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USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM  
Procurement and Supply Management

# Revised assessment of the feasibility of local manufacturing of an injectable contraceptive in SSA



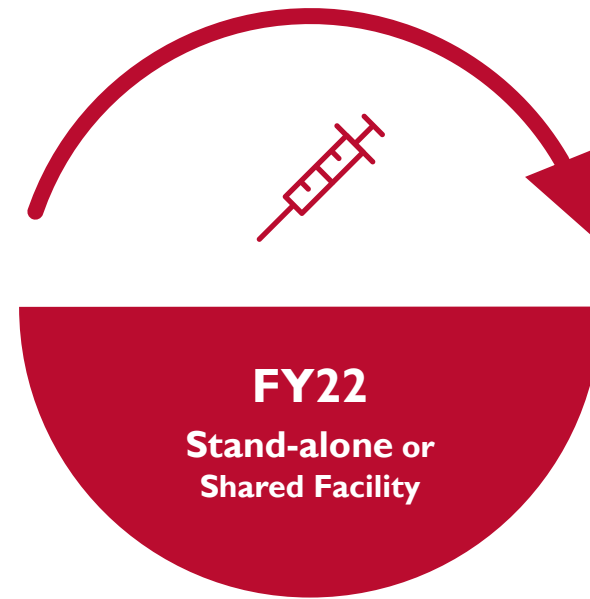
# Agenda

- Project Background
- Approach
- Data sources
- Key assumptions
  - Factory build
  - Operating Costs
  - Revenues
  - Finance
- Results
  - Stand-alone facility
  - Shared facility

