Prioritizing Small Molecules for Local Manufacturing in Ethiopia

Product profile and go-to-market planning

April 2026

Manufacturing Africa

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The contents of this document are meant to be informative of a fact base, rather than provide any specific recommendation. They are based on initial research, interviews, and analysis and are subject to change given continued feedback

Executive summary (1/2)

1 Product overview and disease rationale

- **Small molecule generics (tablets, capsules, oral liquids, and injectables) form the backbone of treatment across communicable and non-communicable diseases**, supporting first-line therapies for infections, cardiovascular conditions, and chronic diseases
- **Together, they cover the majority of treatment use cases across the healthcare system**, with oral solids dominating due to high volumes, ease of administration, and broad applicability
- **Manufacturing platforms are highly standardized and scalable across multiple dosage forms**, enabling production of a wide range of SKUs within a shared facility

2 High-level market assessment

- **The total small molecule FDF market in Ethiopia is ~$345 Mn, with demand heavily concentrated in oral solids** (~70–80% of value), followed by injectables and a smaller share of oral liquids
- **A prioritized portfolio of ~29 FDF products was selected for local production** based on platform alignment, market size, and import substitution potential – including
  - **Tablets:** 16 prioritized products (~$50 Mn total addressable market value)
  - **Capsules:** 5 products (~$6–7 Mn)
  - **Oral liquids:** 8 products (~$7-8 Mn)
- **Production can be sequenced across two horizons** to balance early revenue generation and capability build
  - **Horizon 1:** EFDA-approved products targeting domestic and private markets (fast launch, lower complexity)
  - **Horizon 2:** WHO PQ products targeting donor-funded markets (higher value, higher regulatory requirements)
- **Existing local manufacturing capacity is concentrated in oral solids** (~10 manufacturers produce tablets with relatively high capacity)**,** with limited capabilities in injectables due to higher GMP and sterility requirements, indicating a clear gap in higher-complexity segments

3 Technical and manufacturing overview

- **Small molecule manufacturing can be structured across three core production platforms** – oral solids, oral liquids, and sterile injectables – enabling portfolio scale-up through shared infrastructure and capabilities
- **Oral solids (tablets and capsules) represent the lowest-complexity entry point,** with standardized processes and lower regulatory burden, while oral liquids introduce additional formulation and microbial control requirements
- **Sterile injectables require the highest level of complexity,** including dedicated sterile infrastructure, advanced equipment, and stringent validation and regulatory compliance, which could significantly increase CAPEX and execution risk

Executive summary (2/2)

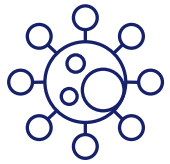
4 Regulatory and IP pathway

- **Three regulatory pathways apply to small molecule manufacturing** – (i) EFDA approval for non-sterile products, (ii) EFDA approval for sterile injectables, and (iii) WHO PQ for donor-funded procurement – enabling a phased market entry across product types and markets
  - **Tablets, capsules, and oral liquids can launch after EFDA approval** (~18–24 months), enabling access to private and RDF markets
  - **Injectables require more complex EFDA approval**, including sterile facility readiness and validation, extending timelines and increasing execution risk
  - **WHO PQ is required for selected donor-funded products (primarily tablets)**, adding ~6–12 months post-EFDA to access international procurement
- **Timely EFDA approval requires parallel preparation of technical dossiers (CTD),** GMP-compliant manufacturing readiness, and validation data (e.g., stability, bioequivalence), with GMP inspection as the primary regulatory gate
- **WHO PQ timelines are driven by dossier completeness,** site inspection readiness, and validation data, requiring early preparation during facility build-out to avoid delays

5 Supply chain feasibility

- **Small molecule manufacturing relies on three key input categories** – APIs, excipients, and packaging – all of which are widely available globally, with no structural supply constraints
- **Supply chain risk is primarily cost-driven rather than availability-driven**, with key exposures including API price volatility, FX fluctuations, and transport/logistics costs
- **Profitability of local manufacturing is highly sensitive to input cost management, particularly for APIs and packaging**, requiring competitive sourcing, bulk procurement, and effective supplier negotiation to achieve viable unit economics

Local production of small molecules FDF[1] is critical to improving access, resilience, and health outcome

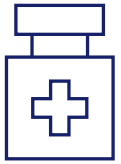


Addresses high burden of communicable and non-communicable diseases

Ensures reliable supply of **first-line, high-volume essential medicines** for high-burden conditions (e.g., antibiotics, cardiovascular drugs, diabetes treatments)

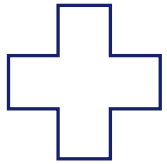
Supports timely response to routine and surge demand

Enables **faster scaling of widely used generics** in response to demand fluctuations (e.g., infectious disease peaks, seasonal needs)



Improves access and affordability of essential medicines (national EML)

Reduces reliance on imports, enabling **more consistent availability of low-cost essential generics** and improved patient access



Strengthens national health system self-sufficiency

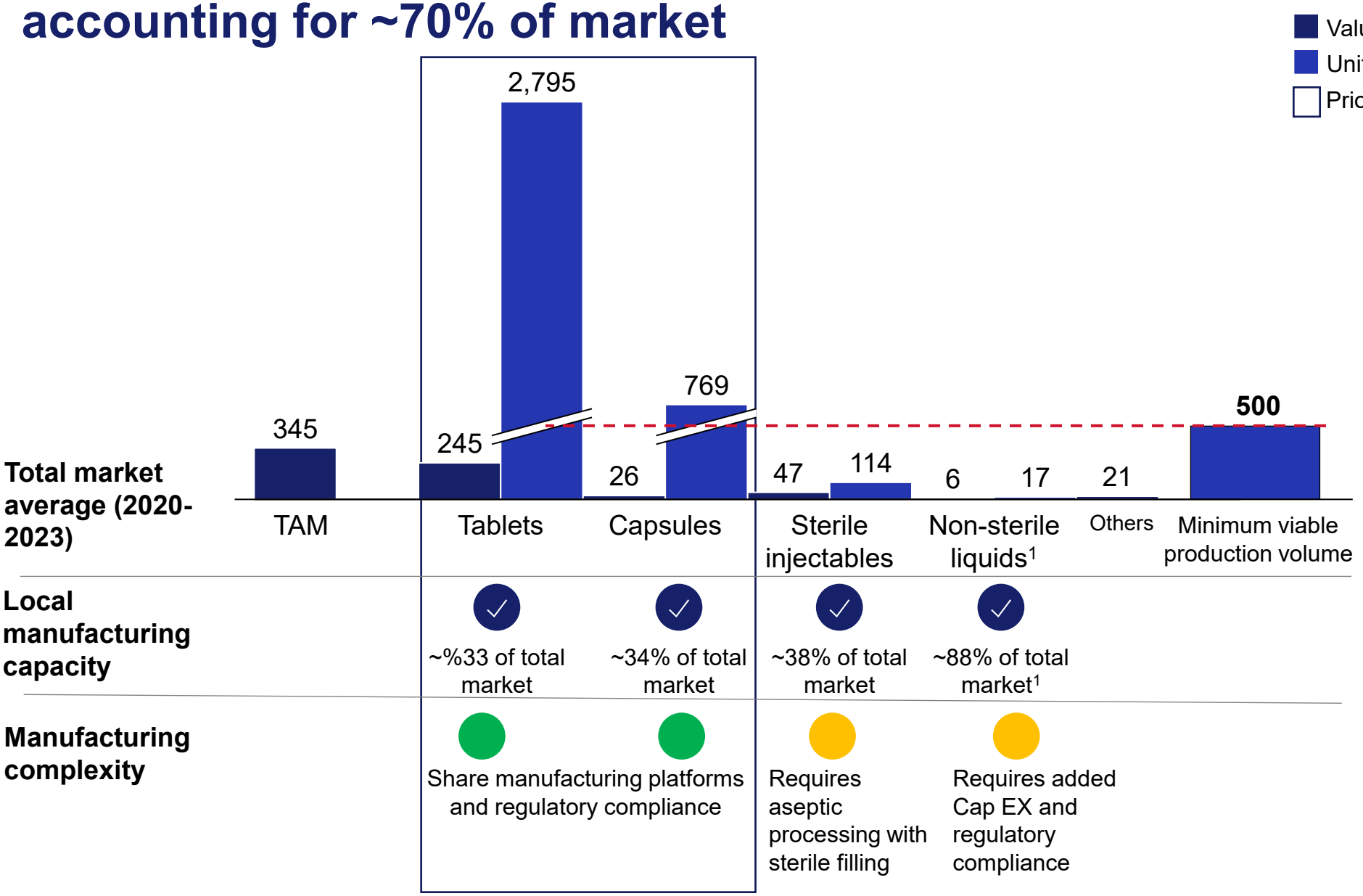
Reduces dependency on external suppliers for core generic medicines, supporting **long-term sustainability of treatment programs**

Enhances supply security and system resilience

Mitigates risks from **import dependency, FX constraints, and global generic supply disruptions**, ensuring continuity of treatment

1. Finished dosage forms

The total market for small molecule FDF is ~345 Mn USD with tablets accounting for ~70% of market



Key takeaways

Tablets and capsules make up for **~80% of the small molecule market in Ethiopia**

Given shared manufacturing platforms and broad molecule applicability, **a combined production facility for tablets and capsules could be attainable in Horizon 1** (next 18-24 months)

A liquids line would require additional equipment and GMP requirements while addressing a significantly lower market

1. The total market for oral liquids is likely higher than official figures suggest, driven by strong private-market sales.

