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

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

FY21
Stand-alone Facility

Preliminary Business Case

and/or

FY22
Stand-alone or Shared Facility

Revised Business Case
Approach

Costs

Factory Build
- Engineering Works
- Construction
- MEP works
- Equipment
- Environment controlled rooms
- Clean room fittings
- QC Lab
- Validation
- Warehouse

Factory Operating Costs
- Salaries
- Repair and Maintenance
- Land Rental
- Regulatory Inspections
- Utilities

Product costs
- API & Excipients
- Packaging
- Registration fees
- Retention fees
- Distribution
- Marketing

Other costs
- Depreciation
- Interest and Loan capital cost
- IT
- Insurance

Revenues

Public Sector
- 80-90% of market donor driven in FP2020 SSA countries (RHSC CGA/Leap)

Private Sector
- 10-20% of market (RHSC CGA/Leap)
Data sources

Quantitative Data

- RHSC’s LEAP report, 2019-2030, PMA reports (Uganda), USAID & UNFPA Shipments
- RSA Tenders, Data from Ethiopia and Kenyan Procurement Agencies
- DKT social marketing statistics, IQVIA Private Sector datasets (Kenya and RSA)
- Prices from vial and carton manufacturers, equipment price lists, Indian import/export data for API, construction based on experience

Qualitative Data

- South Africa: NDOH, SAHPRA, Nurse clinics, industry experts
- Kenya: KEMSA, PPB, Commercial distributor, Commercial provider, Manufacturer
- Ethiopia: 4 manufacturers, Procurement Agency
- Uganda: Private sector expert
Key assumptions

- Factory Build
- Operating Costs
- Revenues
- Finance costs
Scope

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

Size

To manufacture ~20% of total FP2020 SSA MPA volumes, 850 square metres. Construction costs estimated based on experience but inflated for 2022.

Equipment

Manufacturing in campaign (smaller equipment sizes, slight increase in production and QA staff numbers); 2022 prices.

Efficiency assumptions: Vial filling 85%, Packaging 75%

Shared Facility

Assume shared black utilities, shared purified water system (but not distillation unit), shared secondary packaging areas, shared warehouse) and some staff will be pre-existing (plant manager etc)
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**

**Loan amount**
- Time to production and PQ assumed to be 6 years
- Loan to cover capital costs and all operating costs for this period

**Loan term & conditions**
- 10-years assumed
- Assumed permitted to pay off capital and accrued interest early

**Loan interest rates**
- Based on manufacturer interviews & literature/website
  - Commercial Bank: 16% per annum
  - Development Bank: 9.5%

**Corporation tax and Depreciation**
- Corporation tax assumed to be 30% (Ethiopian rate) on profits
- 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

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

- Development Bank Loan* (Year 7)
  - 17.3%

- Commercial Loan (Year 7)
  - -27.4%

- Loan repaid (Year 10+)
  - -15.4%

*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
  o Would not be able to pay off loan within a 10 year term

• A shared facility is likely feasible
  o Profits are sufficient to withstand changes to key assumptions.

• Key points not addressed in this business case are:
  o Challenges in accessing foreign currency to pay for Active Pharmaceutical Ingredient, Excipient and packaging imports
  o Risk of expropriation or of instability in the selected country of manufacture
  o 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
  o The availability of matching funding (i.e. banks require ~50% co-investment)
  o The availability of a willing manufacturer to share facility/technological expertise
  o 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.

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