Prioritizing AD and RUP Syringes for Local Manufacturing in Ethiopia

Product profile and go-to-market planning

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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 (1/3)

1 Product overview and disease rationale

- **AD and RUP syringes are essential components of safe injection delivery** across immunization and therapeutic care
- Together they **cover the majority of injection use cases**, with AD focused on fixed-dose vaccination and RUP on variable-dose clinical use
- **AD syringes are mandated for immunization programs under WHO/UNICEF guidance**, while RUP syringes are conditionally recommended for therapeutic use
- **RUP syringes provide incremental safety over disposable syringes** at a moderate cost premium (~1.2x), while leveraging largely the same production platform as AD syringes

2 High-level market assessment

- **The total addressable syringe market in Ethiopia is 160 Mn units in 2025**, split across immunization (27%) and therapeutics (73%)
  - **AD syringes account for 43 Mn units in 2025** and are expected to reach 51 Mn units by 2035 (CAGR 4% from 2022-2025)
  - **Disposable syringes account for 117 Mn units in 2025** and are expected to reach 151 Mn units in 2035 (CAGR 3% from 2022-2025)
- **AD syringes present an import substitution opportunity for the Ethiopian market**
  - Current AD syringe demand is **100% donor-funded**, centrally procured (primarily via UNICEF) and fully imported
  - Regional AD manufacturing capacity (660 Mn units p.a., e.g., in Rwanda, Kenya) **already addresses broader SSA demand**
  - An Ethiopian plant would therefore **focus primarily on serving domestic demand**, with export optionality contingent on WHO PQ and competitive pricing
- **RUP syringes present an import substitution and local production upgrade opportunity from disposable syringes**
  - Current therapeutic disposable syringe market is largely **driven by RDF and private procurement** (93% of total)
  - Basic disposable syringes are **already locally produced/assembled** (e.g., Fanus Meditech, Elite Pharmaceuticals) or imported
  - RUP syringes would **substitute existing disposables**, with total market expansion dependent on therapeutic use conversion
- **Successful AD and RUP market depends on 3 conditions**
  - **Capturing sufficient combined volume** across immunization and therapeutics to reach minimum efficient scale (~70 Mn units p.a.)
  - **Securing WHO PQ** and competitive pricing to access centralized procurement for AD syringes
  - **Ensuring RUP syringe unit cost parity to disposable syringes** to drive adoption, ensure therapeutic transition and scale

3 Technical and manufacturing overview

- **AD syringe production follows five modular stages** common to most disposable syringe platforms – RUP leverages the same core platform but requires modified molds and assembly tooling
- **AD and RUP syringe production can be integrated in one line**, provided the line is designed for flexibility and production occurs in batches, with changeover requiring mold swaps, assembly adjustments, recalibration and quality revalidation
- **Needle fabrication is a key make-or-buy decision** affecting capital intensity and operational complexity

Executive summary (2/3)

4 Regulatory and IP pathway

- **Two regulatory pathways apply to syringe production – national product registration with EFDA and WHO Prequalification (PQ) – which supports a phased market entry:** RUP syringes can launch after EFDA authorization (~4-5 months from submission), while AD syringes require WHO PQ approval (~6-12 months from submission) to access donor-funded procurement (e.g., UNICEF tenders)
  - **Timely EFDA approval requires parallel preparation of regulatory dossiers and manufacturing ramp-up**, as EFDA readiness depends on validated sterilization processes, documented QMS implementation (ISO 13485/GMP), and inspection-ready facilities
  - **WHO PQ approval typically follows EFDA authorization**, with timelines largely driven by WHO technical review and site inspection scheduling – both largely outside direct control of external parties
  - To avoid delays, **WHO PQ dossier preparation should begin during facility build-out**, ensuring validation data and regulatory documentation are ready once manufacturing processes are established

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5 Supply chain feasibility

- **Syringe manufacturing relies on imported input materials** as domestic production does not meet medical-grade requirements for key inputs
- **No structural supply constraints exist as all critical inputs are globally available from multiple suppliers**, reducing dependency on single suppliers and supporting reliable sourcing

Together, AD and RUP syringes cover the majority of safe injection use cases

Dimension	Category	Auto-disable (AD) syringes	Single-use reuse-prevention (RUP) syringes
Product description 	**Product description**	• Single-use syringe with an integrated locking or disabling mechanism that automatically prevents reuse after a full plunger stroke	• Single-use syringe with a reuse-prevention mechanism that allows variable-dose drawing but disables the device after injection to prevent reuse
	Syringe types	• Fixed-needle AD syringe • Detachable needle AD syringe • Auto-retractable syringe • Breakable-plunger AD syringe	• Fixed-needle RUP syringe • Detachable needle RUP syringe • Plunger-lock RUP syringe • Breakable-plunger RUP syringe
	Dose volume	• 0.05, 0.3, 0.5 mL	• 1, 2, 3, 5, 10 mL
	Regulatory and quality	• WHO PQS (E008 category) • ISO 7886-3 (Auto-disable syringes for immunization)	• WHO PQ (E013 category for therapeutic use) • ISO 7886-4 (Reuse-prevention syringes)
Use of products 	**Primary use**	• Vaccination programs and immunization campaigns	• Therapeutic injections requiring variable dosing (e.g., IM, IV, SC injections, blood collection)
	User setting	• National immunization programs • Primary healthcare centers • Community health campaigns	• Hospitals / Clinics • Laboratories • Emergency services

Source: ISO standards

Key takeaways

AD syringes are **optimized for fixed-dose immunization** and represent a defined segment of total syringe demand

RUP syringes extend **reuse-prevention into therapeutic settings**, where variable dosing is required

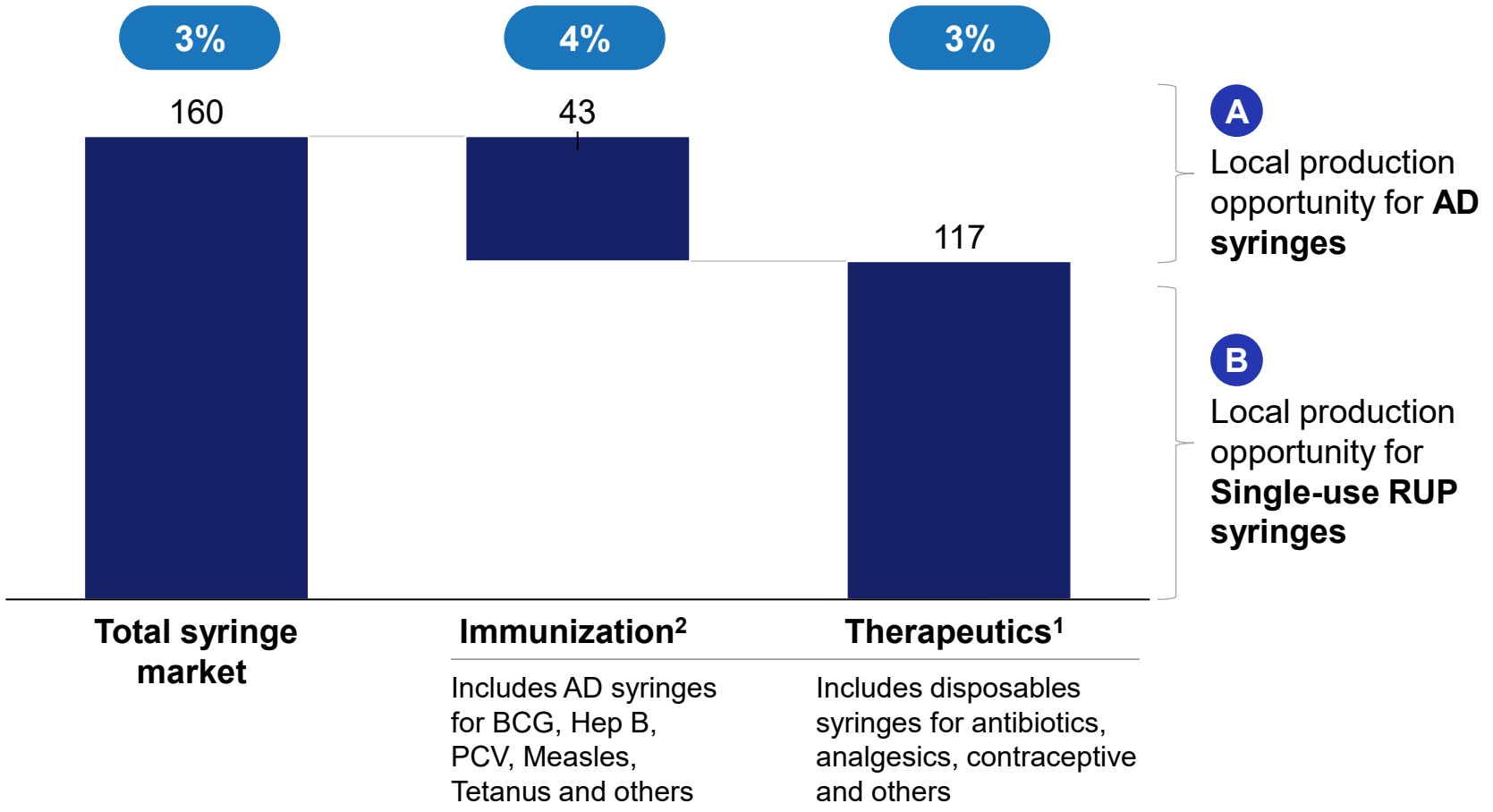
Together, AD and RUP syringes **cover the majority of safe injection use cases** across the healthcare system

While they share core design principles, AD and RUP **differ in dosing flexibility and product configuration**

AD syringes cover immunization needs; therapeutic use presents an additional opportunity via RUP syringes

XX CAGR (2022-2025)

Addressable syringe market by use case in Ethiopia, 2025, Mn units



1. Market estimation based on an average injection of 1,18 per person per year in SSA assuming a lower therapeutic setting in Ethiopia
2. Market estimation based on annual routine immunization rates, reactive outbreak reserves and campaign vaccination (annualized periodic supplementary immunization activities (SIAs)

Source: WHO immunization data, WHO smart syringe policy, press search

Key takeaways

AD syringes primarily serve fixed-dose immunization programs and represents 27% of the total syringe market today

A local AD production facility could serve as a foundation platform, with **potential to expand into single-use reuse-prevention (RUP) syringes** for therapeutic settings (~73% of total market)