Source: EPSS procurement data (2020-2023), ECC import data (2021-2024), Ministry of Health Local Pharmaceutical Manufacturing Assessment (2025)

Production ramp-up could follow a 2-step approach enabling quick commercialization for 29 drugs, with WHO-PQ products added over time

xx Volume (units) xx Value ($)

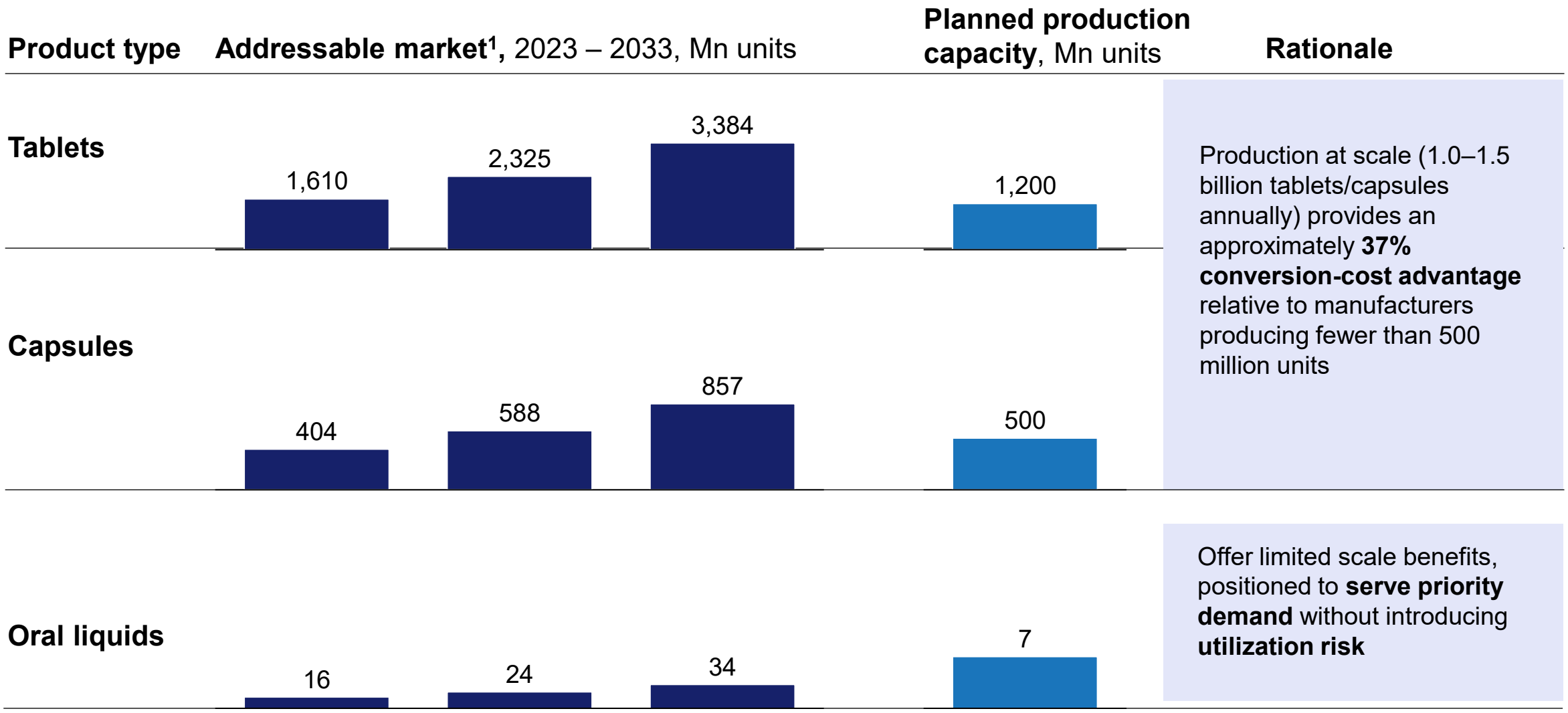
Horizon	0-24 months: Domestic commercialization	>18 months: WHO PQ expansion
FDF in focus	**29 FDF prioritized** for local production, incl., • **13 therapeutic classes** (Pain Management, Gastroenterological, Anti-infectives, Respiratory Infections, Supplements, Maternal Health) • **3 formulations** (16 tablets, 5 capsules, 8 oral liquids)	**4 FDF prioritized** for local production expansion, incl., • **2 therapeutic classes** (HIV/AIDS, Respiratory Infections) • **1 formulation** (tablets)
Total addressable market (TAM)[1]	1,949 Mn 65 Mn	311 Mn 109 Mn
Manufacturing requirements	• Non-sterile solid oral general production line, non-sterile oral liquid production line and sterile liquid production line • National regulatory approval (EFDA) • Standard GMP compliance	• Full GMP + WHO PQ compliance • Compliance with donor procurement standards (~75% of total TAM)

Key takeaways

- **A phased production strategy enables early revenue generation** while building toward donor-facing products
- **Profitability in Horizon 1 depends on scale** and tariff positioning as domestic generics face low margins
- **Securing WHO PQ would access a higher margin market** but increases execution risk and capital intensity

1. Incremental total addressable market, i.e., total market for prioritized small molecule across all dosage forms therapeutics excluding existing local manufacturing capacity

Assuming a combined local manufacturing capacity of ~1,700 Mn, local production could address ~83% of total addressable market



Source: EPSS procurement data (2020-2023), ECC import data (2021-2024), Ministry of Health Local Pharmaceutical Manufacturing Assessment (2025), McKinsey benchmarking tool (POBOS)

Manufacturing complexity increases significantly from non-WHO PQ solids to sterile injectables, driven by regulatory and sterility requirements

Complexity High Moderate Low

	Oral solid dosage forms		Liquid dosage forms	
Manufacturing process complexity	**Tablets (non-WHO PQ) and capsules**	**Tablets (WHO PQ)**	**Oral liquids**	**Sterile injectables[1]**
Sterile production	✗	✗	✗	✓
Process sensitivity	**Low** – robust, standardized processes	**Moderate - high** – stricter control and reproducibility	**Moderate** – microbial and formulation sensitivity	**High** – aseptic processing
Environmental control	**Low**	**Moderate** (controlled environment, not sterile)	**Moderate** (microbial control)	**High**
Equipment and technology requirements	**Low** – simple facility requirements, low automation	**Moderate** – additional requirements for equipment qualification and monitoring	**Moderate** – additional cleaning and sanitation systems, moderate automation	**High** – sterile filling lines, advanced monitoring systems, high automation
Quality control and validation	**Low** – basic QC and standard validation	**High**– expanded QC testing, comprehensive process validation	**Moderate** – additional microbial and cleaning validation	**Moderate** – extensive validation and regulatory requirements

- **Lowest-complexity entry point** with standardized processes and minimal regulatory burden
- **Same core process but significantly higher regulatory and validation requirements,** increasing complexity without major process change
- **Additional process and microbial complexity**, requiring stronger quality systems and more advanced equipment
- **Highest complexity across all dimensions,** requiring sterile infrastructure, advanced capabilities, and stringent regulatory compliance

1. Not included in the financial model

Source: POBOS, McKinsey pharmaceuticals practice, Expert interviews

Regulatory requirements increase significantly from national approval to WHO PQ, with sterile injectables requiring the highest level of compliance

Complexity High Moderate Low

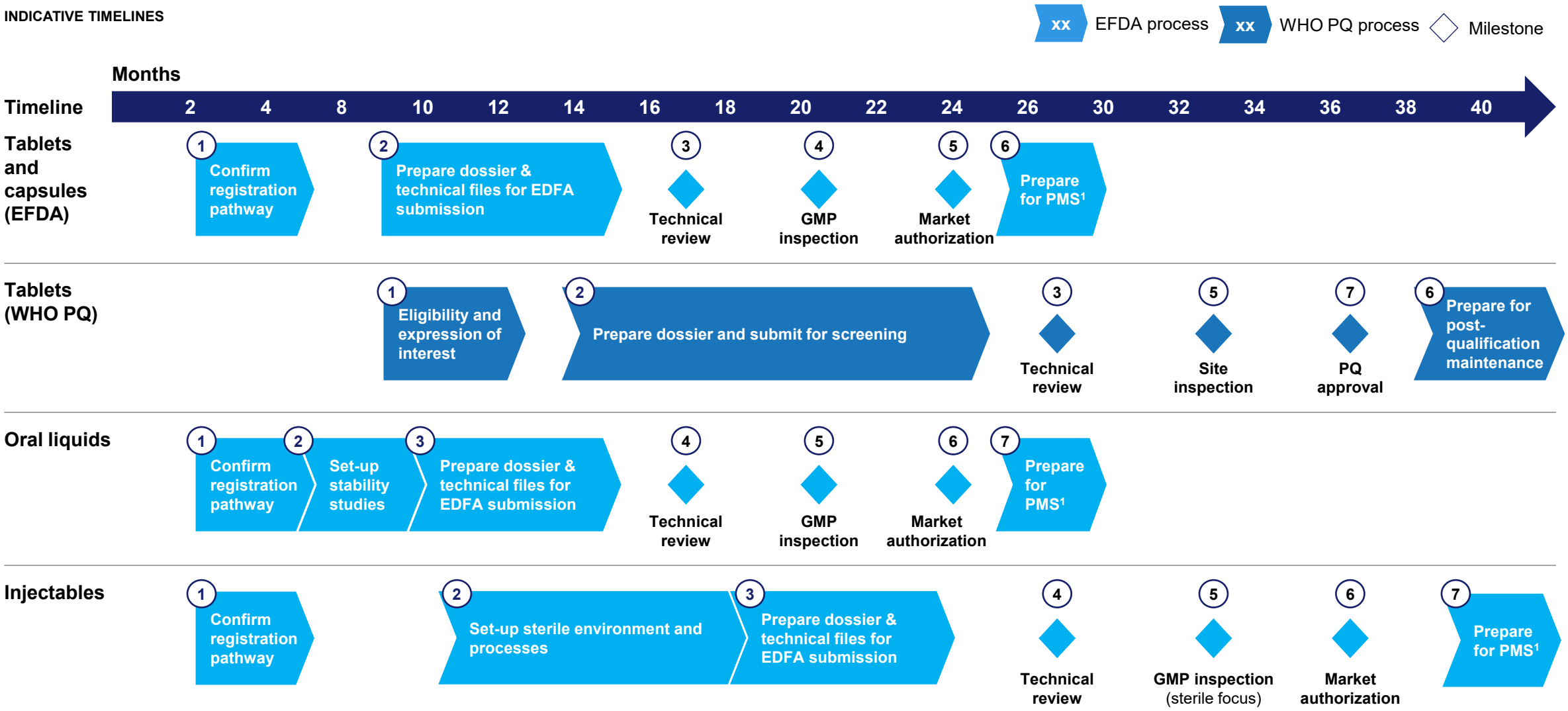
Manufacturing process complexity	Oral solid dosage forms		Liquid dosage forms	
	Tablets (non-WHO PQ) and capsules	Tablets (WHO PQ)	Oral liquids	Sterile injectables[1]
Approval pathway	**National approval (EFDA)** – enabling access to domestic and private markets			
		WHO PQ – required for donor funded procurement		
GMP requirements	**Basic GMP compliance** – standard facility and quality systems sufficient	**Enhanced GMP (WHO compliant)** – requires stricter process controls, documentation, and audit readiness	**GMP with increased microbial control** – requires tighter environmental control and cleaning procedures	**Full sterile GMP (highest level)** – requires dedicated sterile infrastructure (cleanrooms, HVAC)
Documentation and dossier	**Basic regulatory dossier** – limited data requirements, faster approval timelines	**Full WHO PQ dossier** (CTD format incl., stability data) – requires extensive documentation, bioequivalence data, standardized format	**Expanded dossier** – additional formulation-specific data and stability consideration	**Extensive dossier** – requires full validation of sterile processes and detailed risk control documentation
Documentation and dossier	🟢 **Lowest regulatory burden** with fast national approval and limited documentation requirements	🔴 **Significant step-up in regulatory requirements** driven by WHO PQ, with extensive documentation and audit processes	🟡 **Moderate regulatory complexity** due to formulation stability and increased microbial control requirements	🔴 **Highest regulatory burden**, requiring sterile GMP, extensive validation, and stringent ongoing oversight

