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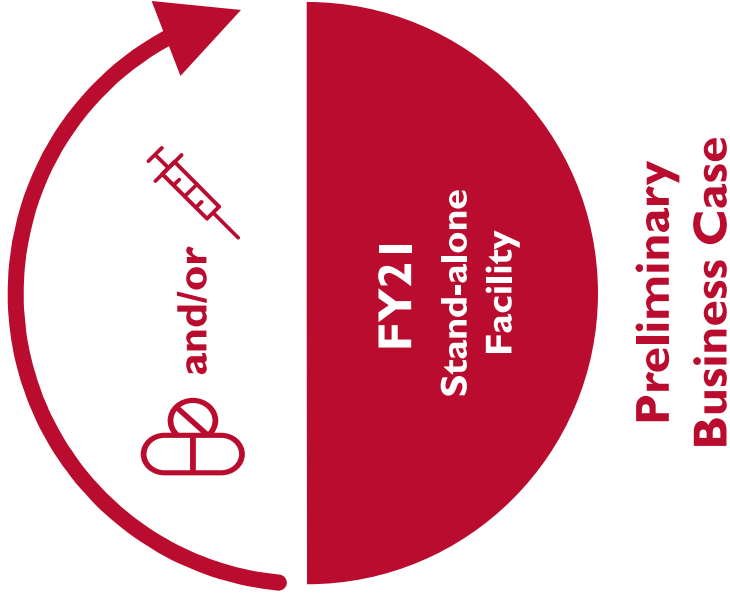
Revised assessment of the feasibility of local manufacturing of an injectable contraceptive in SS