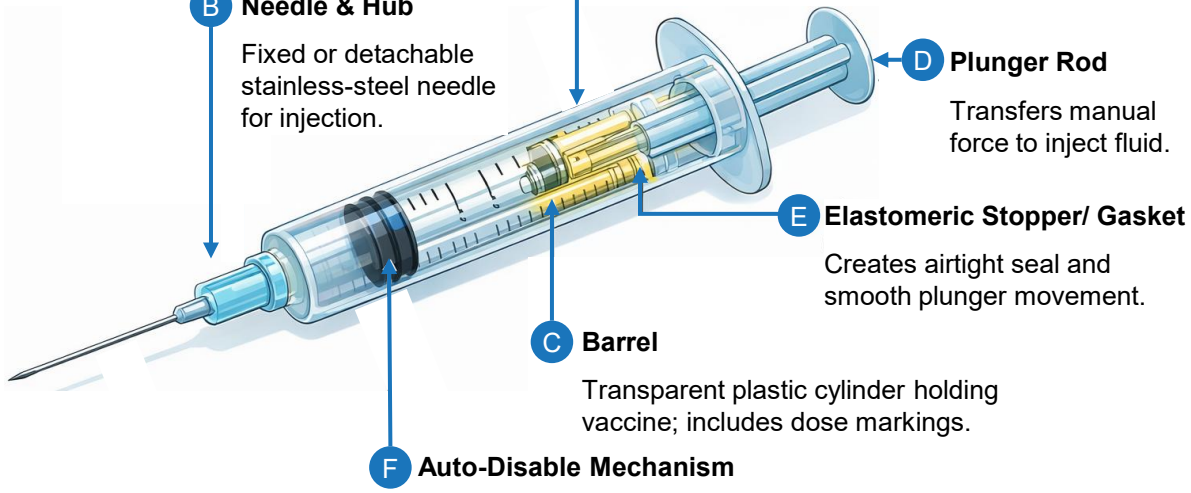
RUP syringes provide enhanced reuse-prevention for variable-dose clinical injections, offering an opportunity to gradually upgrade injection safety standards over time

AD syringe manufacturing is viable – especially if four execution conditions are met

Feasibility conditions	WHO PQ secure access to centralized donor procurement	RUP unit cost parity enables private-sector adoption	Integrated AD and RUP production achieves competitive cost position	Manufacturing partner enables technology and regulatory transfer
What must be true	**Obtained WHO PQ and required ISO certifications** to qualify for UNICEF and donor-funded immunization tenders	RUP manufacturing **cost at or below imported disposable syringe** prices	**Aggregated AD and RUP volumes** (~70 Mn units p.a.) on a shared production platform to reach minimum efficient scale	**Partner with an experienced syringe manufacturer** (JV, tech transfer, or contract manufacturing) to access validated designs, tooling expertise, and regulatory documentation
Why this matters	• **Without certification, market access is restricted to the private sector**, limiting volumes below minimum efficient scale • **AD syringe demand in Ethiopia is fully donor-funded** and centrally procured	• Without price parity, **providers default to lower-cost disposable syringes** • **RUP adoption is necessary** to aggregate sufficient scale and prevent reuse in clinical settings	• Competitive pricing in donor tenders depends on **scale-driven cost absorption** • **Standalone AD or RUP volumes may be insufficient** to match international benchmark prices	Partnership: • **Accelerates pathways to WHO PQ** and thus, EPSS eligibility and donor tenders • **Reduces execution risk** and accelerates time to market
AD syringes	✓		✓	✓
RUP syringes	✓	✓	✓	✓

AD and RUP syringes leverage similar core components, enabling platform expansion across use cases

AD syringe



A Safety Cap
Maintains sterility prior to use.

B Needle & Hub
Fixed or detachable stainless-steel needle for injection.

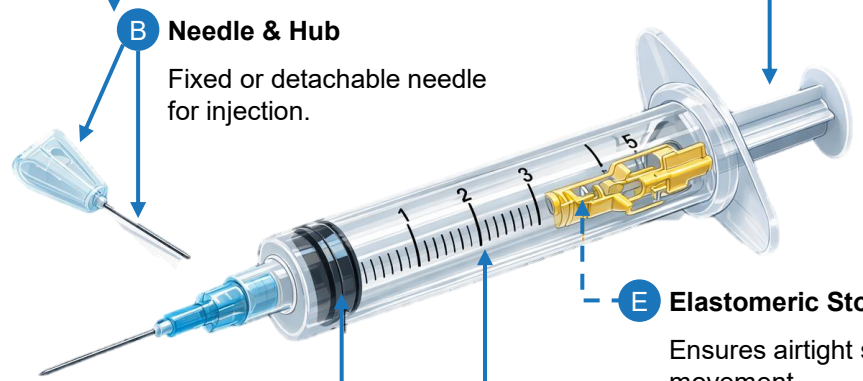
D Plunger Rod
Transfers manual force to inject fluid.

E Elastomeric Stopper/ Gasket
Creates airtight seal and smooth plunger movement.

C Barrel
Transparent plastic cylinder holding vaccine; includes dose markings.

F Auto-Disable Mechanism
Integrated locking or break system that prevents plunger retraction after full depression.

RUP syringe



A Safety Cap
Maintains sterility prior to use.

B Needle & Hub
Fixed or detachable needle for injection.

D Plunger Rod
Allows drawing and injection of variable volume.

E Elastomeric Stopper
Ensures airtight seal and smooth movement.

C Barrel
Transparent cylinder with dose graduations for variable dosing.

F Reuse-Prevention Mechanism
Internal locking, ratchet, or plunger-break system that disables syringe after injection.

Key observations

- AD and RUP syringes **share the same fundamental architecture and components**
- The **key distinction lies in dosing flexibility** and how the reuse-prevention mechanism is activated
- This similarity **enables potential manufacturing platform synergies** across both product types

Syringe manufacturing involves five modular processes, many of which are shared with conventional syringe platforms

Optional process step

NOT EXHAUSTIVE

	Injection molding	Needle fabrication	Assembly	Printing and quality testing	Sterilization & Packaging
Description	Medical-grade polypropylene (PP) is **melted and injected into precision molds** to form syringe components (barrel, plunger rod, needle hub, AD parts) Molded parts are cooled, ejected, and inspected	**Stainless steel tubing is cut, bevel-ground** (typically 3-bevel), cleaned, and siliconized to prepare the needle for hub bonding and smooth tissue penetration.	Needle is bonded to hub; plunger rod and elastomeric gasket are assembled; **the auto-disable mechanism is integrated into the plunger system**; the final plunger assembly is inserted into the barrel and configured	Graduation markings are printed onto barrels; **assembled syringes undergo dimensional verification**, leak testing, and functional checks of plunger movement and AD lock activation	Finished syringes are **sterilized (ETO or gamma)** to validated sterility levels and sealed in sterile barrier packaging for distribution
Inputs	Medical-grade polypropylene (PP) Color masterbatch (if required)	Stainless steel tubing (AISI 304/316) Medical-grade silicone oil	Elastomeric gasket (rubber stopper) Medical-grade adhesive	Medical-grade ink Compressed air (for leak testing)	Ethylene oxide (ETO) or gamma radiation Medical-grade blister/pouch packaging materials
Equipment	High-speed injection molding machine Precision multi-cavity molds (barrel, plunger, hub)	Tube cutting machine Bevel grinding machine Micro-spray siliconization machine	Automated syringe assembly line Needle-to-hub bonding station Plunger insertion unit Lock activation / functional testing station	Pad printing machine Pressure/ leak testing unit Automated vision inspection system	ETO sterilization chambers

Key observations

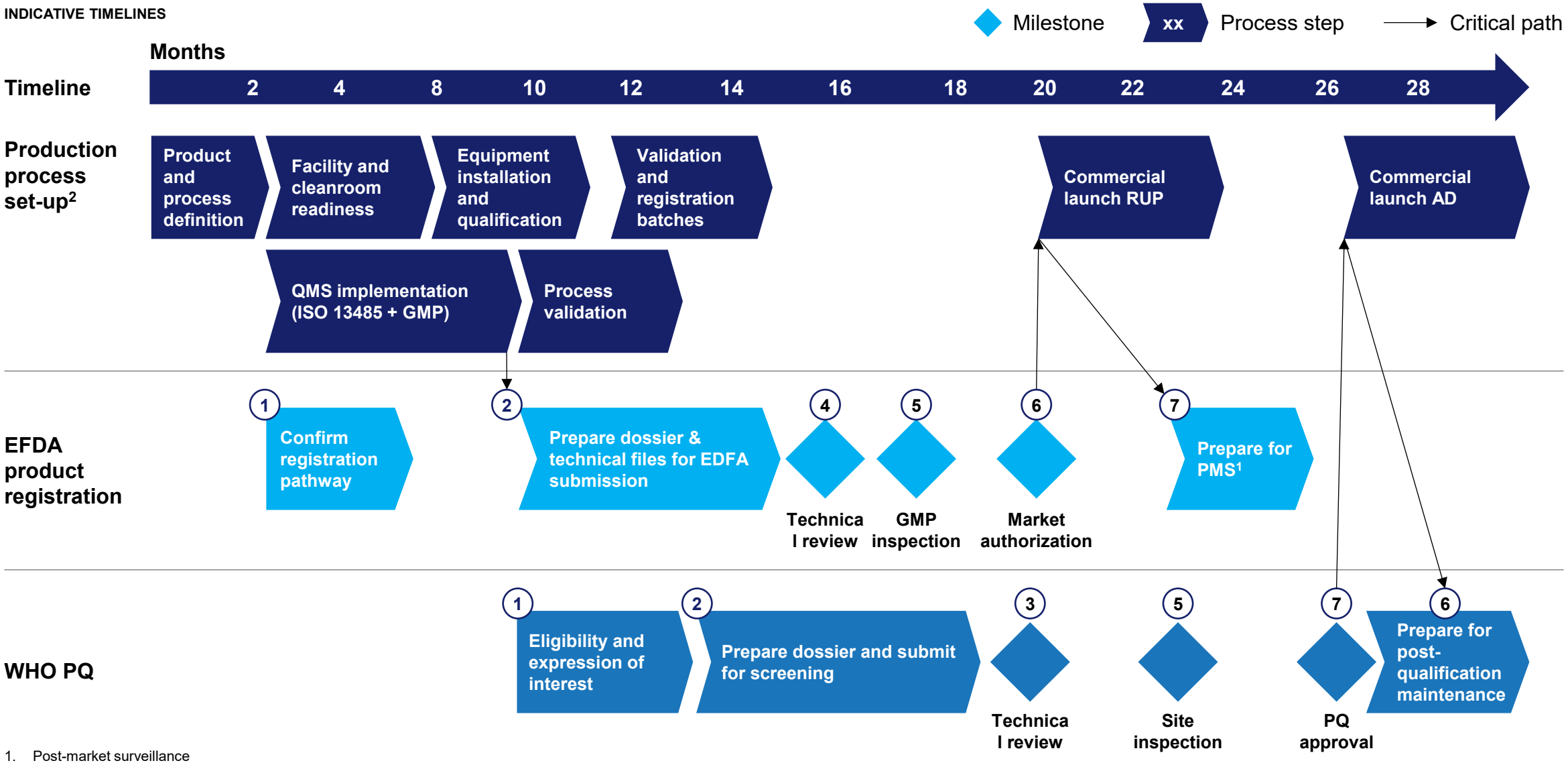
AD syringe production follows **five core modular stages common to most disposable syringe platforms**, with additional integration of the auto-disable mechanism during assembly