1. Not included in the financial model

Source: WHO, EFDA, expert interviews

Non-sterile FDF can be launched within ~24 months via EFDA, while injectables require additional sterile setup

INDICATIVE TIMELINES



1. Post-market surveillance
2. Outlining process steps relevant for national registration and WHO PQ approval – full production ramp-up roadmap outlined in last chapter

Source: Guideline for Registration of Medicines (latest version); GMP inspection and licensing guidelines; WHO Prequalification of Medicines Programme

Supply of APIs, excipients, and packaging is broadly available; profitability is driven by input costs, FX exposure, and sourcing efficiency

	API	Excipients	Packaging
Description	Active pharmaceutical ingredients (APIs) are the **core therapeutic components** across tablets, liquids, and injectables	Excipients (fillers, binders, solvents, stabilizers) enable **formulation performance and stability**	Packaging includes **primary** (blisters, bottles, vials) **and secondary components** (cartons, leaflets)
Availability	← Supply is widely available globally (with hubs in India and China) – no structural supply chain risks exist →		
Sourcing strategy	**Import from qualified global suppliers and secure competitive pricing** through volume aggregation and long-term agreements	**Source from global suppliers with selective localization** of high-volume, simple excipients over time	**Import primary packaging at scale** Localize secondary packaging subject to quality compliance

Key takeaways

- **No structural supply constraints exist across APIs, excipients, and packaging**, supported by a broad global supplier base
- **Supply chain risk is primarily cost-driven rather than availability-driven**, including:
  - Price volatility
  - FX exposure
  - Transport and logistics costs
- **Profitability of local manufacturing is highly sensitive to input cost management**, particularly for APIs and packaging
- **Competitive sourcing, bulk procurement, and supplier negotiation** are critical to achieving viable unit economics
- **Selective localization** (e.g., secondary packaging, simple excipients) can improve resilience and cost competitiveness over time

Agenda

1. Product overview

2. High-level market assessment
3. Manufacturing process
3. Regulatory and IP pathway
4. Supply chain feasibility
5. Risks and mitigants

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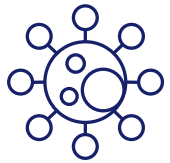

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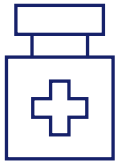

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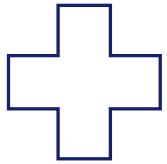

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1. Finished dosage forms

Oral solid dosage forms vary across three independent design dimensions

Dominant global configuration XX% Share in procurement volume

	Oral solid dosage (OSD) forms							Production flexibility
Product types	**Tablets** • Compressed units containing API plus other excipients (diluents, lubricants and others) formed by high pressure compression of powders or granules 78%				**Capsules** • API in powder, granule, pellet, or liquid form enclosed in a hard or soft shell made of gelatin or plant-based polymers 21%			✓ Require different upstream process (compression vs filling), but share several downstream processes
Release mechanism	**Immediate release (IR)** • Drug is released rapidly after administration, with no intentional delay or modification to the dissolution profile. Used for standard therapies		**Modified release (MR)** • Drug release is intentionally altered to control the rate, timing, or location of release in the body. Improves drug stability		**Delayed release (enteric coated)** • Drug release is delayed until the dosage form passes through the stomach, typically dissolving in the intestine. Used to reduce gastric irritation			✓ Share core manufacturing steps, but modified and delayed release require additional coating processes and equipment
Formulation types	**Plain (uncoated)** Compressed solid dosage forms without any coating layer	**Film-coated tablets** Tablets coated with a thin polymer layer to improve stability, appearance, and swallowability	**Enteric coated** Tablets coated with a pH-sensitive layer that prevents dissolution in the stomach and enables release in the intestine	**Multi-layer/ combination** Tablets composed of two or more layers, enabling separation of APIs or different release profiles within a single unit	**Powder-filled** Hard capsules filled with API in powder or granule form. Capsules containing liquid or semi-solid formulations enclosed in a soft gelatin shell	**Pellet-filled** Capsules filled with coated pellets or beads, often enabling modified or controlled drug release	**Liquid filled** Soft capsules containing liquid or semi-solid formulations enclosed in a soft gelatin shell	✓ Generally share base processes, with additional equipment required for complex formulations (e.g., multilayer tablets, pellet or liquid-filled capsules)

Key observations

- **Tablets and capsules differ in their upstream manufacturing processes** (e.g., compression vs encapsulation), but **share common downstream operations** such as packaging, labeling, and quality control
- **Across release mechanisms and formulation types, core processes can be leveraged,** but additional equipment (e.g., coating, multilayer compression, specialized filling) is required for more complex products

1. Multi-layer tablets or liquid-filled capsules

Source: Corden Pharma, China Canaan, Eubioco

Oral liquids dosage forms vary across three independent design dimensions

Dominant global configuration

	Oral liquids dosage forms			Production flexibility
Product types	**Ready to use oral liquids** Liquid preparations administered directly, typically as **solutions, syrups, suspensions, emulsions, or drops**	**Dry powders / granules for reconstitution** Oral liquids supplied as a dry product and **reconstituted before dispensing/use**, commonly used where stability in aqueous form is limited		Require different upstream processes (liquid compounding vs powder handling), but share downstream filling, packaging, and QC
Release mechanism	**Immediate release (IR)** Drug is released rapidly after administration without intentional modification of the release profile	**Modified prolonged release (MR / ER)** Release is intentionally slowed or extended relative to an immediate-release product	**Delayed release** Release is delayed for a period after administration, typically to protect an acid-labile drug or avoid gastric release	Immediate release products use the same base process; modified/delayed release require specialized formulations but are relatively uncommon
Formulation types	**Solution / syrup / elixir** API fully dissolved in the vehicle. Simplest manufacturing and most straightforward content-uniformity control	**Suspension** Insoluble API dispersed in a liquid vehicle; requires tighter manufacturing control	**Emulsion** Drug incorporated in an oil-in-water or water-in-oil dispersed system; needs emulsification and droplet-stability control	Solutions, suspensions, emulsions, and drops can run on the same liquid manufacturing platform, with additional mixing, homogenization, and stability controls for more complex systems
	Oral drops/ concentrates Higher-concentration liquid formats dispensed in small volumes. Require tighter dose-delivery/device control	**Powder for oral suspension / reconstitution** Dry blend filled into bottle/sachet for reconstitution, it avoids some aqueous-stability challenges		

Key observations

Oral liquid dosage forms share common downstream activities such as filling, capping, labeling, and QC, but **differ in upstream formulation and compounding complexity**

Immediate-release formats dominate, while modified and delayed release oral liquids are feasible but comparatively niche

Source: US FDA, CDN WHO, European Medicines Agency

Injectable dosage forms vary across three independent design dimensions

Dominant global configuration

	Injectables dosage forms			Production flexibility
Product types	**Injectables** Sterile injectable **solutions, suspensions, or emulsions** supplied for direct administration, typically in vials, ampoules, bags, or prefilled syringes	**Powders / lyophilized products for reconstitution** Sterile powders reconstituted before administration, often used when solution stability is limited		Share sterile manufacturing principles but require different equipment (e.g., freeze-drying), limiting interchangeability
Release mechanism	**Immediate release (IR)** Drug is released rapidly after administration. Dominant configuration for conventional injectables	**Prolonged / depot release** Modified-release injectables designed to release drug over an extended period	**Biphasic / multiphasic release** Products combining an initial immediate-release fraction with a later extended-release phase	Immediate-release and depot/long-acting injectables require fundamentally different formulation technologies and processes
Formulation types	**Sterile solution** API fully dissolved; generally, the simplest injectable formulation type control	**Sterile suspension / emulsion** Dispersed systems requiring added control of particle or droplet characteristics	**Lyophilized powder for reconstitution** Sterile product freeze-dried to improve stability, then reconstituted before use	Core sterile processes are shared (aseptic/terminal sterilization), but suspensions, emulsions, lyophilized products, and different container formats (vials vs prefilled syringes) require additional equipment
	Vial / ampoule presentation Standard multi- or single-dose primary packaging formats widely used for injectable products	**Prefilled syringe / cartridge /** More user-ready delivery systems that can improve convenience		

Key observations

All injectables share the same high-level sterile manufacturing and quality requirements, but formulation complexity varies significantly, solutions are the simplest; suspensions/emulsions are more complex

Container-closure format matters operationally, vials/ampoules, bags, and prefilled syringes can all serve injectable products, but they imply different filling, component-preparation, and packaging requirements

Source: US FDA, CDN WHO, European Medicines Agency

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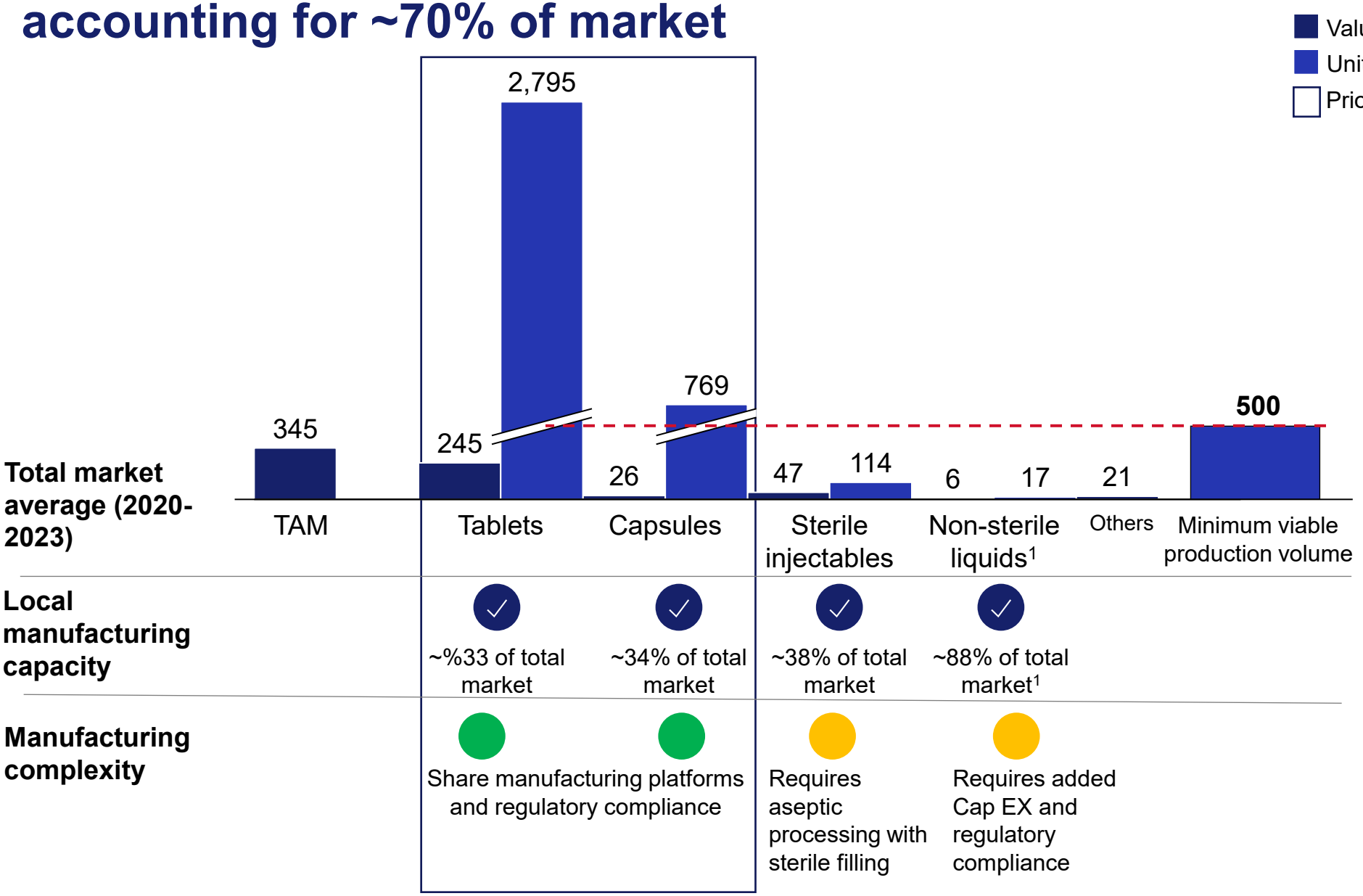
2. **High-level market assessment**
3. Manufacturing process
3. Regulatory and IP pathway
4. Supply chain feasibility
5. Risks and mitigants