Agenda

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

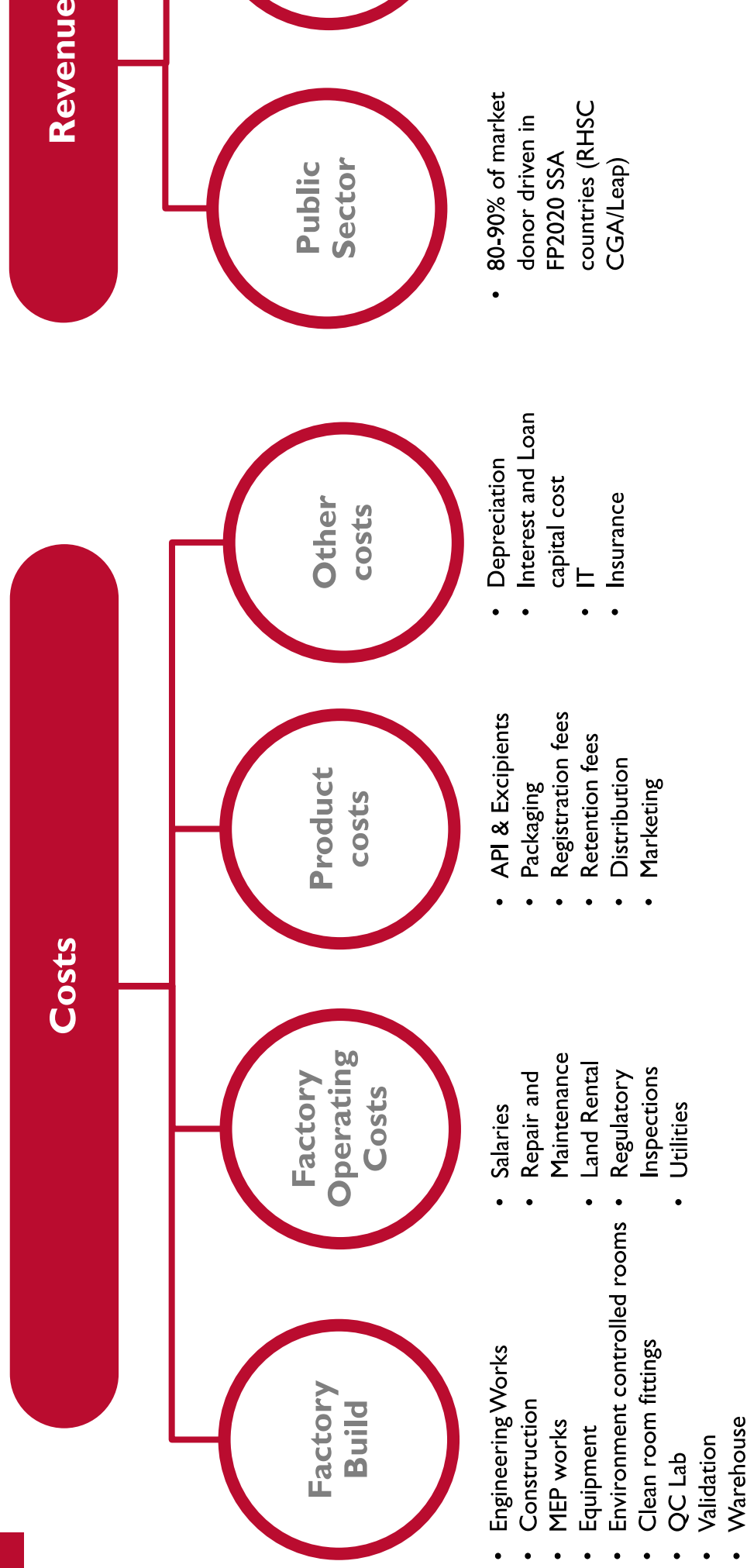
Project Background



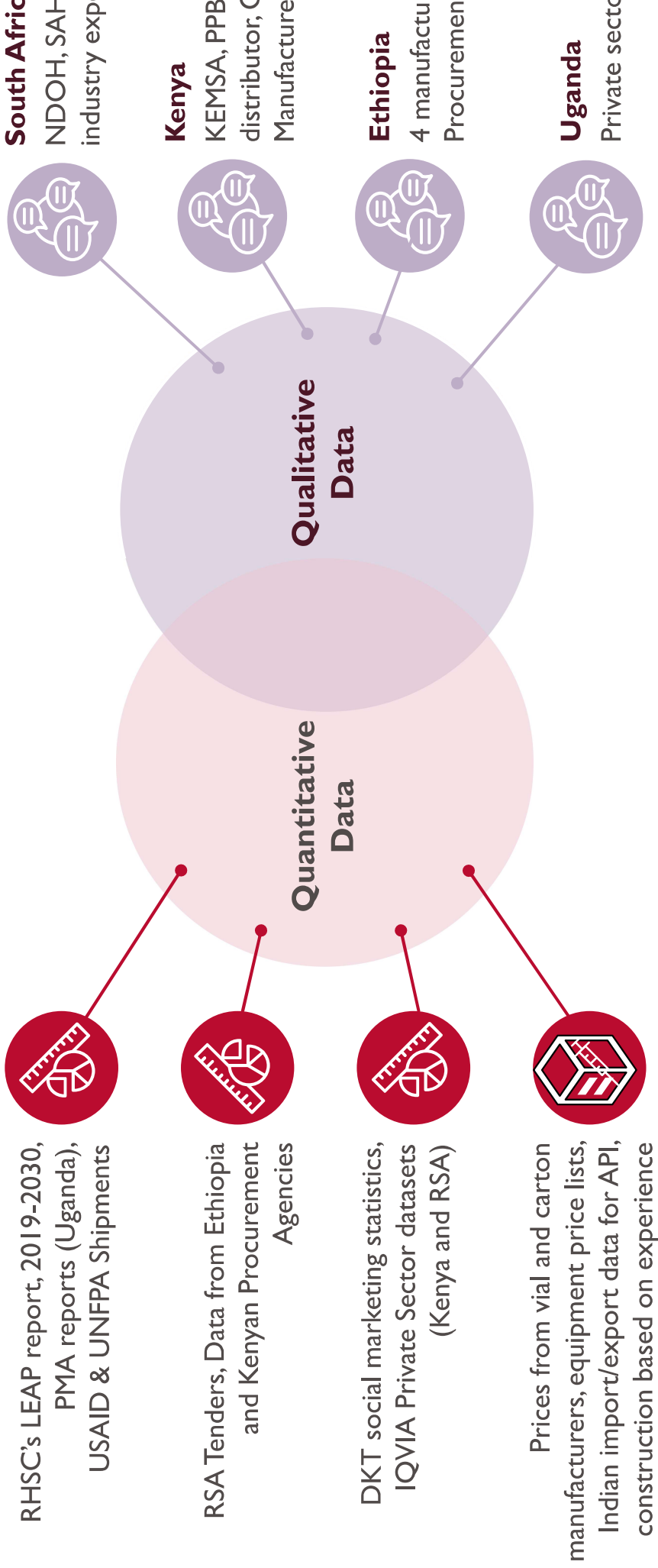
**Preliminary
Business Case**

**Revised
Business Case**

Approach



Data sources



Key assumptions

- Factory Build
- Operating Costs
- Revenues
- Finance costs

Factory Build



MPA in vial only (MPA-IM), for FP2020 SSA countries plus



To manufacture ~20% of total FP2020 SSA MPA/ metres. Construction costs estimated based on inflated for 2022.