# Project Background

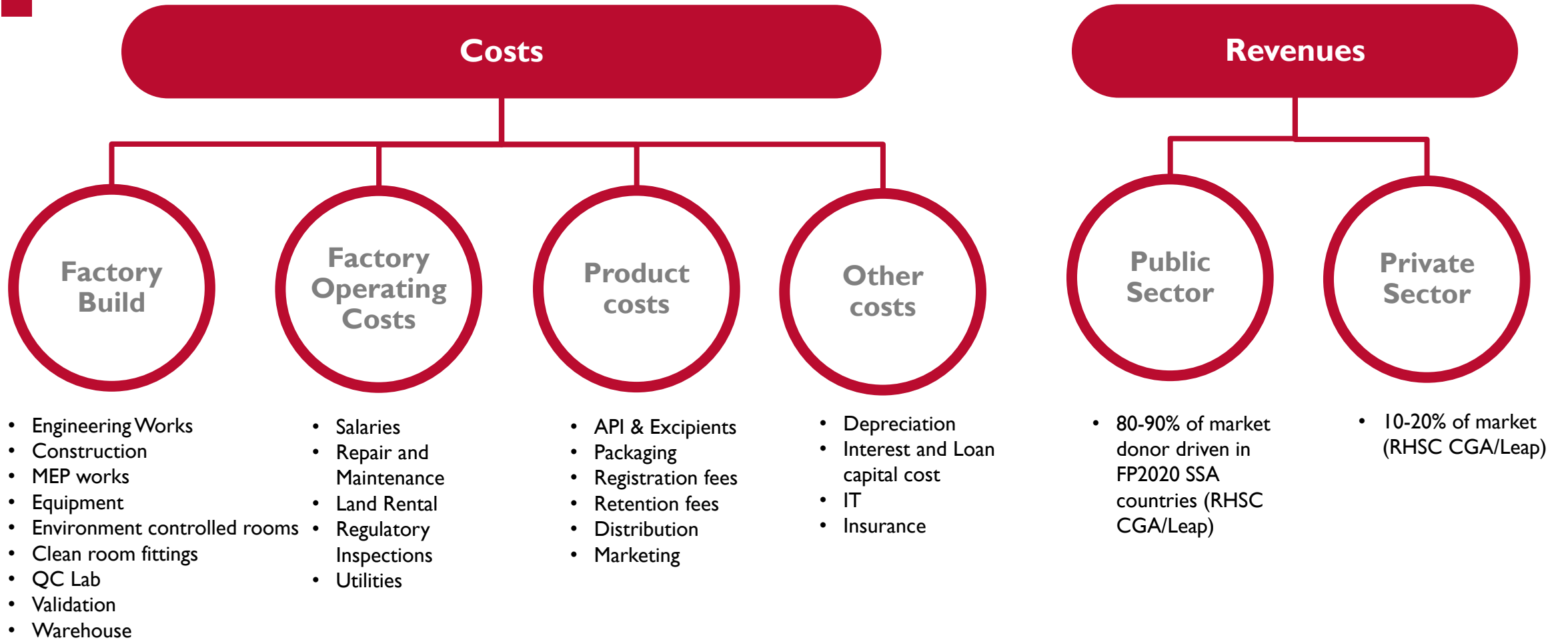


**Preliminary  
Business Case**

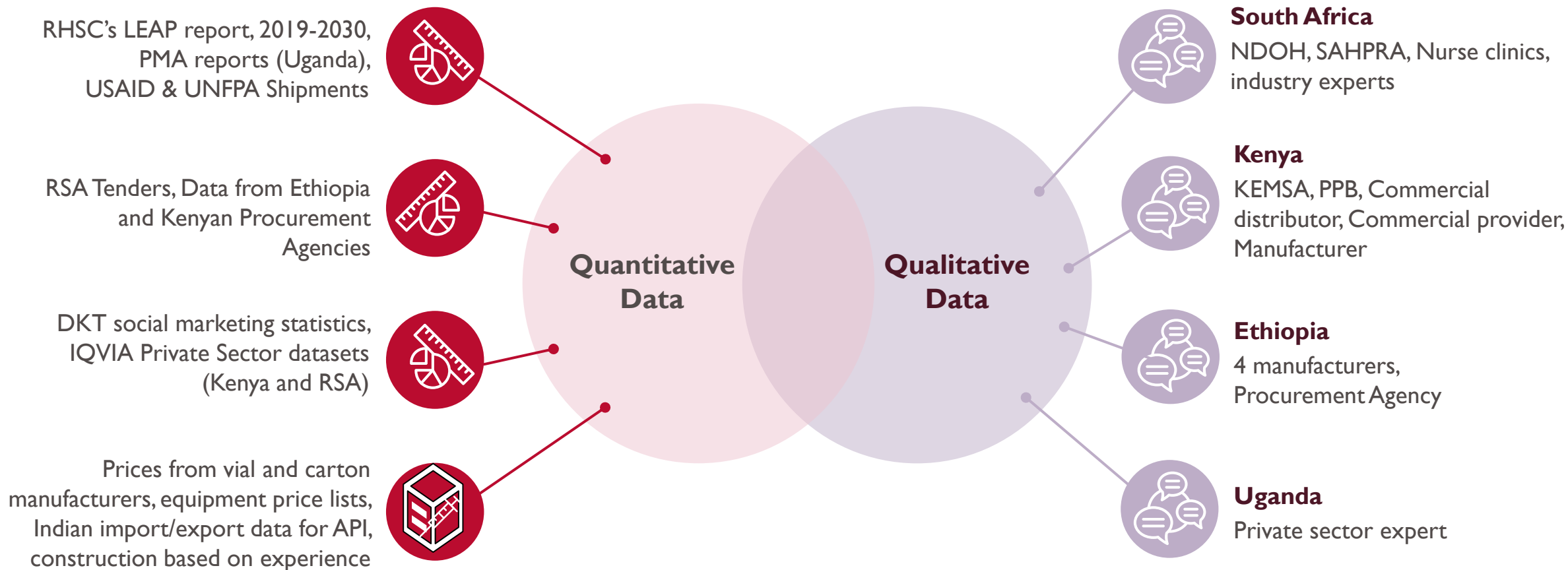


**Revised  
Business Case**

# Approach



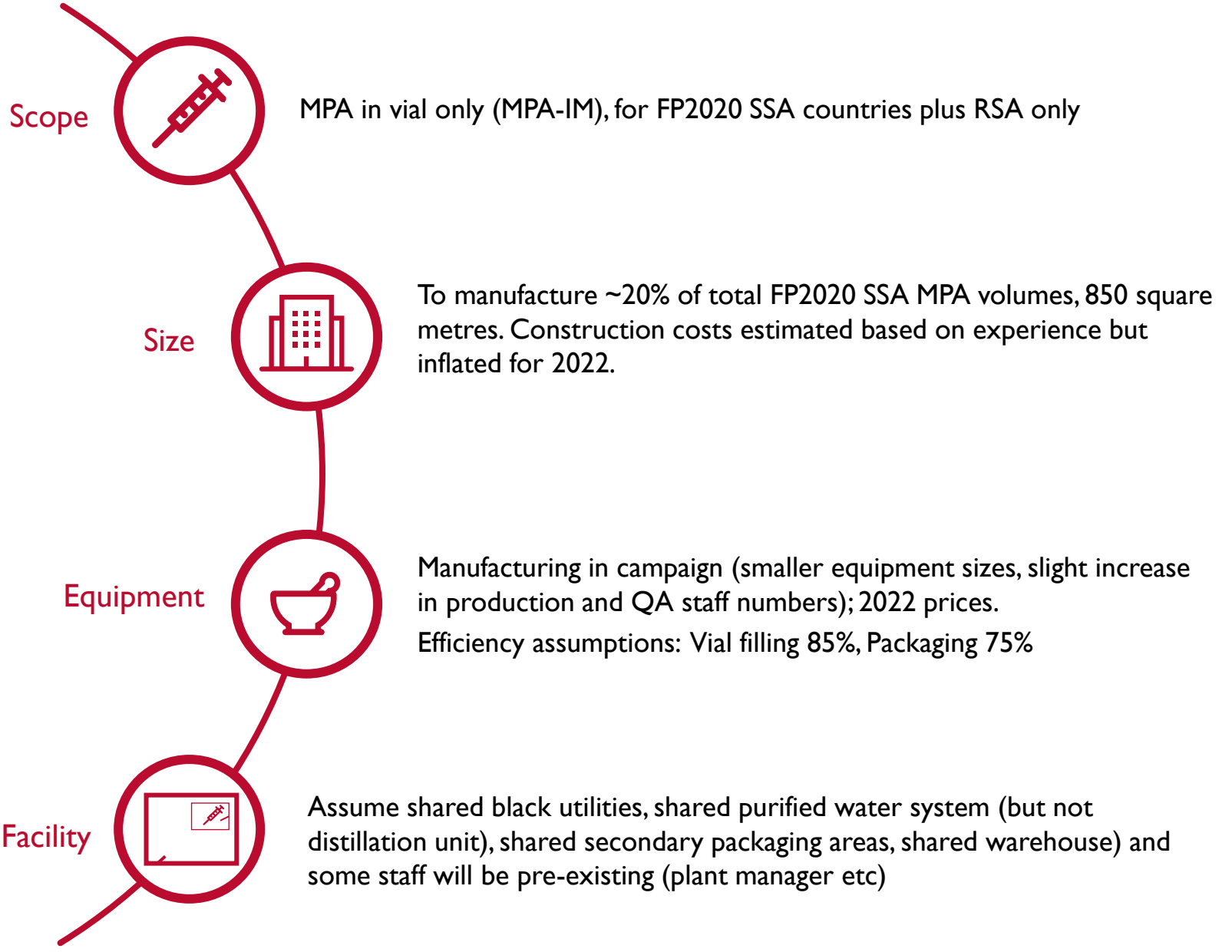
# Data sources



# Key assumptions

- Factory Build
- Operating Costs
- Revenues
- Finance costs

# Factory Build



# Operating Costs

## Staff and Salaries



- Expatriates in supervisory/managerial positions
- Salaries based on local manufacturer interviews (5). Expatriate salaries ~2.75 times as high as local on average
- Effective shift length: Filling 5/8 hours, Packaging 6/8 hours

## Product



- API and Excipient costs from 2019 Indian import/export data for commodities marked as USP, BP, EP. MPA API price taken as that for Farmabios, the PQ'd manufacturer.
- Primary and secondary packaging costs from vial and carton manufacturers (leaflet and export carton assumed to be 10% on top)