The total market for small molecule FDF is ~345 Mn USD with tablets accounting for ~70% of market



Key takeaways

Tablets and capsules make up for **~80% of the small molecule market in Ethiopia**

Given shared manufacturing platforms and broad molecule applicability, **a combined production facility for tablets and capsules could be attainable in Horizon 1** (next 18-24 months)

A liquids line would require additional equipment and GMP requirements while addressing a significantly lower market

1. The total market for oral liquids is likely higher than official figures suggest, driven by strong private-market sales.

Source: EPSS procurement data (2020-2023), ECC import data (2021-2024), Ministry of Health Local Pharmaceutical Manufacturing Assessment (2025)

The small molecule portfolio was prioritized based on platform synergies, market attractiveness, and local production gap

	Step 1 **Prioritization of small molecules for local production**		Step 2 **Mapping of prioritized product over 2 horizons**
Description	**Prioritization of small molecules based on 3 criteria**		**Regulatory pathway and market access define sequencing**
	1 **Platform alignment and manufacturing synergies**	FDF that can **leverage shared production platforms**, enabling efficient scale-up and capability reuse in 3 production lines: • General tablet and capsule line • General oral liquids line • General injectables line	**Horizon 1: National market (near-term launch)** FDF with • National regulatory approval (EFDA) • Standard GMP / non-sterile or basic sterile requirements • Immediate access to domestic and private markets
	2 **Sufficient market size to support scale**	FDF with **minimum market volume of ~6 Mn units annually**, ensuring viability at scale	**Horizon 2**: **Donor markets (scale-up phase)** FDF with • Higher regulatory and quality standards (i.e., WHO PQ) • Access to donor-funded procurement
	3 **Local production gap/import substitution potential**	FDF that have a minimum addressable market of **>10 Mn** for tablets and capsules and **>500K** for liquids [1]	
Outcomes	**42 FDF prioritized for local production**, including • Tablets: 20 • Capsules: 5 • Oral liquids: 8 • Injectables: 9		**Horizon 1:** 38 FDF (national market entry) **Horizon 2:** 4 FDF (WHO PQ/ donor markets)

1. Hydralazine Injection was considered due to its high market value

Production ramp-up could follow a 2-step approach enabling quick commercialization for 29 drugs, with WHO-PQ products added over time

xx Volume (units) xx Value ($)

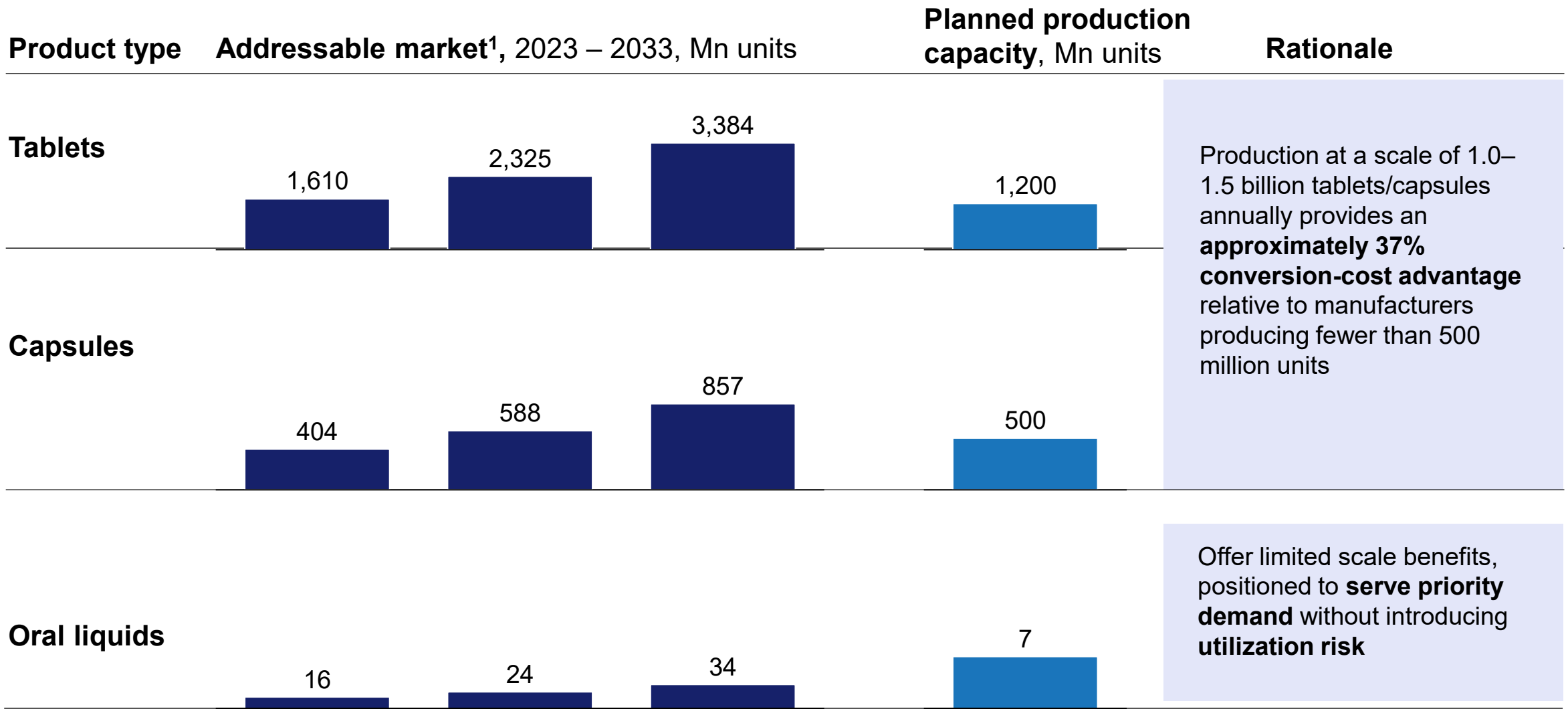
Horizon	0-24 months: Domestic commercialization	>18 months: WHO PQ expansion
FDF in focus	**15 FDF prioritized** for local production, incl., • **13 therapeutic classes** (Pain Management, Gastroenterological, Anti-infectives, Respiratory Infections, Supplements, Maternal Health) • **3 formulations** (16 tablets, 5 capsules, and 8 oral liquids)	**4 FDF prioritized** for local production expansion, incl., • **2 therapeutic classes** (HIV/AIDS, Respiratory Infections) • **1 formulation** (tablets)
Total addressable market (TAM)[1]	1,949 Mn / 65 Mn	311 Mn / 109 Mn
Manufacturing requirements	• Non-sterile solid oral general production line, non-sterile oral liquid production line and sterile liquid production line • National regulatory approval (EFDA) • Standard GMP compliance	• Full GMP + WHO PQ compliance • Compliance with donor procurement standards (~75% of total TAM)

Key takeaways

- **A phased production strategy enables early revenue generation** while building toward donor-facing products
- **Profitability in Horizon 1 depends on scale** and tariff positioning as domestic generics face low margins
- **Securing WHO PQ would access a higher margin market** but increases execution risk and capital intensity

1. Incremental total addressable market, i.e., total market for prioritized small molecule across all dosage forms therapeutics excluding existing local manufacturing capacity

A combined local manufacturing capacity of ~1,700 Mn units would be sufficient to address ~83% of the total addressable market