Needle fabrication is optional to integrate in-house; many plants source pre-fabricated needles to reduce capital intensity and simplify operations**. In-house production requires additional stainless steel tube processing, cleaning/testing equipment,** and separate validation

1. Not exhaustive. Only key equipment mentioned.

Source: Journal of Advances in Medical and Pharmaceutical Sciences Volume 26, Issue 7, Page 57-78, 2024; ISO standards

RUP launch can occur in ~18–20 months subject to EFDA authorization; AD launch requires subsequent WHO PQ



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: Ethiopia FDA, Food, Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA): Guideline for Registration of Medical Devices, WHO

Syringe manufacturing relies on imported medical-grade inputs, but global supply availability limits structural supply risk

Process step	Input material	Sourcing strategy	Leading suppliers (top 3 by market size)
Injection molding	**Polypropylene (PP)**	**High import dependency across all critical inputs**, as local production capabilities not suitable for medical-grade materials **All imports globally available** from multiple suppliers (no structural supply constraints)	Highly competitive market with many players spread globally
Needle fabrication	**Stainless steel tubing**		Highly competitive market with numerous global and regional players
	Silicon oil		Moderately fragmented market with cost-competitive production often located in Asia
Assembly	**Synthetic rubber (elastomers)**		Highly competitive landscape with a mix of established industry leaders and emerging players
	Adhesive		Moderately fragmented market with few global players leading competitive landscape
Packaging	**Blister/pouch packaging**		Highly competitive market with numerous global and regional players

Implications

Limited near-term opportunity for local substitution exist, as domestic production does not meet medical-grade requirements for key inputs

No structural supply constraints, as all critical inputs are globally available from multiple suppliers

Supplier markets are competitive and diversified, reducing dependency on single suppliers and supporting reliable sourcing

Agenda

1. Product overview

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

AD syringes are foundational to Ethiopia's national immunization program and public health system

x Strong drivers of product's public health relevance

Public health relevance

Disease burden	A	**Prevalence**	• **Ethiopia has a high birth cohort** (~3M+ births annually), requiring large volumes of routine immunizations • **Vaccine-preventable diseases** (measles, polio, diphtheria, etc.) remain public health risks if coverage gaps persist
	B	**Mortality**	• Vaccine-preventable diseases remain a **contributor to under-5 mortality** • Safe immunization delivery is essential to **sustaining gains in child survival**
Access gap	C	**Stock-outs**	• Recurring stock-outs of syringes, affecting continuity of immunization and clinical services
	D	**Supply vulnerability**	• **AD syringes are largely imported**, exposing supply to FX constraints and global procurement cycles
Population reach	E	**Patient volume**	• AD syringes are used for all routine childhood immunizations and mass vaccination campaigns (7 Mn people in 2025)
	F	**Treatment setting**	• Used across primary healthcare centers and community outreach programs
System-level impact	G	**System resilience**	• Local production would **reduce dependency** on international supply chains • **Improves supply security** during pandemics or global disruptions
	H	**Prevention impact**	• Directly **enables immunization programs** – one of the highest-impact public health interventions • Supports infection prevention by **preventing unsafe injection reuse**

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Key takeaways

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Together, AD and RUP syringes **cover the majority of safe injection use cases** across the healthcare system

While they share core design principles, AD and RUP **differ in dosing flexibility and product configuration**

Source: ISO standards

RUP syringes enhance injection safety with minimal workflow disruption, at a moderate unit cost premium

RUP syringe guidelines (WHO)

- **Recommended for vaccine reconstitution** (drawing diluent for lyophilized vaccines)
- **Conditionally recommended for therapeutic** IM, ID and SC injections

Why are RUP syringes preferred?

- **Prevent reuse** of syringes in settings with supply gaps or protocol lapses
- **Reduce transmission** of blood-borne infections (HIV, HBV, HCV)
- **Add mechanical safety** independent of user compliance

How do RUP syringes compare to disposable syringes?

Ease of use for healthcare workers

→ **Almost identical user experience,** with minimal additional training required

Manufacturing complexity

↗ **Moderately more complex** due to integration and calibration of reuse-prevention mechanism

Price per unit

↗ **~1.1-1.3 x basic disposable syringe price**

- **RUP:** $0.03-0.08 / unit[1]
- **Therapeutic syringes:** $0.02-0.028 / unit[2]

Cost premium may be **relevant in cost sensitive healthcare settings** but must be weighted against avoided infection risk

1. UNICEF tender based prices (FCA)
2. PAHO listed prices

Source: WHO, PAHO, UNICEF

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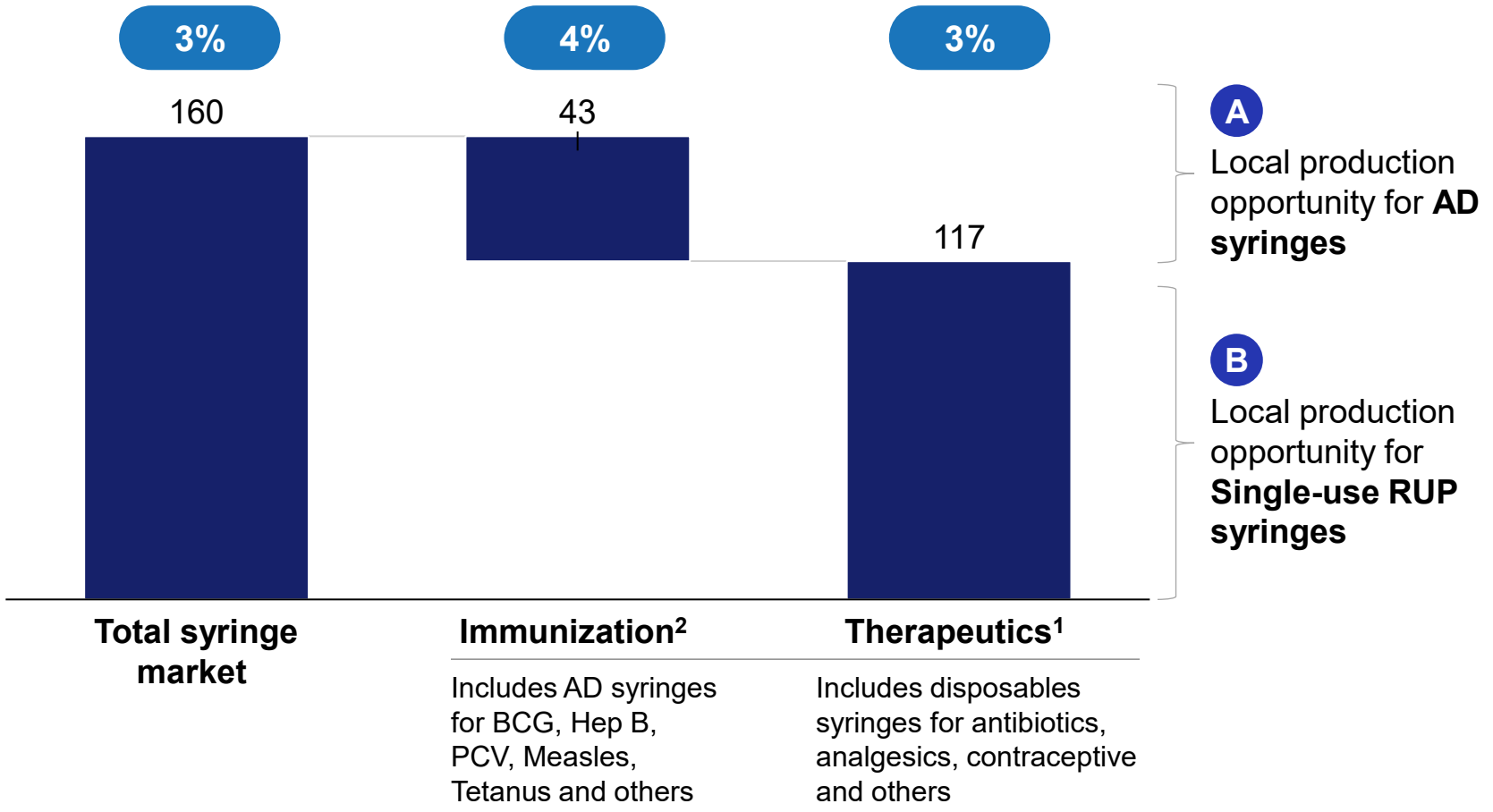
XX CAGR (2022-2025)

