capital gap, currency, distributor performance and quality discipline, are real but operational and fundable, and you, forewarned by Nigeria, are well placed to design around them with the decision gates we set out.

Done with focus on a tight first wave, a disciplined dual-distributor model, and a seeding campaign you measure by your first reorder, Kenya is a market you can win inside a year and then use as the platform for Uganda, Tanzania and Rwanda you set out to build. The path is clear. The work now is to walk it, and we would be glad to walk it with you.

37 Appendix A: Your Launch Checklist

This pulls your whole launch into one checklist your team can run against, so nothing slips between the sections above.

YOUR PRE-LAUNCH AND LAUNCH CHECKLIST

Area	Action	Owner
Regulatory	Appoint your agent; start site GMP recognition	RA team
Regulatory	Submit your two-molecule first wave (CTD); track per molecule	RA team
Regulatory	Per-consignment import authorisation in place	Distributor
Your side	CoPP, free-sale certificate, export docs ready	Export team
Commercial	Sign two complementary distributors (non-exclusive, milestones)	MD
Commercial	MEDS supplier application submitted	Export team
Pricing	Per-molecule USD anchors set before you negotiate	MD
Finance	~US$140k ring-fenced; USD terms agreed	Finance
Logistics	Pharma clearing agent appointed at Mombasa	Ops
Logistics	First order consolidated into a full-container shipment	Ops
Activation	Seeding plan + weekly sell-through readout agreed	Export team

38 Appendix B: Outreach You Can Adapt

These are ready-to-adapt openings for the three relationships that matter most in your first ninety days. Treat them as drafting starting points, not scripts; personalise each with the recipient's name, your specific molecule list and your current indicative pricing.

To a distributor, first contact (to the category or procurement buyer). Subject: WHO-GMP generics, reliable supply, [your 2 to 3 named molecules]. Body: "We are Saral Pharma, a WHO-GMP-certified Indian manufacturer of oral solid-dose generics, currently supplying [Nigeria, Philippines, Sri Lanka]. We are entering Kenya and registering [molecule 1] and [molecule 2] with the Pharmacy and Poisons Board. We believe these fill a gap in your current range, and our spare capacity lets us guarantee the supply continuity we understand is a recurring pain with imported lines. May we send a one-page molecule list with indicative USD pricing and lead times, and arrange a short call with your category buyer." Your most important line is the credible guarantee of supply continuity.

To a distributor, follow-up after interest. Lead with the documentation that de-risks the relationship: your WHO-GMP certificate, certificates of analysis, registration status per molecule, and indicative pricing tied to volume milestones. Propose a non-exclusive start with clear volume targets and advance or letter-of-credit terms on the opening order, framed as protecting both sides on a first transaction.

To the faith-based channel (your MEDS application cover note). Lead with quality and reliability, which is what they buy on: "Saral Pharma is a WHO-GMP-certified manufacturer applying to supply [molecule list] to the MEDS network. We attach our quality documentation and registration status, and we are

committed to the supply reliability and full certification the mission-hospital network depends on."

To your regulatory agent (your brief). State the objective plainly: "We want a clean, query-resistant first submission for [molecule 1] and [molecule 2]. Please review our existing Nigeria and Philippines dossiers, identify exactly what must be reformatted or added for the Board, confirm our site GMP recognition status and any inspection requirement, and give us a realistic timeline and fee schedule." Their pre-submission review is the cheapest insurance you can buy against the delay that hurt you in Nigeria.

YOUR OUTREACH PRIORITIES, FIRST 90 DAYS

Who	Your first-message goal	What de-risks it
Two distributors	Earn a serious second meeting	Supply guarantee + molecule list + pricing
MEDS	Get on the supplier list	Your WHO-GMP + complete quality documentation
Your regulatory agent	A query-resistant first submission	Their pre-submission dossier review

39 Appendix C: How We Verify This

Because we will not ask you to take anything on trust, here is exactly where each kind of figure in a commissioned report is confirmed, so you can see the basis the analysis rests on. In a live report for you, these are done and the results cited inline; here we list them because the client and corridor are illustrative and the figures are directional.