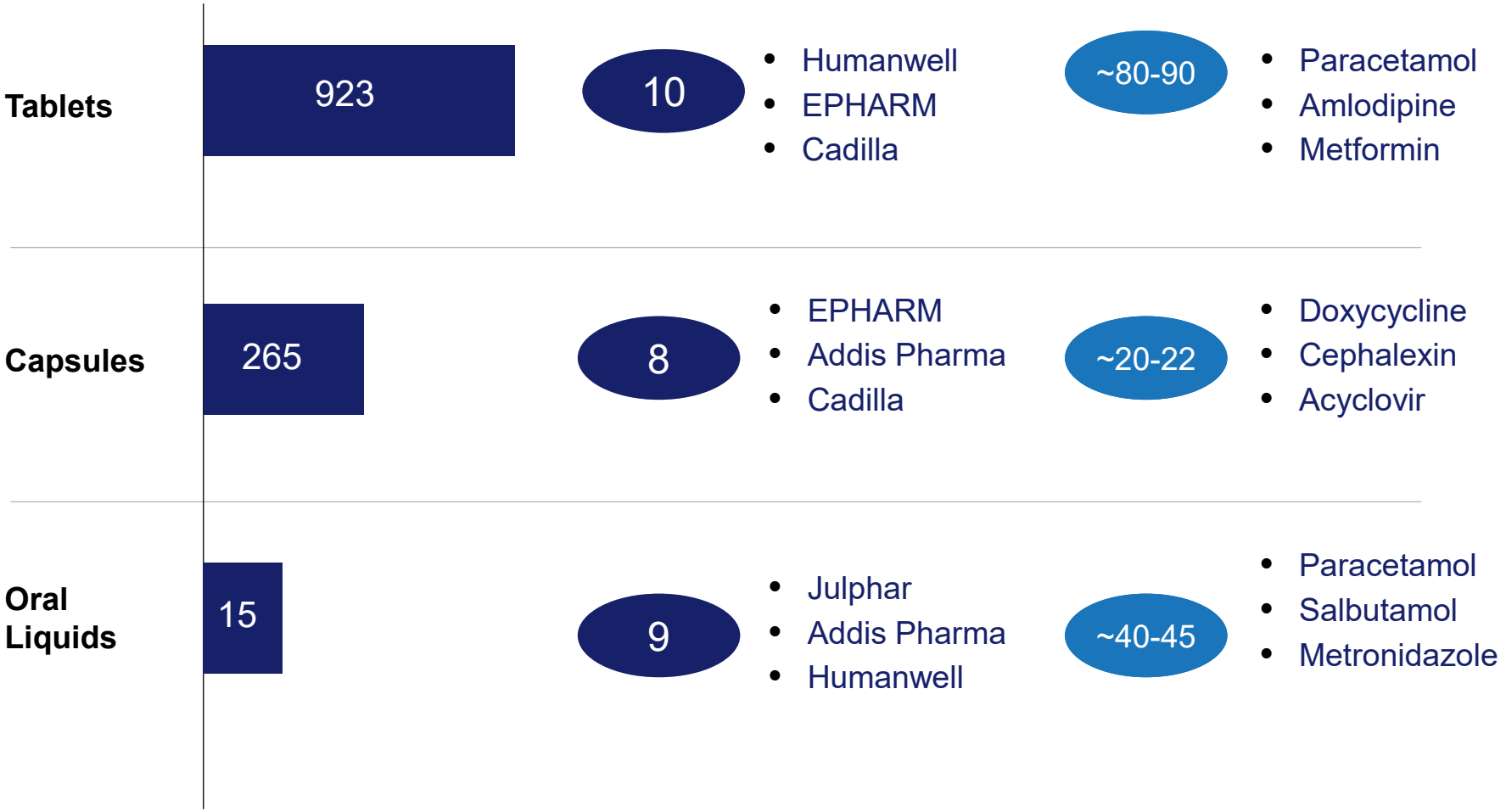


Source: EPSS procurement data (2020-2023), ECC import data (2021-2024), Ministry of Health Local Pharmaceutical Manufacturing Assessment (2025), McKinsey benchmarking tool (POBOS)

Local manufacturing capacity is highest for tablets, with 10 manufacturers producing a combined portfolio of 80-90 drugs

x # of local manufacturers

x # of products produced locally



Key takeaways

- Due to the relative ease of manufacturing and the broader portfolio of tablet products, **most local manufacturers produce generic tablets**

Source: AHRI local manufacturer profile, MoH local pharmaceutical market share report

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3. **Manufacturing process**
3. Regulatory and IP pathway
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Manufacturing complexity increases significantly from non-WHO PQ solids to sterile injectables, driven by regulatory and sterility requirements

Complexity High Moderate Low

	Oral solid dosage forms		Liquid dosage forms	
Manufacturing process complexity	**Tablets (non-WHO PQ) and capsules**	**Tablets (WHO PQ)**	**Oral liquids**	**Sterile injectables[1]**
Sterile production	✗	✗	✗	✓
Process sensitivity	**Low** – robust, standardized processes	**Moderate - high** – stricter control and reproducibility	**Moderate** – microbial and formulation sensitivity	**High** – aseptic processing
Environmental control	**Low**	**Moderate** (controlled environment, not sterile)	**Moderate** (microbial control)	**High**
Equipment and technology requirements	**Low** – simple facility requirements, low automation	**Moderate** – additional requirements for equipment qualification and monitoring	**Moderate** – additional cleaning and sanitation systems, moderate automation	**High** – sterile filling lines, advanced monitoring systems, high automation
Quality control and validation	**Low** – basic QC and standard validation	**High**– expanded QC testing, comprehensive process validation	**Moderate** – additional microbial and cleaning validation	**Moderate** – extensive validation and regulatory requirements
	Lowest-complexity entry point with standardized processes and minimal regulatory burden	**Same core process but significantly higher regulatory and validation requirements,** increasing complexity without major process change	**Additional process and microbial complexity**, requiring stronger quality systems and more advanced equipment	**Highest complexity across all dimensions,** requiring sterile infrastructure, advanced capabilities, and stringent regulatory compliance

Source: POBOS, McKinsey pharmaceuticals practice, Expert interviews

General product tablets and capsules manufacturing can be shown in 3 macro steps: Pre-production, Upstream and Downstream Production

Focus for Ethiopia local manufacturing detailed next

Stage	Pre-production	Upstream Production	Downstream Production				
Process	Sourcing	Intermediates & API production	Formulation[1]		Primary packaging		Secondary packaging
Description	• Raw materials • Packaging materials • Services • Infrastructure • Engineering • Operational supplies	• Reacting • Isolation and Purification • Packaging	• Tablets • Capsules		• Blisters • Bottles • Sachets		• Folding box • Carton

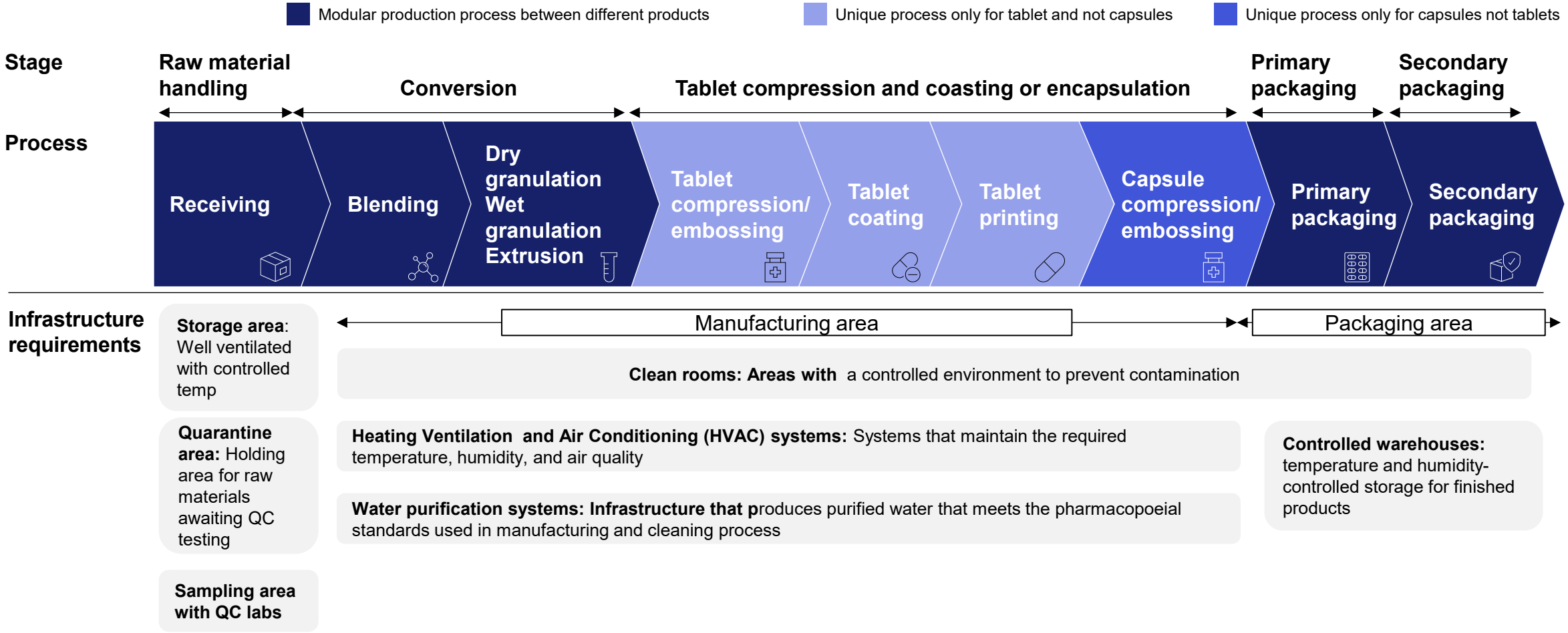
Local manufacturing of APIs and intermediates is very limited

Ethiopian manufacturers perform all downstream production processes

1. List not exhaustive

Source: POBOS, McKinsey pharmaceuticals practice, Expert interviews

There are three distinct zones across the tablet/capsule manufacturing value chain with various required infrastructural components



Key areas for unlocks in Ethiopia

Although Ethiopia has the lowest electricity prices in Africa (~0.009 USD/kwh[1]), **reliable power supply is a challenge**. Power interruptions are estimated to lead to significant batch losses and impact the quality of end products. Additionally, different grades of water purity are required (e.g., potable, bulk purified water, bulk highly purified water), yet **water supply and treatment facilities are unreliable**.

1. Based on GlobalPetrolPrices.com

Source: Press search

Tablet manufacturing involves multiple equipment across the value chain, conversion equipment expected to incur the highest capital spend

XX% %share of total equipment spend across the value chain

Stage	Raw material handling			Conversion			Comp-ression	Coating		Primary packaging	Secondary packaging
Process	Raw material receiving	Raw material testing	Raw material storage	Weighing	Blending	Dry granulation / Wet granulation / Extrusion	Tablet compre-ssion / emboss-ing	Tablet coating	Tablet print-ing	Primary packaging	Secondary packaging
Equipment type	Drums, storage bags and containers Vacuums	Sample-thiefs	Intermedi-ate bulk containers Walk-in refrigerators Walk-in freezers	Dispensing systems Scales / computer controlled weighing systems	V blenders In-bin blenders (for IBCs) Feeders	Granulators (incl. fluidized bed granulators) Conveyors Fluidized bed dryers Wet mills Dry mills Dryers Roller compactors Hot melt extruders	Feeders Tablet presses Tablet embossing machines	Feeders Tablet coating machines Tablet polishing machines	Tablet printing machines	Blister packers Cappers Counters Induction sealers Labelling and serialization equipment	Cartoning equipment Case packers Palletizing equipment
	10-20					30-40	10-20		5-15	15-25	5-10
Tier-1 suppliers	BÖHLE			Glatt		IMA	GEA			BOSCH	
Tier-2 suppliers	PRECISION, AZO, QUADRO, Dec Group, HILLENBRAND, SERVOLIFT, FREWITT			ROMACO, GERTEIS, ThermoFisher SCIENTIFIC, NICOMAC, Diosna, FREUND, MATCON[1], Leistritz, HOSOKAWA ALPINE, POWREX, FETTE COMPACTING, NATOLI, KORSCH, Thomas, PROMACH, Uhlmann, marchesini, CAM							

1. Matcon is owned by IDEX

Source: POBOS, McKinsey pharmaceuticals practice, Expert interviews

Similarly, conversion and encapsulation equipment are expected to account for the highest capital expenditure in capsule manufacturing