## Utilities



Electricity, water and land rental costs based on SEZ documentation, notably Ethiopia's pharmaceutical park (2021)

## Other



- B/E study costs sourced from company specializing in B/E and based on published WHO PQ MPA-IM submission
- Product registration, retention and site inspection fees allowance; based on costs in RSA and Kenya
- Repair and maintenance, IT and site insurance allowance (USD 265K/year)





Market size



- MPA-SC assumed to take 50% of FP2020 SSA MPA volumes; but not launched in RSA
- Growth in injectables investigated and anticipated but not in model

Marketing & Distribution costs



- Based on industry interviews, expressed as % of sale price.
- RSA private sector highest at ~33%,
  - Public sector and FP2020 SSA private sector ~15%

RSA price and market share



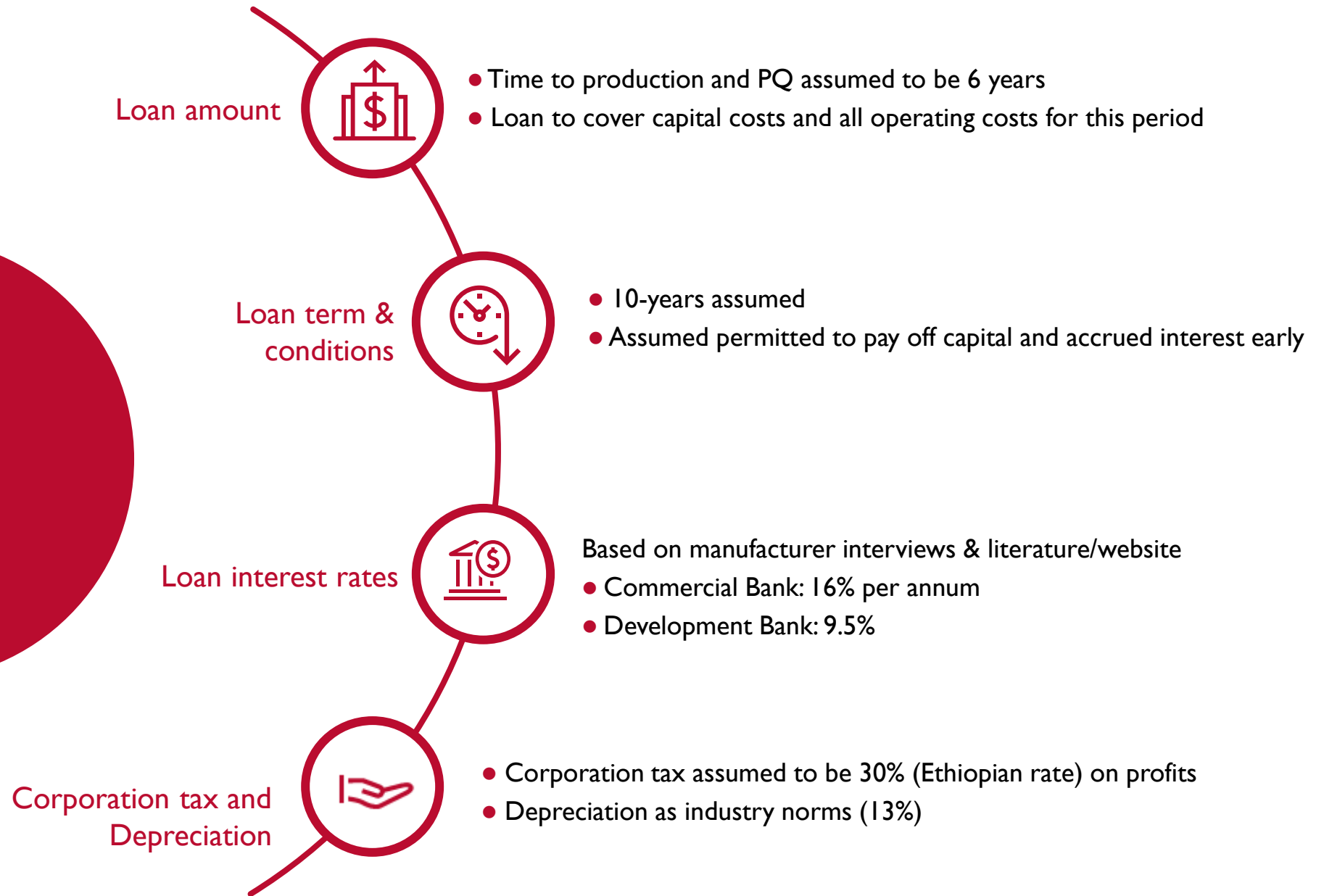
- Public sector price based on 2021 tender price and 30% share of volume based on NDOH allocation formula
- Private sector price based on 20% discount to SEP, to achieve 20% market share (based on analogues)
- Shares achieved within 1 year of achieving WHO PQ (6 years)