Addressable syringe market by use case in Ethiopia, 2025, Mn units



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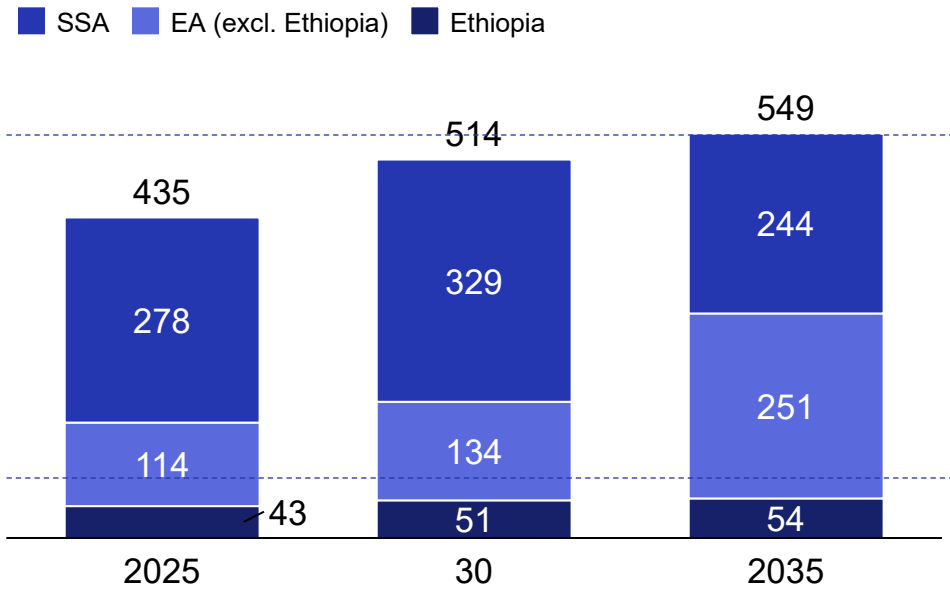
A local AD production facility could serve as a foundation platform, with **potential to expand into single-use reuse-prevention (RUP) syringes** for therapeutic settings (~73% of total market)

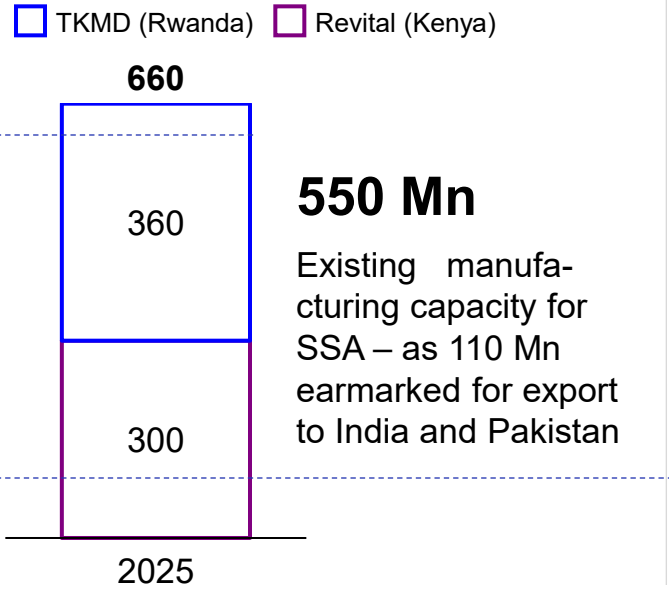
RUP syringes provide enhanced reuse-prevention for variable-dose clinical injections, offering an opportunity to gradually upgrade injection safety standards over time

A. Regional AD syringe manufacturing capacity already addresses SSA demand – Ethiopia opportunity would thus be domestic

Addressable market for AD syringes in Sub-Saharan Africa (SSA)[1], Mn units



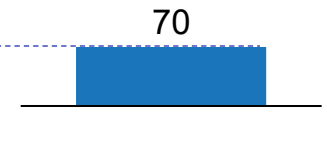
Existing capacity in the region, Mn units



550 Mn

Existing manufacturing capacity for SSA – as 110 Mn earmarked for export to India and Pakistan

Minimum capacity of an Ethiopian plant, Mn units



70 Mn

Minimum volume required for a viable production plant[3]

Implications

Immunization rates are expected to reach ~90% by 2035 covering majority of the targeted population (infants, adolescent girls, and pregnant women)[2]

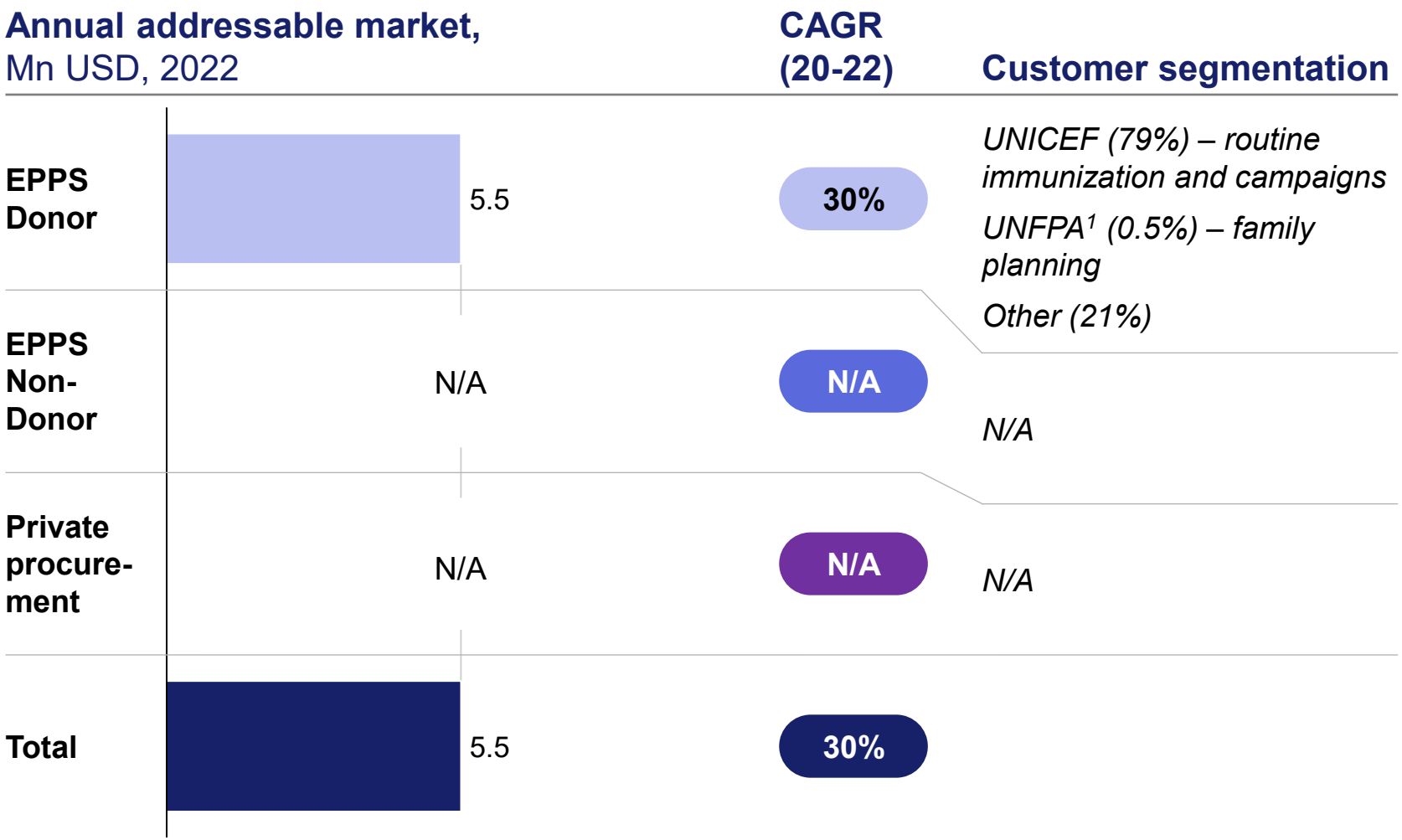
Regional and broader continental market is already largely captured by existing regional players Revital and TKMD – although ~110 Mn of existing capacity are earmarked for export agreements with Pakistan and India

An Ethiopian AD syringe production facility **could focus on meeting local market needs** (~40 Mn AD syringes in 2025) and export to neighboring countries

1. Market estimations based on annual routine immunization rates and reactive outbreak reserves. Ethiopia also includes campaign vaccination (annualized periodic supplementary immunization activities (SIAs) primarily for measles and polio)
2. For this analysis we covered children age 1 for infants, live births as a proxy for pregnant women, and adolescent girls age 12
3. 70–80M units/year AD syringe scale is consistent with publicly reported baseline capacity levels of an African WHO-PQ AD syringe manufacturer (Revital ~72M/year prior to expansion)

Source: UN population prospects, UNICEF, WHO immunization data, WHO smart syringe policy, Revital website, press search

A. Currently AD syringe demand in Ethiopia is 100% donor-funded, with recent growth driven by stock-piling



1. United Nations Population Fund
2. Long-Term Agreement

Source: EPSS procurement data 2020-2022

Key takeaways

AD syringe demand in Ethiopia is **entirely donor-funded**

Recent ~30% CAGR is partly driven by **stock-piling and campaign cycles**

Procurement is **centralized and tender-based** (primarily via UNICEF)

Market access, thus, requires **WHO PQ and competitive pricing** aligned with global LTAs

A. AD syringes vary along three independent design dimensions

XX% Share in procurement

Dominant global configuration

	Options			Production flexibility
Needle configu-ration	**Fixed needle (23G / 25G)** 70-80%[2] Standard format, needle is permanently attached to the barrel	**Detachable needle** 10-15% Needle connects via Luer interface, allowing flexibility in needle gauge and replacement	**Auto-retractable / Breakable-plunger[4]** >5% Advanced safety designs, needle retracts into the barrel or plunger breaks after injection	✓ Requires retooling – i.e., different mold inserts and assembly modules
Disabling mechanism	**Plunger locking mechanisms** Standard AD mechanism, the plunger locks after full depression	**Internal barrel/clip mechanisms** Disablement occurs via internal clip or barrel deformation. Requires specific internal mold geometry	**Retractable spring mechanisms** Uses a spring-loaded retraction system. Requires separate mechanical assembly	✗ Requires retooling and different assembly architecture, i.e., different assembly lines
Doses	**0.05 mL[3] (BCG)** 1% Shorter barrel and different plunger stroke. Used for neonatal TB vaccination	**0.3 mL[1]** 1% Smaller-dose format used for certain pediatric or fractional-dose vaccines.	**0.5 mL** 98%[2] Dominant global immuni-zation format. Standard WHO EPI for vaccines. Used for pediatric immunization vaccines	✓ Only requires different mold inserts in same injection molding machine

Key observations

Certain configurations are commonly paired (e.g., fixed needle + plunger lock), but dimensions remain technically independent except for retractable designs

The **most common configuration globally** is fixed-needle, 0.5 mL, plunger-lock AD syringes

1. Larger formats are occasional or specialized
2. UNICEF Supply Division reports that almost all routine immunization AD syringes procured are 0.5 mL fixed-needle formats
3. Sometimes 0,1 mL in older programs
4. Auto-retractable and breakable-plunger AD syringes are generally fixed-needle designs

Source: EPSS procurement data, TeamsStandMed, Retractable Website, Acupoint injection instruments.