XX% %share of total equipment spend across the value chain

Stage	Raw material handling			Conversion			Encapsulation	Primary packaging	Secondary packaging
Process	Raw material receiving	Raw material testing	Raw material storage	Weighing	Blending	Dry granulation / Wet granulation / Extrusion	Encapsulation	Primary packaging	Secondary packaging
Equipment type	Drums, storage bags and containers Vacuums	Sample-thiefs	Inter-mediate bulk containers Walk-in refrigerators Walk-in freezers	Dispensing systems Scales/ computer controlled weighing systems	V blenders In-bin blenders (for IBCs)	Granulators (incl. fluidized bed granulators) Conveyors Fluidized bed dryers Wet mills Dry mills Dryers Roller compactors Hot melt extruders Spheronizers	Feeders Capsule filling machines Capsule polishing machines Capsule sorting machines Capsule printing machines	Blister packers Cappers Counters Induction sealers Labelling and serialization equipment	Cartoning equipment Case packers Palletizing equipment
	10-20			30-40			20-30	15-25	5-10
Tier-1 suppliers	BOHLE			Glatt		IMA	GEA	BOSCH	
Tier-2 suppliers	PRECISION, SERVOLIFT, AZO, FREWITT, MATCON [1]			FREUND, Diosna		POWREX	Harro Höfliger, MG2, Qualicaps [2]	Uhlmann, marchesini, CAM	Uhlmann, marchesini, CAM

1. Matcon is owned by IDEX
2. Qualicaps is owned by Mitsubishi

Source: POBOS, McKinsey pharmaceuticals practice, Expert interviews

Oral liquid manufacturing requires less equipment and can be done at varying levels of automation

XX% %share of total equipment spend across the value chain[1]

Stage	Bulk liquid manufacturing			Bulk liquid manufacturing			Filling and primary packaging		Secondary packaging
Process	**Raw material receiving**	**Testing**	**Storage and dispensing**	**Vehicle prep**	**Ingredient addition**	**Homogenization**	**Bottle filling**	**Caping / sealing /labeling**	**Cartooning / case packing**
Equipment type	Drums, totes, bags, containers Material transfer bins	Weighing equipment, samplers QC lab instruments (Moisture analyzer, pH meters where relevant)	Temp controlled storage rooms and dispensing booth	Purified water system Preparation tanks Agitated vessels Transfer pumps Flow meters	Stainless steel mixing High sheer mixers Powder induction systems	Homogenizers Inline filters Transfer pumps Vacuum deaeration tank Bulk holding tanks Recirculation loops Sieves / strainers	Liquid filling machines infeed systems Conveyor systems Filling nozzles	Capping machines Induction sealers Labeling machines Vision inspection systems	Cartoners Case packers Tamper / seal inspection units
	3-5%	2-4%	4-6%	8-12%	12-18%	10-15%	18-25%	12-18%	8-12%
Tier-1 suppliers	GEA, SYNTEGON, ROMACO beyond technology, MARCHESINI GROUP, IMA SPA Sustain Ability								
Tier-2 suppliers	BAUSCH+STRÖBEL, OPTIMA, Uhlmann UHLMANN GROUP								

1. Based on price benchmarks

Source: POBOS, McKinsey pharmaceuticals practice, Expert interviews

There are a few critical technical challenges that could increase cost of operations for local manufacturers

Low Medium High

Challenge	Description	Level of impact on cost
Delayed purchase of spare parts and replacements to obsolete equipment	Local players **still face challenges accessing forex** for the importation of required equipment due to FX shortage and the **lengthy and cumbersome procedure for manufacturers to access it**[1]	
Unreliable utility supply	While local electricity costs are lower vs. India or China, this is offset by **relatively frequent power outages**. Similarly, w**ater supply and treatment facilities for required purified water is unreliable**	
Shortage of technical expertise	Existing local manufacturers have stated that there is a **shortage of skilled manpower** caused by **low levels of qualification, work experience and high staff turnover**. This has led to increased their spend in scarce forex to bring in expatriates	
Shortage of well-equipped waste facilities	Ethiopia faces significant **limitations in waste management infrastructure** for industrial and hazardous waste. For example, the Adama waste management facility remains partially operational, causing prolonged delays for local manufacturers seeking access. As a result, some are compelled to rent storage space for waste products	

1. Although the Ethiopian Birr was floated in mid-2024, foreign exchange shortages remain a challenge in the short term due to Ethiopia's status as a net importer. Additionally, the currency floatation resulted in a devaluation of the Birr, increasing import costs, potentially driving inflation, and further straining foreign exchange availability

Source: UNCTAD: Improving the local landscape for local production of essential antibiotics in Ethiopia, press search

Agenda

1. Product overview
2. High-level market assessment
3. Manufacturing process
3. **Regulatory and IP pathway**
4. Supply chain feasibility
5. Risks and mitigants

Regulatory requirements increase significantly from national approval to WHO PQ, with sterile injectables requiring the highest level of compliance

Complexity High Moderate Low

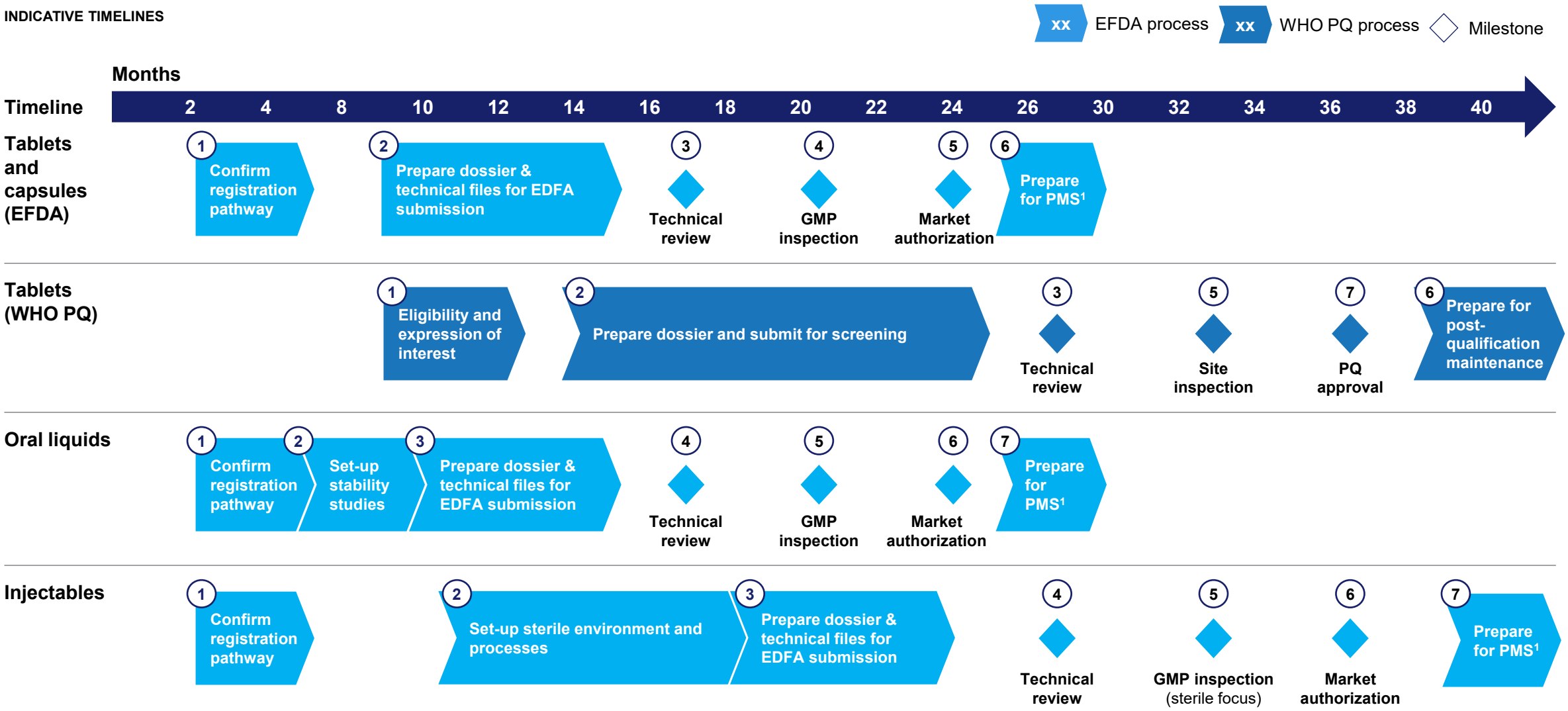
Manufacturing process complexity	Oral solid dosage forms		Liquid dosage forms	
	Tablets (non-WHO PQ) and capsules	Tablets (WHO PQ)	Oral liquids	Sterile injectables[1]
Approval pathway	**National approval (EFDA)** – enabling access to domestic and private markets			
		WHO PQ – required for donor funded procurement		
GMP requirements	**Basic GMP compliance** – standard facility and quality systems sufficient	**Enhanced GMP (WHO compliant)** – requires stricter process controls, documentation, and audit readiness	**GMP with increased microbial control** – requires tighter environmental control and cleaning procedures	**Full sterile GMP (highest level)** – requires dedicated sterile infrastructure (cleanrooms, HVAC)
Documentation and dossier	**Basic regulatory dossier** – limited data requirements, faster approval timelines	**Full WHO PQ dossier** (CTD format incl., stability data) – requires extensive documentation, bioequivalence data, standardized format	**Expanded dossier** – additional formulation-specific data and stability consideration	**Extensive dossier** – requires full validation of sterile processes and detailed risk control documentation
Documentation and dossier	🟢 **Lowest regulatory burden** with fast national approval and limited documentation requirements	🔴 **Significant step-up in regulatory requirements** driven by WHO PQ, with extensive documentation and audit processes	🟡 **Moderate regulatory complexity** due to formulation stability and increased microbial control requirements	🔴 **Highest regulatory burden**, requiring sterile GMP, extensive validation, and stringent ongoing oversight

1. Not included in the financial model

Source: WHO, EFDA, expert interviews

Non-sterile FDF can be launched within ~24 months via EFDA, while injectables require additional sterile setup

INDICATIVE TIMELINES



1. Post-market surveillance
2. Outlining process steps relevant for national registration and WHO PQ approval – full production ramp-up roadmap outlined in last chapter

Source: Guideline for Registration of Medicines (latest version); GMP inspection and licensing guidelines; WHO Prequalification of Medicines Programme

Timely EFDA approval requires parallel dossier preparation and inspection-ready manufacturing

◆ Technical review, GMP inspection, market authorization

	1-2 months 1 Confirm registration pathway	3-5 months 2 Prepare dossier & technical files for EDFA submission	1-2 months 6 Prepare for post-market surveillance
Critical actions required for WHO PQ readiness	• Confirm device classification (generic medicine, dosage form) • Identify applicable GMP standards • Determine whether bioequivalence (BE) is required • Conduct optional pre-submission meeting with EFDA • Align on labeling language requirements	• Compile CTD dossier (Module 1-5 as applicable) • Finalize product formulation and specifications • Include bioequivalence data or waiver justification • Provide dissolution and (formulation) stability data • Document manufacturing process and controls • Compile QMS/GMP evidence • Prepare labeling & patient information leaflet in EFDA format	• Establish complaint handling system • Establish pharmacovigilance/adverse event reporting process • Define recall procedure • Train staff on reporting timelines • Establish post-market data review procedure
Final documents required	• Applicable standards list • Regulatory strategy memo • Proof of legal manufacturer registration	• Administrative dossier (application form, fees, legal docs) • CTD technical dossier • Labeling and IFU • Stability data • Bioequivalence data (if required)	• PMS plan • Pharmacovigilance SOP • Complaint handling SOP • Record-keeping procedure