FP2020 price and market share



- Public sector price based on UNFPA Catalogue price, assume 20% market share
- Private sector price based on IQVIA WHS price in Kenya audit, assume 12% share
- Shares achieved within 1 year of achieving WHO PQ (6 years)

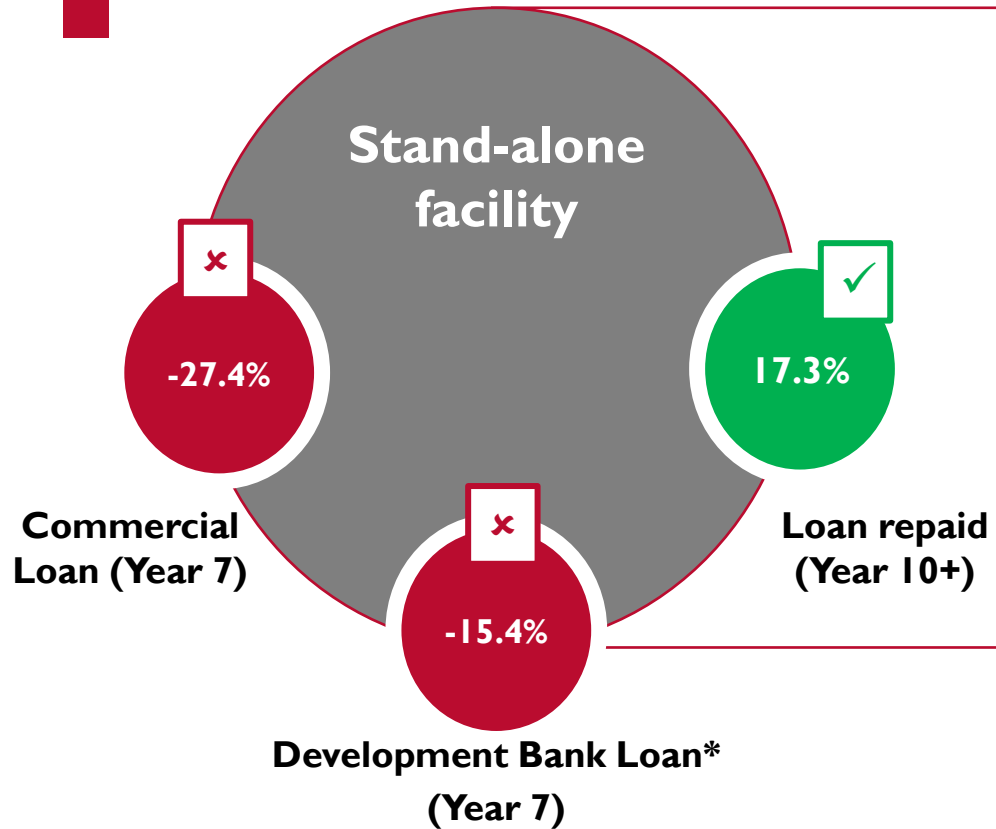
# Finance



# Results

- *Is facility sufficiently profitable after interest to pay off loan at end of loan term (10 years)?*
- *Is facility profitable once loan is paid off?*