Manufacturing in campaign (smaller equipment in production and QA staff numbers); 2022 pricing Efficiency assumptions: Vial filling 85%, Packaging



Assume shared black utilities, shared purified water system (distillation unit), shared secondary packaging areas, share some staff will be pre-existing (plant manager etc)

Operating Costs

Staff and Salaries

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

Product

- API and Excipient costs from 2019 Indian imp commodities marked as USP, BP, EP. MPA API pri Farmabios, the PQ'd manufacturer.
- Primary and secondary packaging costs from v manufacturers (leaflet and export carton assume

Utilities

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

Other

- B/E study costs sourced from company specializing in E published WHO PQ MPA-IM submission
- Product registration, retention and site inspection fees costs in RSA and Kenya
- Repair and maintenance, IT and site insurance allowan

Revenues

Market size

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

Marketing & Distribution costs

- Based on industry interviews, expressed as % of sales
- RSA private sector highest at ~33%,
- Public sector and FP2020 SSA private sector lowest

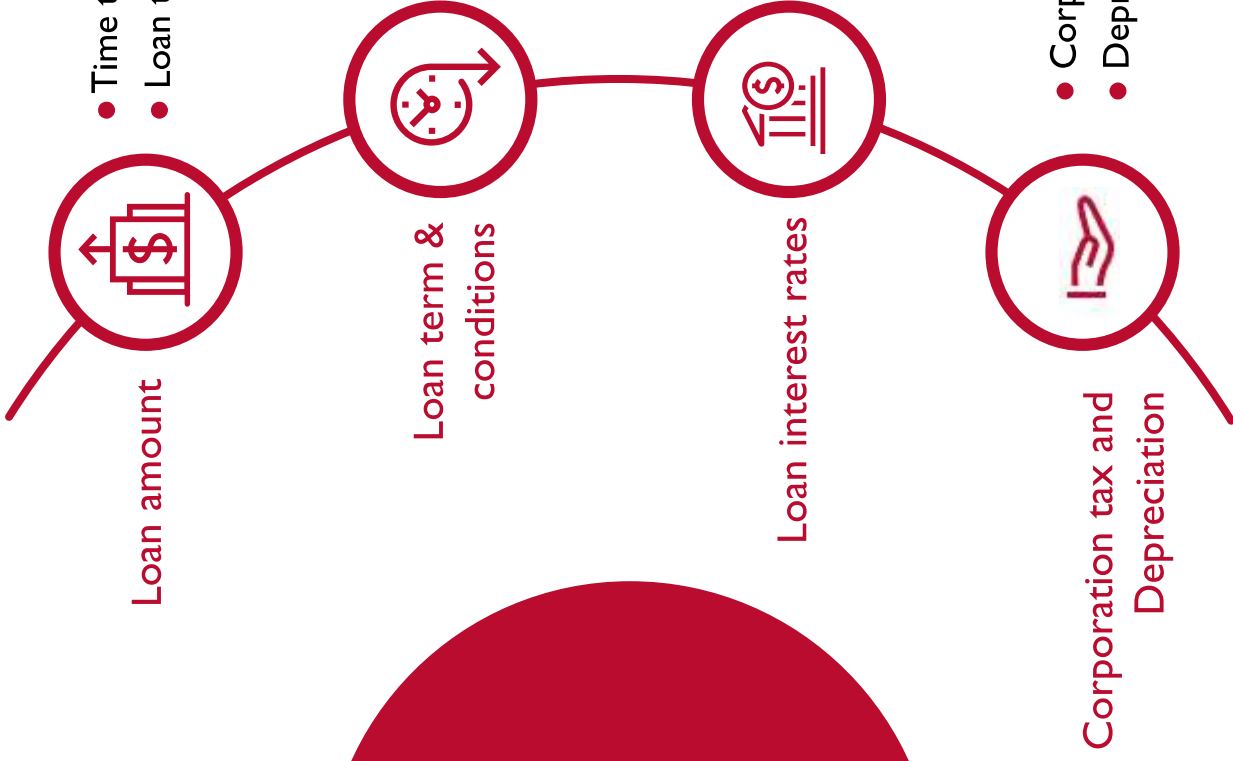
RSA price and market share

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

FP2020 price and market share

- Public sector price based on UNFPA Catalogue price, as a % of sales
- Private sector price based on IQVIA WHS price in Kenya
- Shares achieved within 1 year of achieving WHO PQ (6 months)

Finance



- Time to production and PQ assumed to be 6 years
- Loan to cover capital costs and all operating costs for t

- 10-years assumed
- Assumed permitted to pay off capital and acc

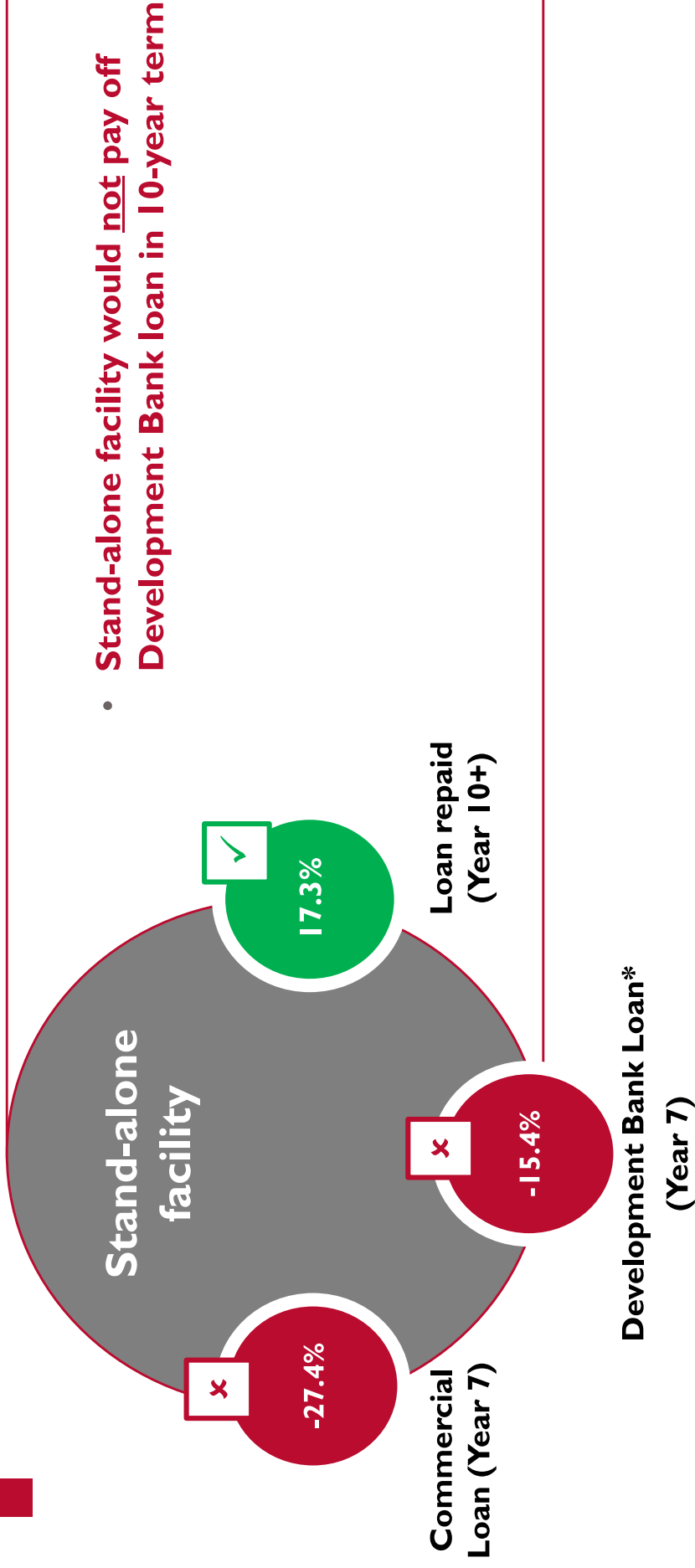
- Based on manufacturer interviews & literature/
- Commercial Bank: 16% per annum
 - Development Bank: 9.5%