Source: Ethiopia FDA, Guideline for Registration of Medicines (latest version); GMP inspection and licensing guidelines

Key observations

EFDA readiness is driven by GMP compliance and manufacturing maturity, including validated processes and QMS implementation

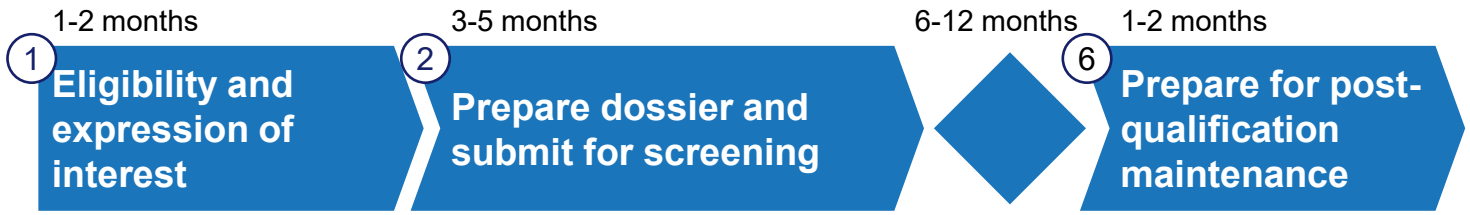
Dossier preparation (CTD) must run in parallel with facility readiness to meet launch timelines

Oral liquids require additional formulation stability and microbial control considerations vs solid dosage forms

GMP inspection is the primary regulatory gate before market authorization

Early alignment with EFDA (e.g., a pre-submission engagement) reduces timeline and inspection risk

WHO PQ approval is gated by validated manufacturing and site inspection readiness, typically extending beyond EFDA authorization



Critical actions required for WHO PQ readiness	• Align on applicable WHO PQ requirements for finished pharmaceutical products (FPPs) • Confirm product eligibility (e.g., essential medicines, donor relevance) • Ensure EFDA approval or submission readiness	• Compile full CTD dossier (Modules 1-5 as applicable) • Include bioequivalence data • Provide stability data • Document manufacturing process and controls • Demonstrate GMP-compliant QMS implementation • Align labeling and IFU to WHO format • Ensure EFDA status documentation is included	**Technical review, site inspection, PQ approval**	• Maintain pharmacovigilance and vigilance reporting • Notify WHO of significant changes • Undergo periodic re-inspection and compliance monitoring
Final documents required	• Expression of Interest (EOI) submission • Legal manufacturer status documentation • Preliminary product information	• WHO PQ CTD dossier • Bioequivalence report • Stability data package • Risk management report • QMS documentation summary • EFDA regulatory status evidence		• PQ maintenance plan • Change control records • Annual performance reports

Source: WHO PQ Medicines Program

Key observations

WHO PQ timelines are primarily driven by technical review and site inspection scheduling, factors that are largely outside the control of the manufacturer

Bioequivalence, stability data, and GMP-compliant QMS are the primary gating requirements

WHO PQ should be initiated during facility build-out but will typically conclude **6-12 months after EFDA authorization**

Dossier preparation and validation **must run in parallel with facility readiness**

EFDA approval for injectables requires early sterile facility readiness and parallel dossier preparation

◆ Technical review, GMP inspection, market authorization

	1 — 1-2 months **Confirm registration pathway**	2 — 3-6 months **Design and set-up sterile environment and process**	2 — 3-5 months **Prepare dossier & technical files for EDFA submission**	6 — 1-2 months **Prepare for post-market surveillance**
Critical actions required for WHO PQ readiness	• Confirm product classification • Identify sterile GMP requirements • Define sterilization approach (aseptic vs terminal sterilization) • Conduct optional pre-submission meeting with EFDA • Align on dossier requirements	• Design cleanroom layout (ISO 5–8 zones) • Set up HVAC systems and environmental controls • Procure and install sterile filling and filtration equipment • Establish aseptic and material flows • Develop environmental monitoring program • Initiate process validation and media fill planning	• Compile CTD dossier (Module 1-5 as applicable) • Include sterility assurance and validation protocols • Provide stability data and specifications • Document manufacturing process and controls • Compile QMS/GMP evidence • Prepare labeling & patient information leaflet in EFDA format	• Establish complaint handling system • Establish pharmacovigilance/adverse event reporting process • Define recall procedure • Train staff on reporting timelines • Establish post-market data review procedure
Final documents required	• Applicable GMP standards • Regulatory strategy memo • Product classification documentation	• Facility design documentation • Environmental monitoring plan • Process validation protocols	• CTD technical dossier • Sterility validation documentation • Labeling and IFU • Stability data • QMS documentation summary	• PMS plan • Pharmacovigilance SOP • Complaint handling SOP • Record-keeping procedure • Batch traceability documentation

Source: Ethiopia FDA, Guideline for Registration of Medicines (latest version); GMP inspection and licensing guidelines

Key observations

- **EFDA readiness is driven by sterile manufacturing capability**, including cleanroom infrastructure, validated processes, and QMS implementation
- **Sterile facility setup must run in parallel with facility set-up**, and is a prerequisite for submission and inspection
- **GMP inspection (sterile focus) is the primary regulatory gate** before market authorization
- **Injectables introduce significant additional complexity vs non-sterile products**, driven by sterility and validation requirements

Agenda

1. Product overview
2. High-level market assessment
3. Manufacturing process
3. Regulatory and IP pathway
4. Supply chain feasibility
5. Risks and mitigants

Supply of APIs, excipients, and packaging is broadly available; profitability is driven by input costs, FX exposure, and sourcing efficiency

	API	Excipients	Packaging
Description	Active pharmaceutical ingredients (APIs) are the **core therapeutic components** across tablets, liquids, and injectables	Excipients (fillers, binders, solvents, stabilizers) enable **formulation performance and stability**	Packaging includes **primary** (blisters, bottles, vials) **and secondary components** (cartons, leaflets)
Availability	← Supply is widely available globally (with hubs in India and China) – no structural supply chain risks exist →		
Sourcing strategy	**Import from qualified global suppliers and secure competitive pricing** through volume aggregation and long-term agreements	**Source from global suppliers with selective localization** of high-volume, simple excipients over time	**Import primary packaging at scale** Localize secondary packaging subject to quality compliance

Source: Expert interviews, EPPS data, UN Comm Trade data

Key takeaways

- **No structural supply constraints exist across APIs, excipients, and packaging**, supported by a broad global supplier base
- **Supply chain risk is primarily cost-driven rather than availability-driven**, including:
  - Price volatility
  - FX exposure
  - Transport and logistics costs
- **Profitability of local manufacturing is highly sensitive to input cost management**, particularly for APIs and packaging
- **Competitive sourcing, bulk procurement, and supplier negotiation** are critical to achieving viable unit economics
- **Selective localization** (e.g., secondary packaging, simple excipients) can improve resilience and cost competitiveness over time

Broad API availability shifts supply chain risk to FX availability, API price volatility and long delivery lead times

Horizon 1 | Horizon 2 | Broad global supplier base | Concentrated supplier base

Required APIs for priority small molecule drugs

Ciprofloxacin	Diclofenac Sodium	
Cloxacillin Sodium	Omeprazole	
Erythromycin	Ibuprofen	
Gentamicin	Ivermectin	
Metronidazole	Albendazole	
Paracetamol	Doxycycline Hyclate/Monohydrate	
Pantoprazole	Sulfamethoxazole + Trimethoprim	
Phenobarbitone	Ferrous Sulphate + Folic Acid	
Praziquantel	Nifedipine	
Vitamin K1	Sulfamethoxazole + Trimethoprim	
Atropine	Mebendazole	
Azithromycin		
Cimetidine	Hydralazine	
TLD (3TC + DTG + TDF)	Lamivudine + Dolutegravir + Tenofovir DF	

Global availability

Off-patent APIs with multiple qualified suppliers across several regions (US, EU, India and China)

Limited supplier base concentrated in China

More concentrated supplier base for Dolutegravir due to historical licensing structure

Supply chain implications

Most APIs are off-patent with multiple qualified global suppliers

Upstream supply concentration is generally low, with limited exceptions (e.g., Praziquantel, Dolutegravir)

Primary supply risks therefore relate to

- **FX availability** due to USD-based imports
- **API price volatility** due to raw materials and energy costs (e.g., 20-40% price swings during Covid-19)
- **Minimum order quantities** leading to high inventory holdings an expiry risks
- **Long lead times** based on production slot bookings, shipping and customs clearance

Source: Expert interviews, EPPS data, UN Comm Trade data

Excipients are widely available with no structural supply constraints; risks are driven by price volatility, FX exposure, and logistics

Deep dive to follow · High · Moderate · Low

Dosage forms	Typical excipient categories	Supply availability	Top global suppliers	Key risks	Recommended sourcing strategy
Tablets and Capsules 	• Fillers • Binders • Disintegrants • Lubricants • Coatings	Broad, competitive global market with multiple suppliers Standard excipients widely available	DFE pharma, ROQUETTE, BASF	Limited structural risk	**Import from global suppliers** (sourcing based on quality and cost) **Explore local production** for high-volume, simple excipients over time
Oral liquids 	• Sweeteners • Solvents • Suspending agents • Preservatives • Flavors • Buffers	Broad, competitive global market with multiple suppliers Slightly more specialized excipients, but still widely available	ROQUETTE, CRODA, DUPONT	Limited structural risk – but higher quality consistency and supplier qualification required	**Import from qualified suppliers** with consistent quality **Maintain limited buffer stock** for critical inputs
Injectables 	• Buffers • Tonicity agents • Solvents • Stabilizers • Sterile-grade excipients	More concentrated supplier base for sterile-grade excipients Availability generally sufficient, but fewer qualified suppliers	J.T.Baker, MERCK	Higher quality and compliance requirements (sterile grade) Supplier qualification and validation more complex	**Apply dual sourcing strategy** for critical sterile excipients **Establish strong supplier qualification** and QA processes **Maintain buffer stock** for critical inputs

Key takeaways

No structural supply constraints for excipients across dosage forms, supported by a broad and competitive global supplier base

Primary risks relate to price volatility, FX exposure, and logistics, rather than availability

Sterile injectables introduce higher supplier qualification and quality risks, requiring more robust sourcing strategies

Source: Expert interviews, EPPS data, UN Comm Trade data

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Starch-based excipients presents an opportunity for local production given access and availability of required raw materials

Prioritized for further assessment xx % of locally manufactured small molecules containing excipient