Your trade and corridor figures (market size, India's share, growth) are confirmed against United Nations Comtrade and Kenyan customs for your specific HS codes, with the data year on every figure. Your duty and tax treatment is confirmed against the East African Community Common External Tariff and Kenya Revenue Authority guidance per molecule, since essential-medicine classification is what gives you the duty-free, VAT-exempt status. Your registration requirements, timelines and fees are confirmed directly against the current Pharmacy and Poisons Board schedule and an experienced local agent, because these change.

Your competitive, buyer and distributor specifics are confirmed against current company and procurement information and, where it helps, direct enquiry, so the named counterparts and their roles are right at the time we write for you. Your demand and health-system figures are confirmed against the latest national health budget, insurance-coverage and epidemiological data. Where any figure cannot be confirmed to this standard, we label it Estimated and state the basis, and our quality check fails any hard number presented as fact without a source. This sample uses directional estimates throughout, because its client and corridor are illustrative.

WHERE EACH FIGURE GETS VERIFIED

Figure	How we verify it
Trade / corridor size + share	UN Comtrade + Kenyan customs, by HS code, with data year

Figure	How we verify it
Duty / VAT treatment	EAC CET + Kenya Revenue Authority, per molecule
Registration time / fees	Pharmacy and Poisons Board + your local agent (current)
Competitors / buyers / distributors	Company + procurement data, direct enquiry
Demand / health-system	National health budget, insurance + epidemiological data

40 Appendix D: Glossary

The key terms and abbreviations we have used, in case any are new to your team.

GLOSSARY

Term	Meaning
PPB	Pharmacy and Poisons Board, Kenya's medicines regulator
KEMSA	Kenya Medical Supplies Authority, public-sector procurement
MEDS	Mission for Essential Drugs and Supplies, faith-based procurement
CTD	Common Technical Document, the dossier format for registration
CoPP	Certificate of Pharmaceutical Product, an export document
CoA	Certificate of Analysis, batch-level quality evidence
WHO-GMP	World Health Organization Good Manufacturing Practice certification
EAC / AfCFTA	East African Community customs union / African Continental Free Trade Area
ICD Embakasi	Inland Container Depot near Nairobi for cargo clearance
On-time-in-full	Delivery measure: right quantity, on the promised date

41 A Note on How This Was Built

This is a sample of how we work and what you receive, written as if you were our client, because that is the only way it tells you anything true about working with us. The company and corridor here are an illustrative hypothetical so the document reads as a real, personalised deliverable; the market sizes, shares and price ranges are directional estimates rather than live-cited figures.

A report we build for you is put together the same way but grounded in current sources for your own product, HS code and market, and every named company, price, duty rate and figure is labelled Verified, with a cited source, or Estimated, with the basis for the estimate, and our quality check fails any hard number that is not sourced. We do not invent contacts, prices or duty rates; where something

cannot be verified, we tell you so and tell you what to confirm before you act.

We also owe you the truth about the answer itself, not just the figures. This report happened to land on a conditional go, but our verdict follows the evidence, not your hopes or ours. If the honest call for your corridor were do not do this, or not yet, or not this way, we would tell you plainly and explain why, because real money is involved and the most useful thing an advisor can do is stop you making an expensive mistake early. A clear no from us is worth as much as a yes. We will not sugarcoat a weak case to keep you comfortable, and we will name the specific mistakes that would cost you, so that whatever you decide, you decide it with your eyes open.

One thing we deliberately leave out of an Insight report like this is a bespoke financial model, a unit-economics or break-even projection built from your own costs. An honest model needs your real ex-works costs, target volumes and terms, which we gather with you on a call. That, along with named buyer introductions and the custom model, is part of Expert Advisory. The Insight report stops at the market, strategy, regulatory, channel and execution work that does not need a meeting to be accurate and honest, and gives you all of it, in full.