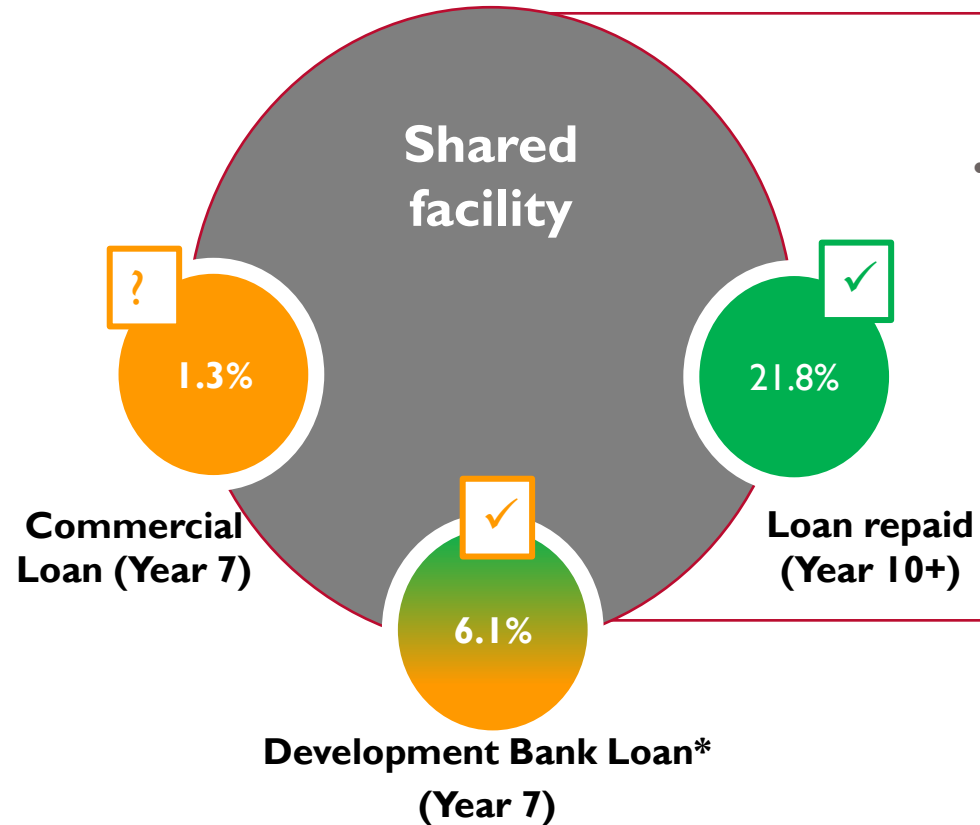
# Stand Alone Facility – Profitability



- Stand-alone facility would not pay off Development Bank loan in 10-year term

\*Assumed 10-year term; Ethiopian Development Bank will offer up to 20 years

# Shared Facility - Profitability



- **Shared facility would pay off Development bank loan in 10-year term even if:**
  - Interest rate increased by 2% (from 9.5% to 11.5%); or
  - Donor price fell by 15% from current UNFPA catalogue price; or
  - Share of South African public sector fell to 20%; or
  - WHO Prequalification, registration or peak market shares delayed by one year

\*Assumed 10-year term; Ethiopian DB will offer up to 20 years

# Summary and Conclusions


- A stand-alone facility is likely not feasible
  - Would not be able to pay off loan within a 10 year term
- A shared facility is likely feasible
  - Profits are sufficient to withstand changes to key assumptions.
- Key points not addressed in this business case are:
  - Challenges in accessing foreign currency to pay for Active Pharmaceutical Ingredient, Excipient and packaging imports
  - Risk of expropriation or of instability in the selected country of manufacture
  - Potential expansion of subcutaneous presentation of MPA (MPA-SC) into South Africa or further reductions in donor prices paid in FP2020 Sub-Saharan African countries
  - The availability of matching funding (i.e. banks require ~50% co-investment)
  - The availability of a willing manufacturer to share facility/technological expertise
  - Expansion and sales beyond Sub-Saharan African FP2020 and South Africa
- Further investigations with local manufacturers and development banks may be appropriate



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The USAID Global Health Supply Chain Program-Procurement and Supply Management (GHSC-PSM) project is funded under USAID Contract No.AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and cost-effective health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a healthier future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national supply chain systems, and provides global supply chain leadership. For more information, visit [ghsupplychain.org](http://ghsupplychain.org).

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