- Corporation tax assumed to be 30% (Ethiopian rate) o
- Depreciation as industry norms (13%)

Results

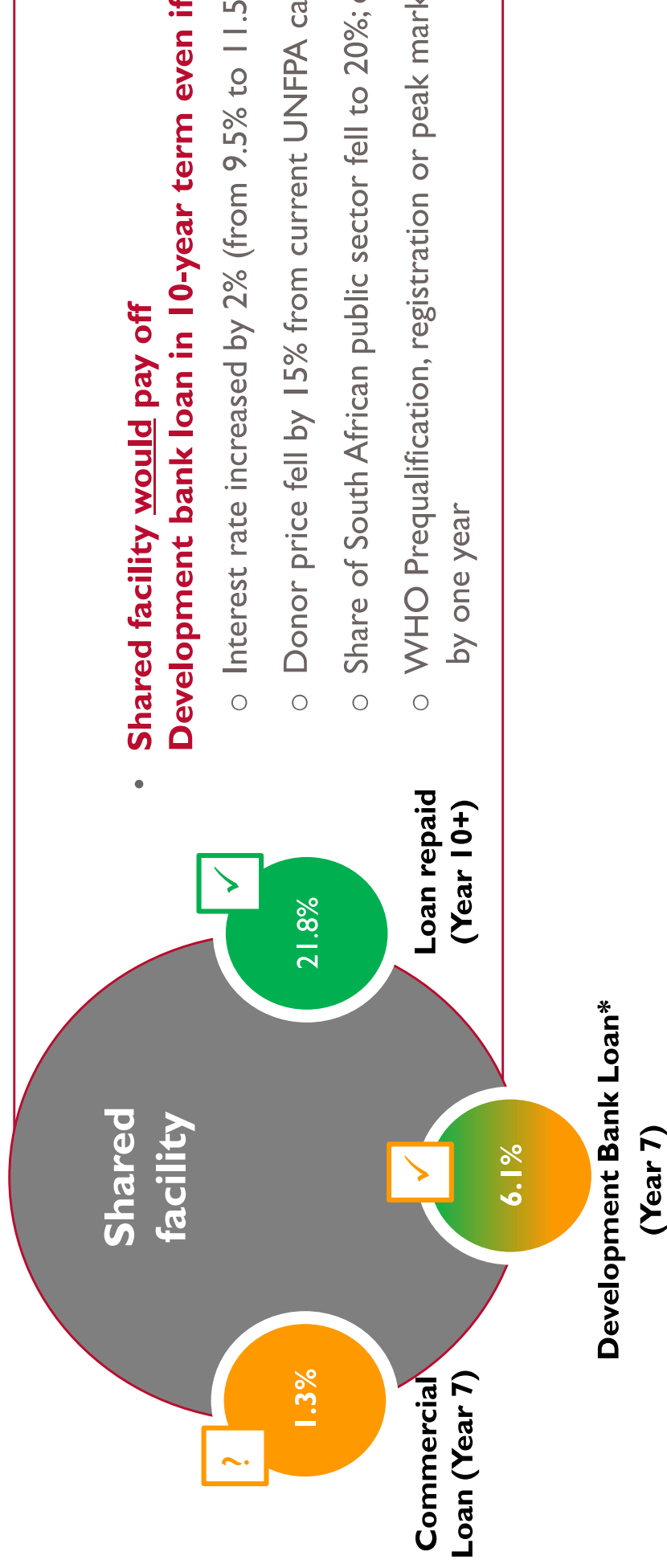
- *Is facility sufficiently profitable after interest to pay off loan at end of loan term (10 years)?*
- *Is facility profitable once loan is paid off?*

Stand Alone Facility – Profitability



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

Shared Facility - Profitability



*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 other key ingredients
 - 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 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 No. AID-OAA-I-15-0004. GHSC-PSM connects technical solutions and proven commercial processes to promote efficient and health supply chains worldwide. Our goal is to ensure uninterrupted supplies of health commodities to save lives and create a better future for all. The project purchases and delivers health commodities, offers comprehensive technical assistance to strengthen national health systems, and provides global supply chain leadership. For more information, visit ghsupplychain.org.

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