HIGH LEVEL ESTIMATES

		Demand and Relevance		Manufacturing viability		
Product[2]	**Purpose**	**Utility for local manufacturing**[1]	**Estimated demand,** volume in t[1]	**Demand multiple to reach EoS**	**Key raw material input**	**Local availability**
Microcrystalline Cellulose	Binder	65-75%	20 - 25	Requires further assessment	Pulp	✗
Starch	Binder	65-75%	35-40	x 10 – 30	Maize starch	✓
Magnesium Stearate	Lubricant	65-75%	5-10	Requires further assessment	Oleo-chemicals	✗
Sodium Starch Glycolate	Disintegrant	55-65%	10-15		Starch	✓
Lactose	Filler	75-85%	20-25		Whey	✗

Key takeaways

- **Starch-based excipients are the most feasible candidates** for local production, given Ethiopia's access to maize and existing agro-processing capabilities
- Minimum volumes required to reach EoS **significantly exceed current domestic pharmaceutical demand**, limiting viability as a standalone pharma-grade investment
- A **commercially viable model** would likely require
  - Integration with food-grade starch production (**Richland PLC**), with additional GMP-compliant finishing
  - Regional exports

1. Local manufacturer data from 2014-2016 EC, estimate excipient density
2. Products prioritized by usage in local manufacturing

Source: Expert interviews, EPPS data, UN Comm Trade data

Packaging represents a significant share of unit costs, but is readily available globally with limited structural supply risk

	OSD			Liquid			
Product types	**Tablets and capsules**			**Oral liquids**		**Injectables**	
Primary packaging	**Aluminum blisters**	**Plastic blisters**	**HDPE[2] Bottles**	**HDPE Bottles**	**Glass bottles**	**Glass ampoules**	**Glass vials**
Average procurement costs ($ per unit[1])	0.015	0.01	0.002	0.02	0.05	0.01	0.016

Availability and sourcing

- **Broad and competitive global supplier base**, particularly in China and India
- **Standard packaging formats** widely available across all dosage forms
- **No structural supply constraints** across primary packaging types

Implications

- **Import primary packaging from global suppliers** to ensure cost competitiveness
- **Leverage bulk procurement** to reduce unit costs
- **Establish supplier agreements** for price and volume stability

! **Secondary packaging (cartons, leaflets) can be sourced locally**, subject to

- Quality and compliance with pharma standards
- Where local quality is insufficient, imports remain required

ROMADI PACKAGING

Minaye PACKAGING PLC

1. Per unit of dosage form (e.g., 1 tablet or capsule, 1 syrup bottle
2. High-density polyethylene

Source: Indicative supplier quotes and listings, local procurement benchmark costs, expert interviews

Agenda

1. Product overview
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5. Risks and mitigants

Small molecule manufacturing is attractive but subject to key scale, product mix, and cost risks, requiring disciplined execution (1/3)

✓ Risks that would be mitigated through partnership build

Dimensions		Key risks	Mitigation levers
Market access and demand		**Fragmented demand across private and RDF markets**, reducing demand visibility vs donor-driven segments	**Build diversified channel strategy** across RDF, private distributors, and institutional buyers
		Limited pricing power in highly competitive generics market, with exposure to import parity pricing	**Focus on cost competitiveness** and prioritize higher-margin SKUs
	✓	**Dependence on product mix to achieve viable economics**, with many SKUs offering low margins	**Optimize portfolio toward high-volume** and higher-value products
Manufacturing and operations	✓	**Underutilization of capacity**, given need to aggregate volume across multiple SKUs to reach scale	**Phase ramp-up and prioritize anchor products** to secure early utilization
	✓	**Complexity of multi-product manufacturing** (multiple dosage forms, SKUs) increasing operational risk	**Standardize processes** and limit initial SKU complexity
	✓	**Workforce capability gaps in GMP and validation**, particularly for injectables and WHO PQ products	**Invest early in workforce training, SOPs, and quality systems** to ensure consistent performance at scale

Strategic partnerships (particularly for product design, technology transfer, and manufacturing capabilities) **can significantly de-risk execution** across multiple dimensions.

Small molecule manufacturing is attractive but subject to key scale, product mix, and cost risks, requiring disciplined execution (2/3)

✓ Risks that would be mitigated through partnership build

Dimensions		Key risks	Mitigation levers
Supply chain	✓	**Reliance on imported APIs and packaging**, exposing operations to FX and logistics risks	**Secure long-term supplier agreements** and hedge FX exposure
	✓	**Input cost volatility (APIs, excipients, packaging)** impacting margins in low-price market	**Maintain buffer inventory for critical components** to mitigate supply disruptions, ensure cost discipline and diversify sourcing
	✓	**Potential quality variability from suppliers**, affecting product quality and regulatory compliance	**Implement supplier qualification and dual sourcing strategies** to ensure consistent quality and reliability
Regulatory and compliance		**Delays in EFDA approval or WHO PQ**, delaying access to donor-funded markets and pushing out revenue ramp-up	**Initiate WHO PQ preparation during facility build-out** to enable parallel regulatory and manufacturing readiness
	✓	**Misalignment between facility readiness and regulatory timelines**, resulting in idle capacity or costly rework	**Align regulatory roadmap with production ramp-up milestones** to avoid delays and idle capacity
	✓	**Failure to meet donor and international quality standards**, limiting eligibility for key tenders and reducing competitiveness	**Implement GMP-compliant QMS early** and leverage external regulatory expertise to ensure compliance with donor standards
Financial attractiveness	✓	**High upfront CAPEX (~$48M)** with delayed revenue ramp-up	**Phase investments** and align capacity build with demand
		IRR highly sensitive to utilization, product mix, and pricing, with downside risk if scale not achieved	**Secure sufficient volume** and optimize SKU selection
	✓	**Margin erosion from input cost inflation** and competitive pricing pressure	**Stress-test downside scenarios** (pricing, utilization, FX) and incorporate buffers into financial planning

Strategic partnerships (particularly for product design, technology transfer, and manufacturing capabilities) **can significantly de-risk execution** across multiple dimensions.

Small molecule manufacturing is attractive but subject to key scale, product mix, and cost risks, requiring disciplined execution (3/3)

✓ Risks that would be mitigated through partnership build

Dimensions		Key risks	Mitigation levers
Partner model		**Selection of suboptimal partner model** leading to slower capability build or limited control over key decisions	**Evaluate partner models upfront** based on trade-offs between speed, control, and long-term capability ownership
		Dependence on partners for critical capabilities (technology, WHO PQ, commercialization), creating execution risk and potential misalignment on incentives	**Negotiate clear and beneficial partnership terms** (e.g., scope of technology transfer, access to PQ dossiers, commercial rights) to ensure alignment & reduce dependency risks
		Insufficient knowledge transfer limiting long-term capability ownership and scalability	**Ensure structured knowledge transfer and capability build provisions are embedded** in partnership agreements
Route-to-market and execution		**Misalignment between production ramp-up and tender timelines**, leading to missed procurement cycles and delayed revenue realization	**Align product roadmap with procurement cycles and tender timelines** to ensure timely market entry
	✓	**Suboptimal product sequencing** (e.g., delayed AD syringe launch) limiting access to donor-funded demand	**Sequence product launches** (e.g., RUP/domestic first, AD/donor second) to enable early revenue while building capabilities
	✓	**Weak coordination across engineering, regulatory, and commercial functions**, delaying execution and increasing complexity	**Establish a central program management office (PMO)** to drive coordinated, cross-functional execution *(outlined on p. 56)*

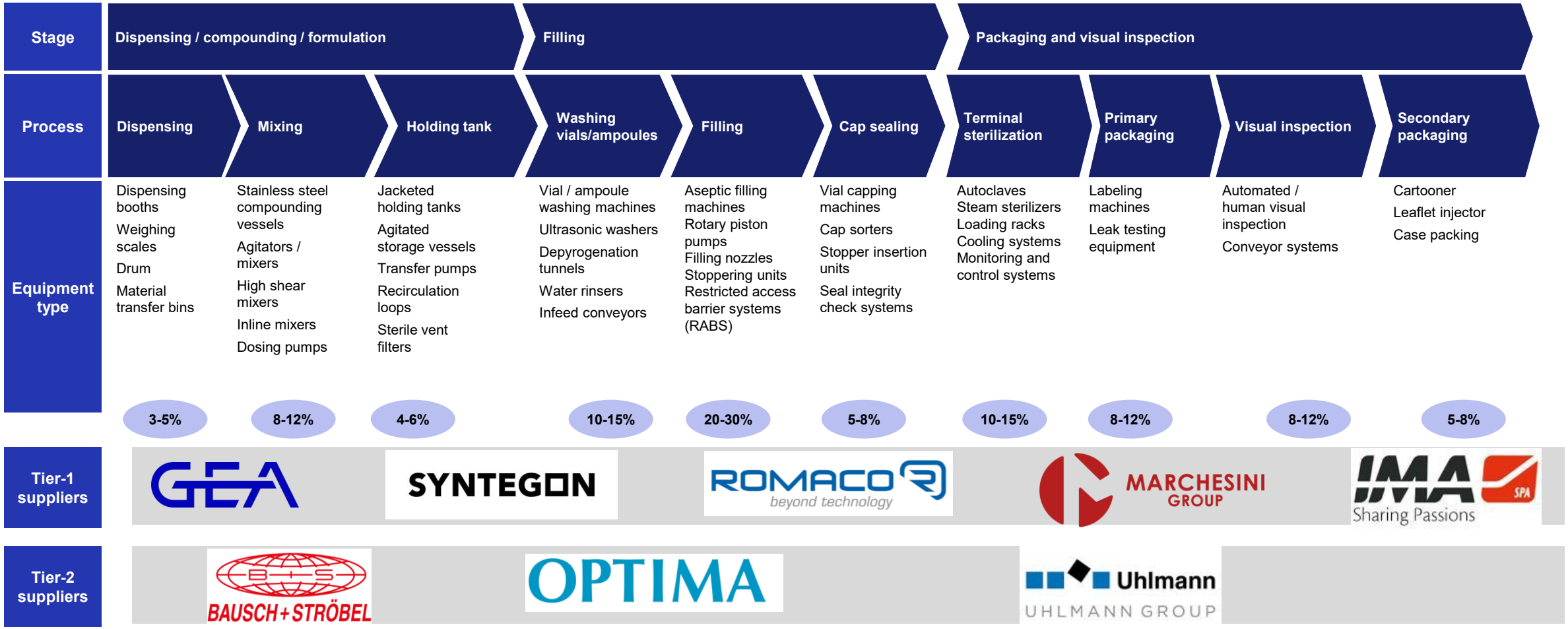
Strategic partnerships (particularly for product design, technology transfer, and manufacturing capabilities) **can significantly de-risk execution** across multiple dimensions.

The contents of this document are meant to be informative of a fact base, rather than provide any specific recommendation. They are based on initial research, interviews, and analysis and are subject to change given continued feedback

UKaid
from the British people

Injectable manufacturing requires aseptic manufacturing procedures as well as terminal sterilization

XX% % share of total equipment spend across the value chain[1]



SYNTEGON owned by Bosch

1. Based on price benchmarks

Source: POBOS, McKinsey pharmaceuticals practice, Expert interviews