A. Competitive AD syringe market led by Chinese suppliers, with procurement access as the key differentiator

Leading suppliers of AD syringes, FY 20-22

Suppliers	Value[2], Mn USD	AD syringes supplied[1]
Tiankang Medical	1.8	**0.5 mL** **2 mL** with needle 21G
Becton Dikson	1.5	**0.5 mL** **0.5 mL** with fixed needle 23G
Sanavit Pharma	0.7	**1 mL** with needle
Shifeng medical	0.5	**0.5 mL** with fixed needle 23G **0.3 mL** with needle 23G
Sanxin Medtec	0.3	**0.5 mL** with fixed needle 23G
Others	2.5	**0.5 mL** with needle 23G **2 mL** with needle 21G
Total	**7.3**	

1. Not exhaustive
2. Comulative from 2020-2022

Source: EPSS procurement data 2020-2022

Key takeaways

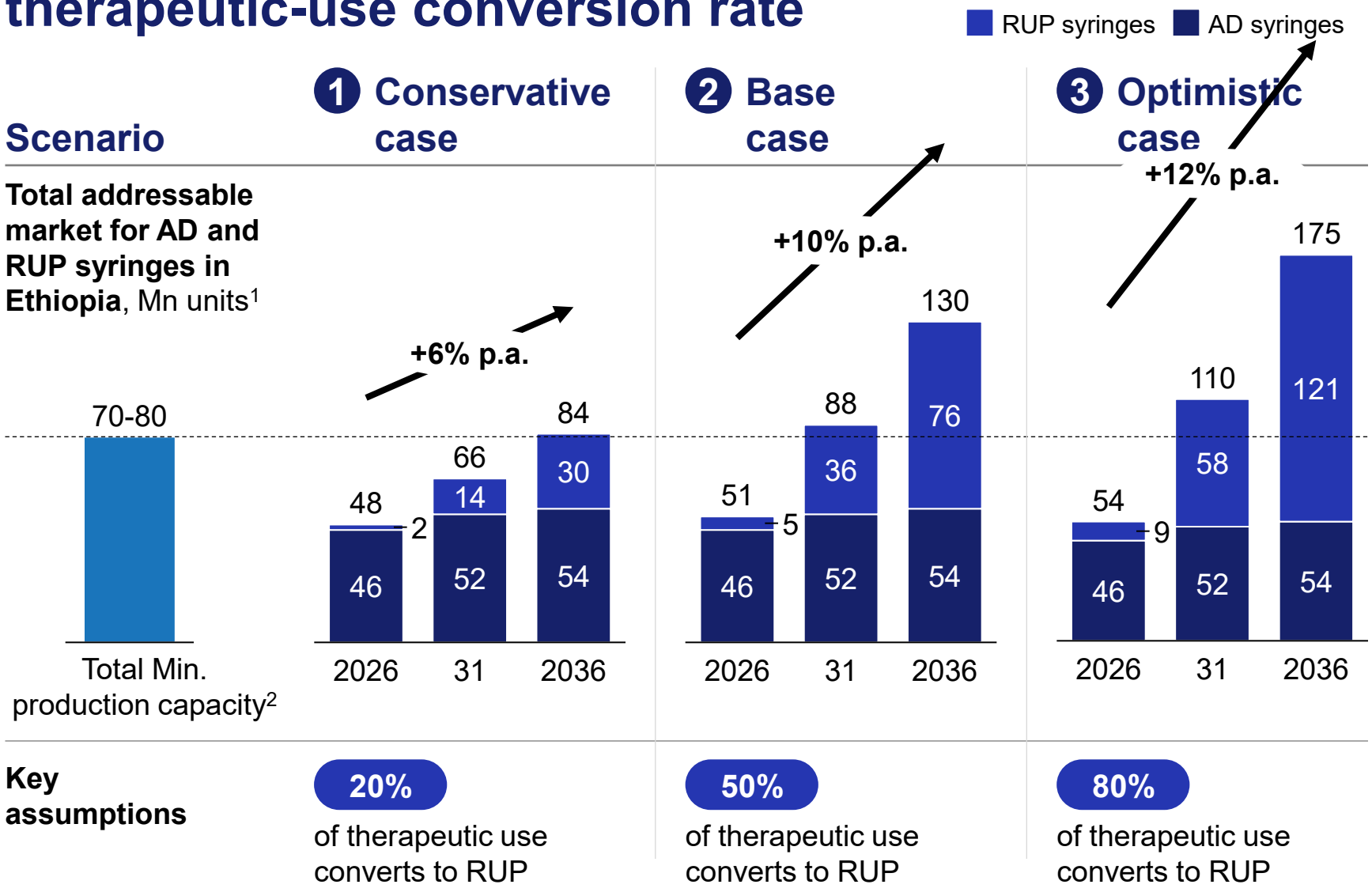
Chinese companies account for +35% of total market share, which indicates strong cost competitiveness and scale advantages

Market concentration is moderate, with **top 5 players accounting for 65% of total market share**

There is limited differentiation in core product formats, with most suppliers focusing on 0.5 mL with fixed needle 23G.

Competition is driven by price, reliability, and procurement eligibility (WHO PQ)

B. Total RUP syringe market size depends on therapeutic-use conversion rate



1. Syringes addressable market share calculated for RUP using average injection of 1,18 per person per year in SSA assuming a lower therapeutic setting in Ethiopia; and for AD syringes - annual routine immunization rates, reactive outbreak reserves and campaign vaccination
2. A minimum economically meaningful line scale of ~50M units/year is consistent with publicly reported capacities for newly added syringe-related lines (e.g., ~36–50M/yr prefilled syringe lines) and with common disposable syringe plant sizing ranges (~50–200M/yr). 70–80M units/year AD syringe scale is consistent with publicly reported baseline capacity levels of an African WHO-PQ AD syringe manufacturer (Revital ~72M/year prior to expansion)

Source: Imarc group report, Delpharm, Biorxiv, WHO Smart syringe policy, press search

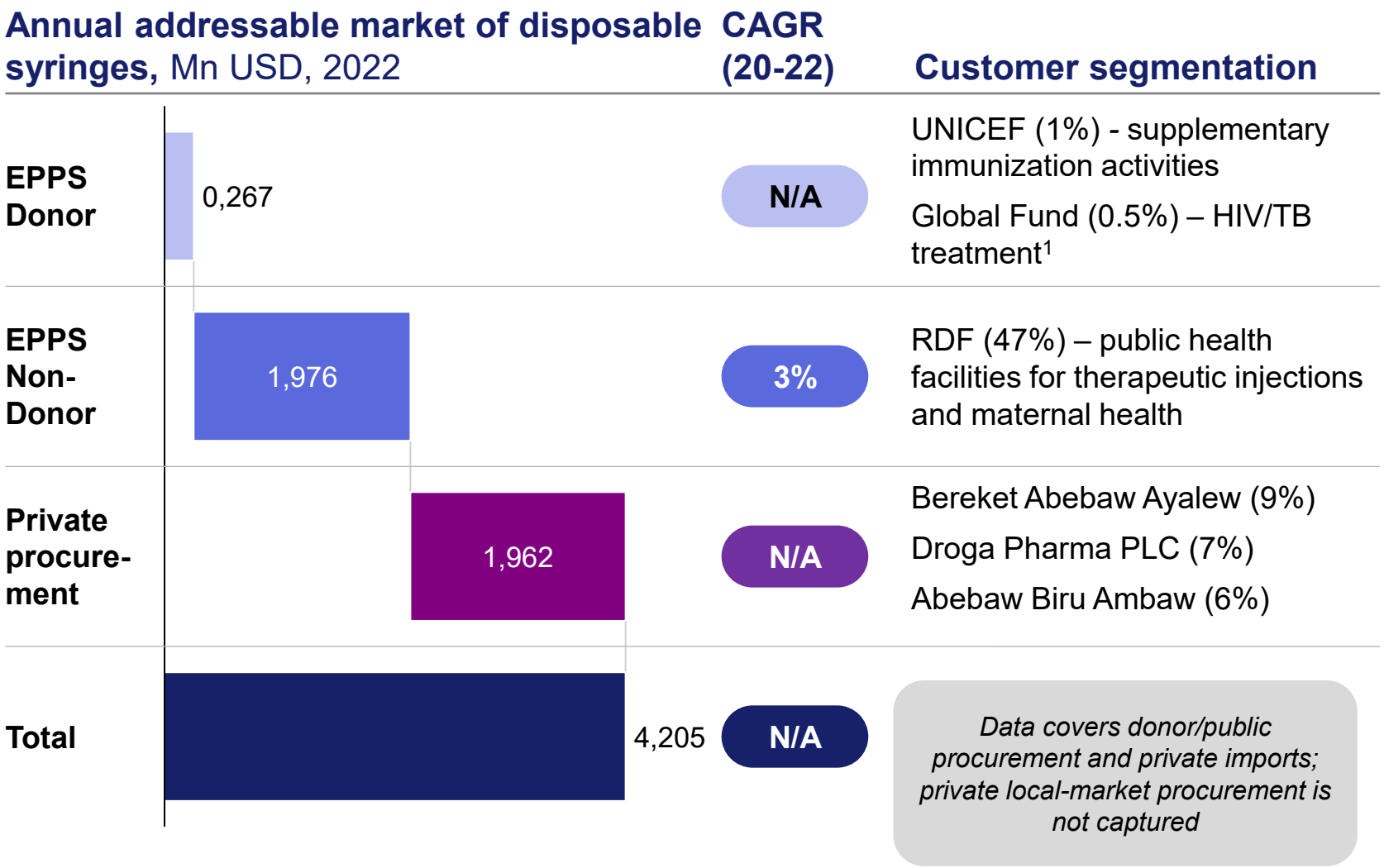
Key takeaways

RUP market is substitution-driven –volumes depend on conversion from basic disposable syringes in therapeutic use

Meeting minimum viable production scale **requires meaningful therapeutic-use conversion** (≥50% in base case)

Successful conversion **materially expands total addressable market beyond AD-only demand**, improving plant economics

B. Local addressable market for RUP syringes is 4.2 Mn USD, primarily driven by public and private procurement



1. Where injectable therapeutics are applicable

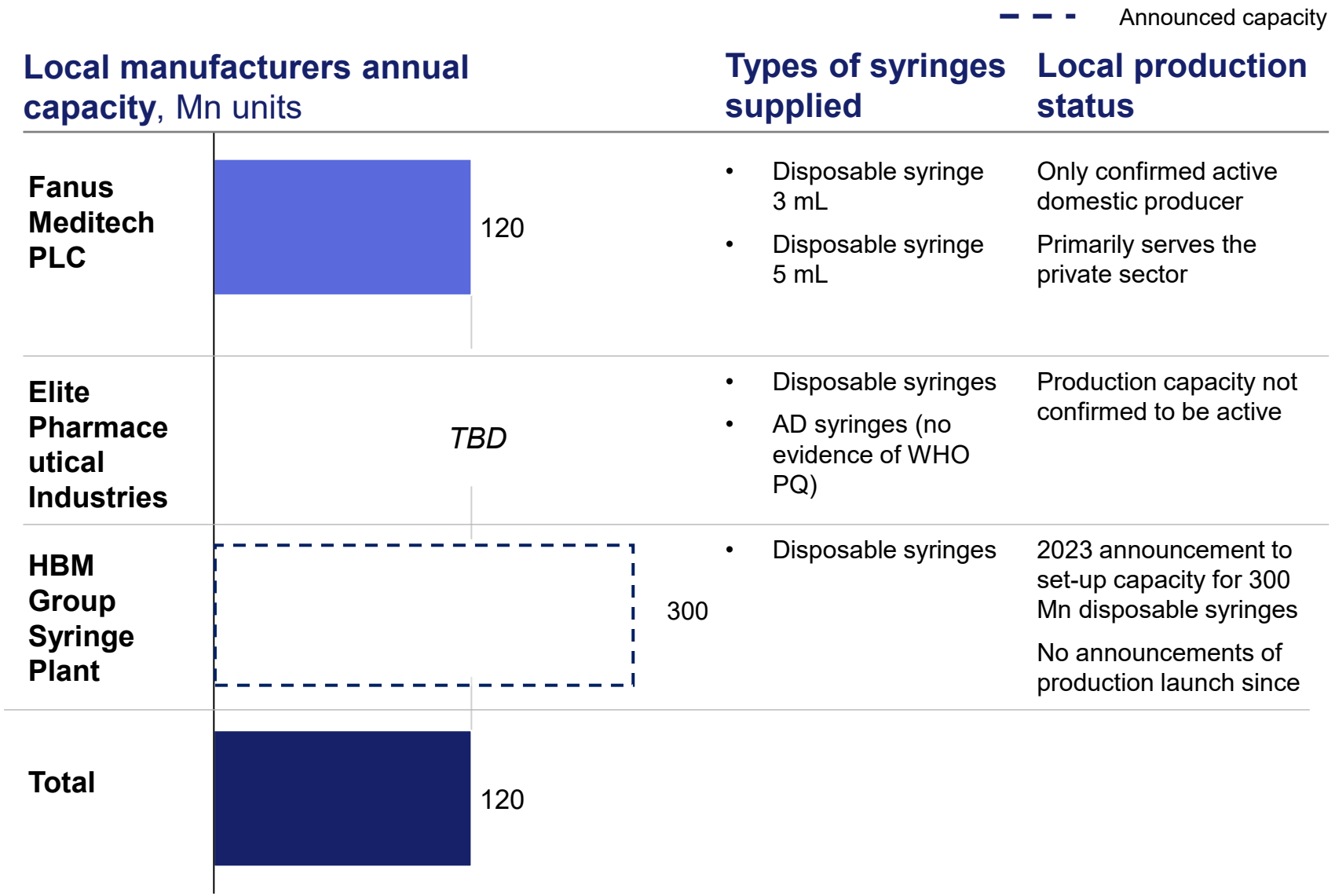
Source: EPSS procurement data 2020-2022, ECC Data

Key takeaways

Disposable syringe market **has a considerable size of 4.2 Mn USD largely driven by public institution and private procurement** (~93% of total)

Broader adoption of RUP syringes in therapeutic settings, particularly within the private sector, will depend on **achieving competitive pricing** that is at least **equal to standard disposable syringes** to ensure market acceptance and minimize switching resistance

B. Domestic disposable syringe production capacity exceeds national demand, but lacks WHO PQ



Source: Company's website, press search

Key takeaways

Despite a stated capacity of ~120M units per year, the **continued import of ~23M syringes annually suggests that Fanus Meditech is operating below full capacity**

To date, **no Ethiopian syringe manufacturer has** reported **WHO PQ status**

Market viability depends on procurement access (WHO PQ, donor tenders) given the absence of WHO PQ among local players, **market gaps remain particularly in RUP syringes segments**

RUP syringes vary along three independent design dimensions

XX% Share in procurement Dominant global configuration

	Options			Production flexibility
Needle configu-ration	**Fixed needle** 74% Integrated needle simplifies use and reduces parts handling	**Detachable/ mount needle** 24% Needle connects via Luer interface, allowing flexibility in needle gauge and replacement	**No needle supplied** N/A Syringe sold without needle, used with separate needle/cannula	Requires module changeover and validation Not simultaneous production
Disabling mechanism	**Plunger locking / breaking mechanisms** Plunger locks after full depression (or breaks if re-use attempted)	**Internal barrel/clip mechanisms** Locking element engages the barrel after delivery stroke, preventing plunger withdrawal	**Retractable spring mechanisms** Uses a spring-loaded retraction system. Requires separate mechanical assembly	Requires mold change and plunger feeding adjustment Retractable spring requires a different assembly line
Doses	**1 mL** 6% Common for small-volume therapeutic dosing (and some specialized uses)	**2, 3 and 5 mL** 73% Common for routine therapeutic use and (in immunization settings) vaccine reconstitution volumes	**10 mL** 14% Larger-volume therapeutic applications (and some reconstitution/flush contexts)	Only requires different mold inserts in same injection molding machine

Key observations

Certain **configurations are often paired** (e.g., fixed needle + plunger-lock/clip mechanism) but needle type, disabling mechanism, and dose remain technically independent for except retractable spring designs

Most common RUP formats globally are **fixed-needle 2 mL and 5 mL syringes** with plunger-locking/clip mechanisms

Source: EPSS procurement data, WHO Unicef, Retractable Website, Acupoint injection instruments.

AD syringe manufacturing is viable – especially if four execution conditions are met

Feasibility conditions	WHO PQ secure access to centralized donor procurement	RUP unit cost parity enables private-sector adoption	Integrated AD and RUP production achieves competitive cost position	Manufacturing partner enables technology and regulatory transfer
What must be true	**Obtained WHO PQ and required ISO certifications** to qualify for UNICEF and donor-funded immunization tenders	RUP manufacturing **cost at or below imported disposable syringe** prices	**Aggregated AD and RUP volumes** (~70 Mn units p.a.) on a shared production platform to reach minimum efficient scale	**Partnership with an experienced syringe manufacturer** (JV, tech transfer, or contract manufacturing) to access validated designs, tooling expertise, and regulatory documentation
Why this matters	• **Without certification, market access is restricted to the private sector**, limiting volumes below the minimum efficient scale • **AD syringe demand in Ethiopia is fully donor-funded** and centrally procured	• Without price parity, **providers default to lower-cost disposable syringes** • **RUP adoption is necessary** to aggregate sufficient scale and prevent reuse in clinical settings	• Competitive pricing in donor tenders depends on **scale-driven cost absorption** • **Standalone AD or RUP volumes may be insufficient** to match international benchmark prices	Partnership: • **Accelerates pathways to WHO PQ** and thus, EPSS eligibility and donor tenders • **Reduces execution risk** and accelerates time to market
AD syringes	✓		✓	✓
RUP syringes	✓	✓	✓	✓

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4. Regulatory and IP pathway
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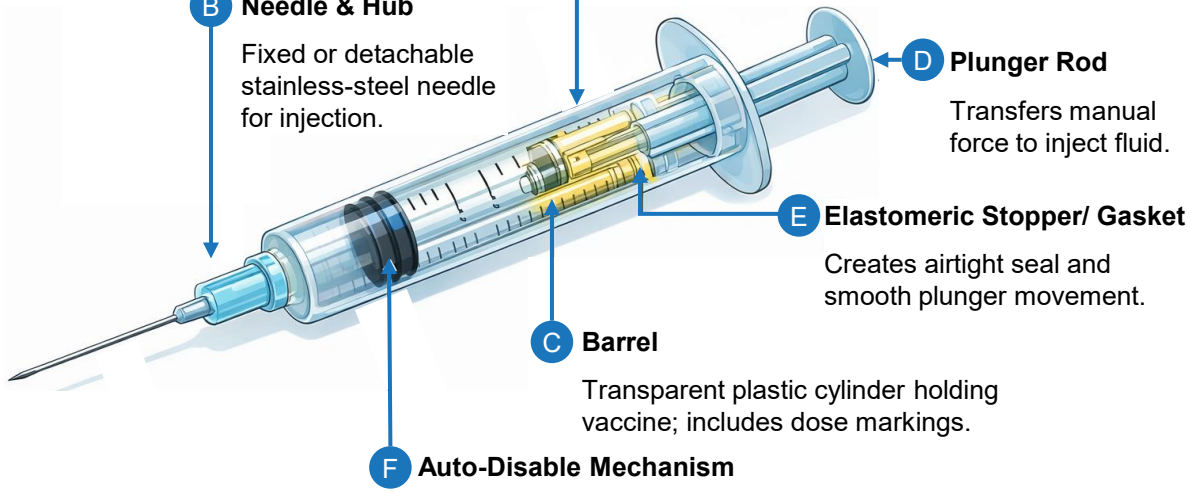
6. Risks and mitigants

AD and RUP syringes leverage similar core components, enabling platform expansion across use cases

AD syringe



A Safety Cap
Maintains sterility prior to use.

B Needle & Hub
Fixed or detachable stainless-steel needle for injection.

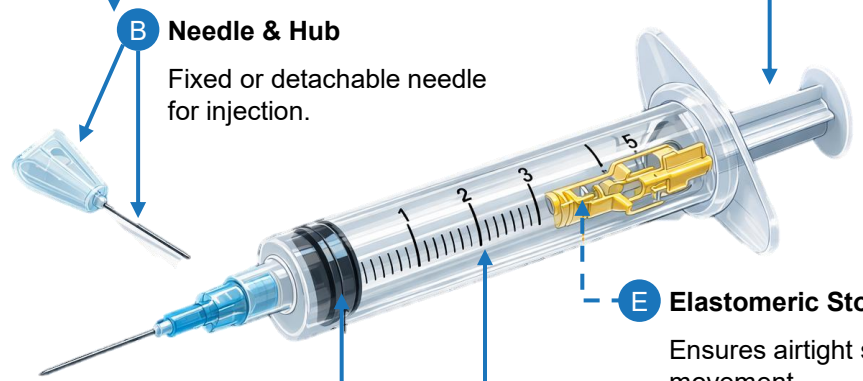
D Plunger Rod
Transfers manual force to inject fluid.

E Elastomeric Stopper/ Gasket
Creates airtight seal and smooth plunger movement.

C Barrel
Transparent plastic cylinder holding vaccine; includes dose markings.

F Auto-Disable Mechanism
Integrated locking or break system that prevents plunger retraction after full depression.

RUP syringe



A Safety Cap
Maintains sterility prior to use.

B Needle & Hub
Fixed or detachable needle for injection.

D Plunger Rod
Allows drawing and injection of variable volume.

E Elastomeric Stopper
Ensures airtight seal and smooth movement.

C Barrel
Transparent cylinder with dose graduations for variable dosing.

F Reuse-Prevention Mechanism
Internal locking, ratchet, or plunger-break system that disables syringe after injection.

Key observations

- AD and RUP syringes **share the same fundamental architecture and components**
- The **key distinction lies in dosing flexibility** and how the reuse-prevention mechanism is activated
- This similarity **enables potential manufacturing platform synergies** across both product types

AD syringe manufacturing involves five modular processes, many of which are shared with conventional syringe platforms

Optional process step

NOT EXHAUSTIVE

	Injection molding	Needle fabrication	Assembly	Printing and quality testing	Sterilization & Packaging
Description	Medical-grade polypropylene (PP) is **melted and injected into precision molds** to form syringe components (barrel, plunger rod, needle hub, AD parts) Molded parts are cooled, ejected, and inspected	**Stainless steel tubing is cut, bevel-ground** (typically 3-bevel), cleaned, and siliconized to prepare the needle for hub bonding and smooth tissue penetration.	Needle is bonded to hub; plunger rod and elastomeric gasket are assembled; **the auto-disable mechanism is integrated into the plunger system**; the final plunger assembly is inserted into the barrel and configured	Graduation markings are printed onto barrels; **assembled syringes undergo dimensional verification**, leak testing, and functional checks of plunger movement and AD lock activation	Finished syringes are **sterilized (ETO or gamma)** to validated sterility levels and sealed in sterile barrier packaging for distribution
Inputs	Medical-grade polypropylene (PP) Color masterbatch (if required)	Stainless steel tubing (AISI 304/316) Medical-grade silicone oil	Elastomeric gasket (rubber stopper) Medical-grade adhesive	Medical-grade ink Compressed air (for leak testing)	Ethylene oxide (ETO) or gamma radiation Medical-grade blister/pouch packaging materials
Equipment	High-speed injection molding machine Precision multi-cavity molds (barrel, plunger, hub)	Tube cutting machine Bevel grinding machine Micro-spray siliconization machine	Automated syringe assembly line Needle-to-hub bonding station Plunger insertion unit Lock activation / functional testing station	Pad printing machine Pressure/ leak testing unit Automated vision inspection system	ETO sterilization chambers

Key observations

AD syringe production follows **five core modular stages common to most disposable syringe platforms**, with additional integration of the auto-disable mechanism during assembly

Needle fabrication is optional to integrate in-house; many plants source pre-fabricated needles to reduce capital intensity and simplify operations**. In-house production requires additional stainless steel tube processing, cleaning/testing equipment,** and separate validation

1. Not exhaustive. Only key equipment mentioned.

Source: Journal of Advances in Medical and Pharmaceutical Sciences Volume 26, Issue 7, Page 57-78, 2024; ISO standards

RUP production leverages the same core manufacturing platform as AD syringes, with limited incremental modifications

NOT EXHAUSTIVE

	Injection molding	Needle fabrication	Assembly	Printing and quality testing	Sterilization & Packaging
Alignment with AD production	✓	✓	✓	✓	✓
Key differences	**RUP barrel volumes** are larger (1-10 mL)	N/A	More complex locking mechanisms (as lock must activate after injection)	More plunger travel testing and verification of variable-dose accuracy	N/A
Implicat-ions	**Same injection molding machines** can be used but different molds required	**Same stainless steel tubing**, bevel grinding and siliconization	Machines remain automated assembly lines, but with **different tooling and set-up** (e.g., modified plunger insertion modules, different lock activation calibration)	**Equipment and tools remain the same**	**No additional equipment required**, same packaging materials and sterile barrier systems used

Key observations

Injection molding, needle fabrication, sterilization, and packaging are largely identical between AD and RUP syringes

The primary **technical difference lies in the assembly stage**, where the reuse-prevention mechanism and plunger travel design differ

Transitioning from AD to RUP production **requires new molds & modified assembly tooling**, but not a fundamentally new production platform

AD & RUP syringes **can share the same production line** when using **non-retractable mechanisms, compatible barrel geometries, modular assembly tooling**, & the same sterilization and packaging process

1. Not exhaustive. Only key equipment mentioned.

Source: ISO standards, Manufacturer technical documentation (e.g., Hindustan, BD)

A number of standards have to be upheld to obtain WHO PQ and unlock donor funded markets for AD syringes

Standards relevant to AD syringe manufacturing

Standard	GMP Good Manufacturing Practices	ISO 13485 – Quality Management System	ISO 7886-3 – Auto-disable syringes for fixed-dose immunization	WHO prequalification
Issuing authority	Ethiopian Food and Drug Authority (EFDA)	Accredited Certification Body (e.g., TÜV, BSI, SGS)	International Organization for Standardization (ISO)	Required for procurement through UN agencies and global immunization programs.
Description	Manufacturing facility must comply with GMP principles, including: • Controlled cleanroom environments • Defined material & personnel flow • Segregation of sterile and non-sterile areas • Validated manufacturing processes • Documented SOPs and batch records • Qualified equipment (IQ/OQ/PQ) and • Environmental monitoring program	This is a quality management system certification that ensures medical devices are manufactured under consistent compliance. How to obtain ISO 13485 certation: 1. Implement full QMS 2. Develop SOPs 3. Conduct risk management (ISO 14971) 4. Perform internal audit 5. Select accredited certification body 6. Stage 1 audit (documentation) 7. Stage 2 audit (on-site) 8. Certification issued (3-year cycle) 9. Annual surveillance audits	This is a product performance standard that defines performance and quality specifications for AD syringes used for immunization This document provides standards on: • **AD feature:** lock geometry, ratchet engagement precision, fracture zone consistency, activation force window • **Fixed dosing accuracy:** Barrel internal volume, Plunger stopper geometry, Dead space at needle hub interface • **Needle requirements:**	WHO prequalification is required for procurement through UN agencies Steps to obtain WHO PQ: 1. Submit full product dossier to WHO 2. Provide ISO 13485 certification 3. Provide GMP inspection evidence 4. Risk management documentation(ISO 14971 compliant) 5. Usability testing evidence 6. Calibration traceability 7. Production-run samples 8. Ongoing change & defect reporting

Source: ISO, WHO, Expert interviews

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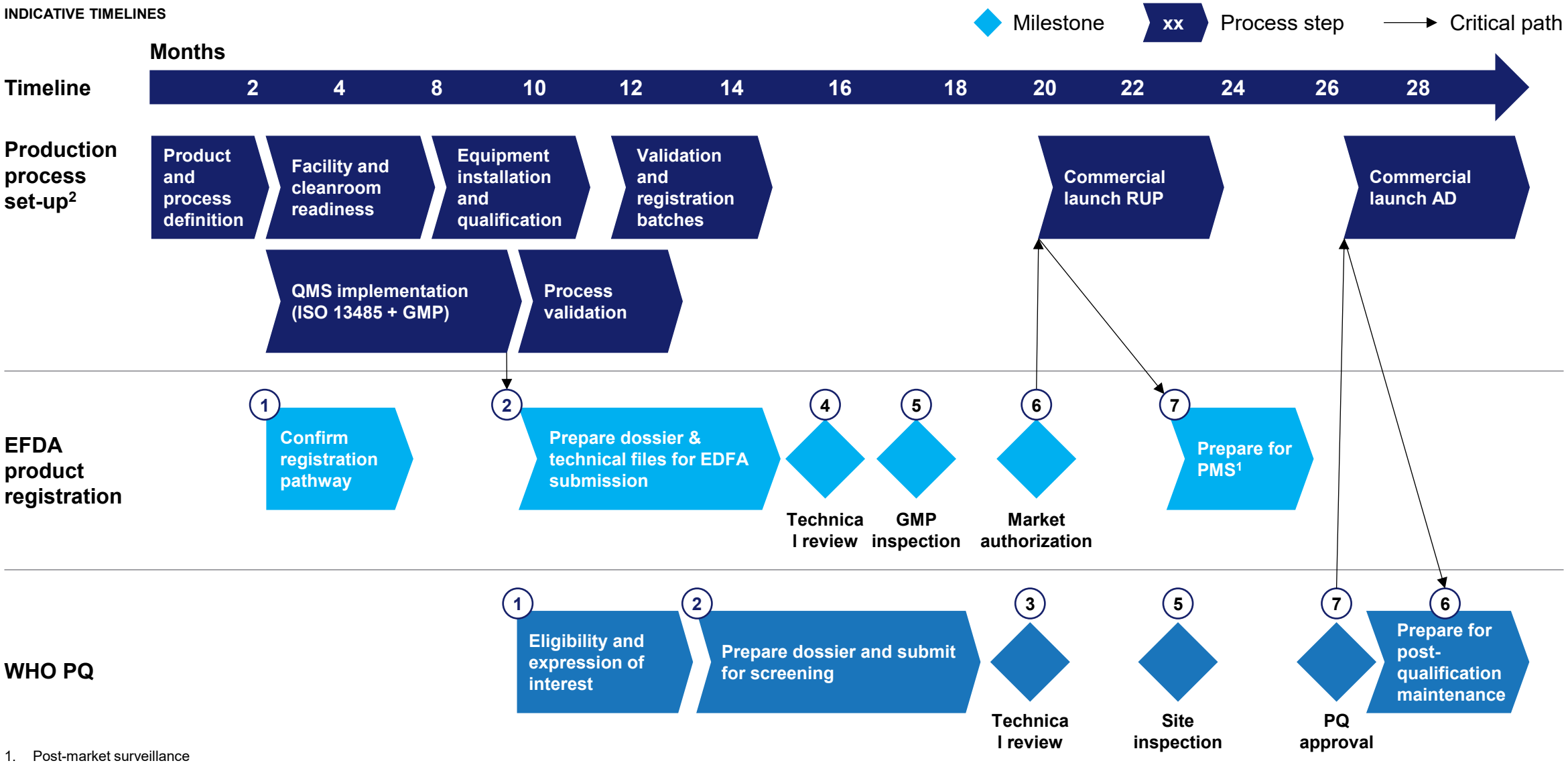
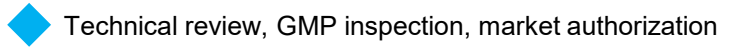
RUP launch can occur in ~18–20 months subject to EFDA authorization; AD launch requires subsequent WHO PQ



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: Ethiopia FDA, Food, Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA): Guideline for Registration of Medical Devices, WHO

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



	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 to take	• Confirm device classification (likely class B/C sterile device) • Confirm required standards (ISO 7886, ISO 13485, ISO 11135, ISO 14971) • Determine whether GMP inspection will be required • Conduct optional pre-submission meeting with EFDA • Align on labeling language requirements	• Compile full technical file (per EFDA device guideline) • Finalize device description & intended use • Complete risk management file (ISO 14971) • Document manufacturing process flow • Include sterilization validation plan/results • Compile QMS evidence (ISO 13485 certification or readiness) • Prepare labeling & IFU[2] per EFDA format	• Establish complaint handling system • Establish vigilance/adverse event reporting process • Define recall procedure • Train staff on reporting timelines • Establish post-market data review procedure
Final documents required	• Device classification justification memo • Applicable standards list • Regulatory strategy memo • Proof of legal manufacturer registration	• Administrative dossier (application form, fees, legal docs) • Technical file[1] • Labeling and IFU • Batch manufacturing record samples	• PMS plan • Vigilance SOP • Complaint handling SOP • Incident reporting template • Record-keeping procedure

1. Should include device description, design specifications, risk managament reports, manufacturing process description, sterilization validation report, packaging validation report, performance testing results, QMS documentation summary, ISO 13485 certificate
2. Instruction for use

Source: Ethiopia FDA, Food, Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA): Guideline for Registration of Medical Devices

Key observations

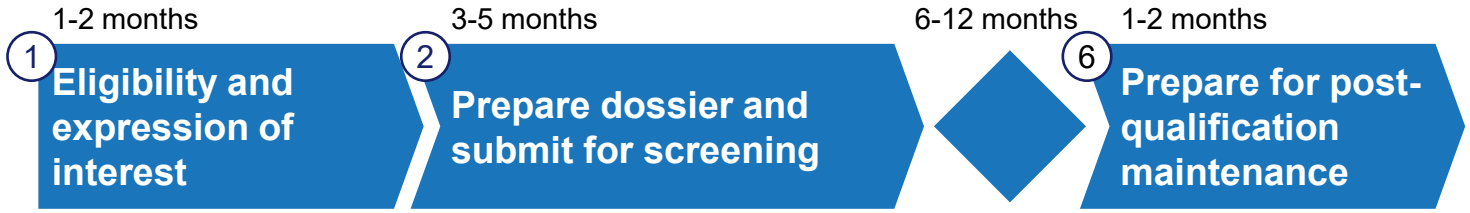
EFDA readiness is driven by manufacturing maturity, incl., validated sterilization, documented QMS implementation and inspection readiness

Technical file submission must run in parallel with facility set-up to meet launch timelines

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 to take	• Align on applicable international standards	• Compile full technical file per WHO device PQ guidance • Include validated sterilization and performance data • Demonstrate QMS implementation (ISO 13485) • Align labeling and IFU to WHO format • Ensure EFDA status documentation is included		• Maintain vigilance reporting • Notify WHO of significant changes • Undergo periodic re-inspection
Final documents required	• Expression of Interest (EOI) submission • Legal manufacturer status documentation • Preliminary product information	• WHO PQ technical dossier • Sterilization validation report • Risk management report • QMS documentation summary • EFDA regulatory status evidence		• PQ maintenance plan • Change control records • Annual performance reports

Source: WHO

Key observations

WHO PQ timelines are primarily driven by technical review and site inspection scheduling, both largely outside control by external parties

WHO PQ should be initiated during facility build-out but will typically conclude **3–6 months after EFDA authorization**, supporting a phased launch strategy (RUP first, AD post-PQ)

Validated sterilization and implemented QMS are the primary gating requirements

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

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Syringe manufacturing relies on imported medical-grade inputs, but global supply availability limits structural supply risk

Process step	Input material	Sourcing strategy	Leading suppliers (top 3 by market size)
Injection molding	**Polypropylene (PP)**	**High import dependency across all critical inputs**, as local production capabilities not suitable for medical-grade materials **All imports globally available** from multiple suppliers (no structural supply constraints)	Highly competitive market with many players spread globally
Needle fabrication	**Stainless steel tubing**		Highly competitive market with numerous global and regional players
	Silicon oil		Moderately fragmented market with cost-competitive production often located in Asia
Assembly	**Synthetic rubber (elastomers)**		Highly competitive landscape with a mix of established industry leaders and emerging players
	Adhesive		Moderately fragmented market with few global players leading competitive landscape
Packaging	**Blister/pouch packaging**		Highly competitive market with numerous global and regional players

Implications

Limited near-term opportunity for local substitution exist, as domestic production does not meet medical-grade requirements for key inputs

No structural supply constraints, as all critical inputs are globally available from multiple suppliers

Supplier markets are competitive and diversified, reducing dependency on single suppliers and supporting reliable sourcing

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Syringe manufacturing is viable but subject to key market, execution, and cost risks, which require active mitigation (1/3)

✓ Risks that would be mitigated through partnership build

Dimensions	Key risks	Mitigation levers
Market access and demand	**High dependence on donor-funded demand (e.g., UNICEF/Gavi)**, creating exposure to funding cycles and procurement decisions	**Engage early with UNICEF, RDF, and key donors** to secure demand visibility and align on procurement requirements
	✓ **Failure to secure tender access or preferred supplier status** (e.g., due to delayed WHO PQ), limiting access to the largest demand pools	**Achieve WHO PQ and prequalification early** to unlock access to donor-funded tenders
	✓ **Price pressure from international suppliers** (primarily Asia), with risk of undercutting local production economics	**Build and continuously track cost competitiveness** vs. Asian suppliers to ensure pricing viability in tenders
	Limited substitution from basic disposable syringes to RUP syringes, constraining demand growth and reducing achievable scale in therapeutic segments	**Engage with RDF and clinical stakeholders to drive adoption of RUP syringes**, supported by cost parity and demonstrated safety benefits
Manufacturing and operations	**Underutilization of capacity**, with economics highly sensitive to achieving scale (~60–70M units)	**Phase production ramp-up and secure anchor volumes upfront** to ensure early utilization
	✓ **Delays in ramp-up or yield stabilization**, delaying revenue generation and impacting IRR	**Leverage experienced operators and technical partners** to accelerate ramp-up and stabilize yields
	✓ **Workforce capability gaps impacting quality and operational efficiency**, particularly during early scale-up	**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.

Syringe manufacturing is viable but subject to key market, execution, and cost risks, which require active mitigation (2/3)

✓ Risks that would be mitigated through partnership build

Dimensions		Key risks	Mitigation levers
Supply chain		**Reliance on imported inputs (e.g., PP resin, needles)**, exposing operations to external supply dependencies	**Negotiate long-term supplier agreements** with price and volume stability
		Exposure to FX volatility and logistics disruptions, impacting input costs and continuity of supply	**Maintain buffer inventory for critical components** to mitigate supply disruptions
	✓	**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		**IRR highly sensitive to utilization and pricing**, with downside risk if scale (~60–70M units) is not achieved	**Secure minimum viable volumes** (~60–70M units) early to ensure utilization
		Margin erosion from input cost inflation or tender price pressure, particularly in a highly competitive global market	**Maintain strict cost discipline** and continuously benchmark against international competitors
	✓	**High upfront CAPEX with delayed revenue ramp-up**, impacting payback period and overall investment attractiveness	**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.

Syringe manufacturing is viable but subject to key market, execution, and cost risks, which require active mitigation (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, comercial 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.

Methodology: AD syringe market demand forecasts

Components of epidemiological approach

Population Base (2025)

- Live births
- Pregnant Women
- Girls aged 12 (HPV cohort)

Dose assumption

- 8 routine injectable doses per child
- +1 BCG dose per child
- 1 maternal (tetanus) dose
- 1 HPV dose

Coverage adjustment

- Infant mortality rate
- National immunization coverage rate

Campaign & buffer adjustment[1]

- +15% periodic SIAs (annualized)
- +5% reactive outbreak reserve

Main sources

- UN World Population Prospects
- WHO/UNICEF coverage estimates (WUENIC))
- Ethiopian national immunization Schedule

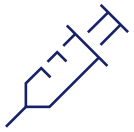
Main formula used

AD syringe Demand = ((live births – (1 * infant mortality rate)) × 9) x (1+20%) + (Pregnant Women ×1) + (Girls aged 12 ×1) × Coverage rate

1. Campaign and outbreak reserve uplift (+20%) is applied only to the child immunization component (9-dose schedule), since SIAs primarily target children (e.g., measles/polio), while maternal and adolescent doses are not uplifted

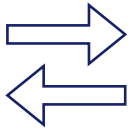
Methodology: RUP syringes replacement scenarios

Components of epidemiological approach



Disposable syringe consumption (2025)

- Total Ethiopian population (2025)
- Average nº of injections per person p.a[1]
- AD syringe market demand



Replacement scenarios

- 20% replacement of disposable market
- 50% replacement
- 80% replacement

Adoption Curve

- Gradual transition applied over multiple years (not immediate full replacement)

Main sources

- UN World Population Prospects
- WHO/UNICEF coverage estimates (WUENIC))
- Ethiopian national immunization Schedule

Main formulas used

Disposable syringe consumption = ((Population x average nº of injections) - AD syringe market demand)

RUP Demand = Disposable syringe consumption x replacement rate x Adoption

1. 1,18 injections per African person per year used as a proxy as it includes *all injection types*

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

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