Sustainable Vaccines Manufacturing in Africa

Business case simulation for a Fill & Finish Contract Manufacturing Organization in Africa to cover the demand for human vaccines on the continent

April 2023 - Project 20.2155.8-015.00

Presented in Addis Ababa, Global event on enhancing the sustainability of investment for vaccine manufacturing in Africa, 27-29 June 2023.

german cooperation
DEUTSCHE ZUSAMMENARBEIT

Implemented by

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African Union

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

UNITED NATIONS
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AVMI AFRICAN VACCINE MANUFACTURING INITIATIVE

Global event on enhancing the sustainability of investment for vaccine manufacturing in Africa.
27-29 June 2023

United Nations Conference Centre, UNECA,
Addis Ababa, Ethiopia

Commissioned Service Provider: Unizima

Unizima is a biomanufacturing services provider, delivering the expertise and technology needed to enable geographically diversified manufacturing of biologics such as vaccines, monoclonal antibodies and insulin. We are part of the Univercells Group and share its ground-breaking technology and engineering innovations.

We provide a full suite of solutions that includes strategy, product licensing, design and build of facilities and workforce development, allowing clients to accelerate the implementation and operations of their facilities and projects. Our team has extensive global experience in manufacturing strategy, investment profitability analysis, engineering, biologics manufacturing, GMP and Quality Assurance, Regulatory Affairs, supply chain, logistics management, training and recruitment.

Since our inception in 2020, we have served as a trusted partner for biopharma manufacturers, governments and global health agencies to make sustainable biologics production in low- and middle-income countries and emerging markets a reality. We are driven by the end goal of delivering life-changing biologics to people who would otherwise lack access to them.

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Presented by UNIZIMA:

Benoit GREGOIRE, BD Manager & Sr Tech Transfer Expert

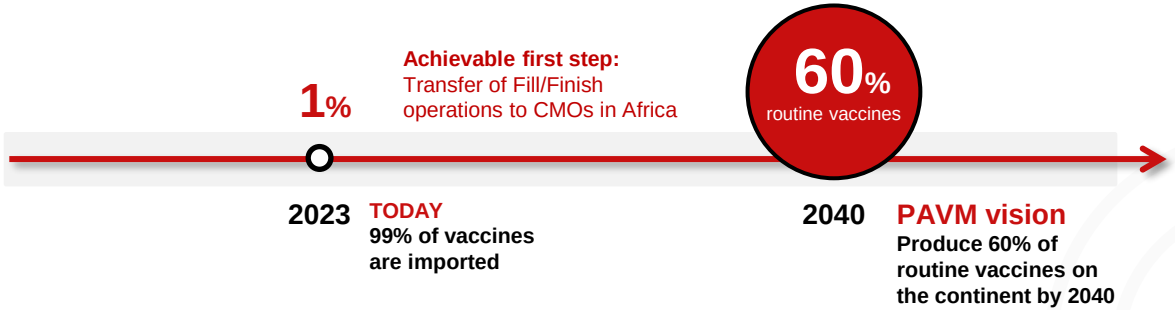
Introduction and Content

GIZ commissioned a study to allow investors and funders to assess the competitiveness of a CMO for Vaccines F/F in Africa (ToR – Sep 2022)

	Scope	Deliverables
1	Facility design for a model greenfield F/F CMO, including lab, office and warehousing space	Process assumptions Capex and Opex estimates
2	Costing simulation tool	Simulation calculator for operating the facility, including ability to enter variable data points for Capex and Opex Costing stimulation for various vaccines from different origins to fill capacity Comparative import costing calculation for same vaccines, including freight
3	Recommendations and strategic advice for sustainable CMO plants in Africa	Optimal capacity and product mix, including mono vs multi product lines Optimal technology choice Glass vs BFS Optimal number of CMO sites based on financial viability

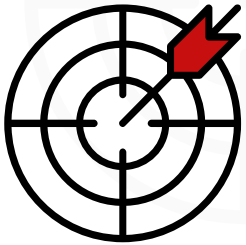
The Partnership for African Vaccine Manufacturing set out the vision to localize the manufacturing of 60% of vaccines used in Africa by 2040 *

Commitment to localize vaccine manufacturing, to **improve the resilience** of Africa's healthcare systems



Capacity needed to achieve PAVM goal

2.1 billion **doses** → 60% → **280** million **containers*** → Should be allocated to a network of circa **5** factories



needed in 2040

*as per number of doses per container defined by PAVM including diluents for freeze-dried vaccines

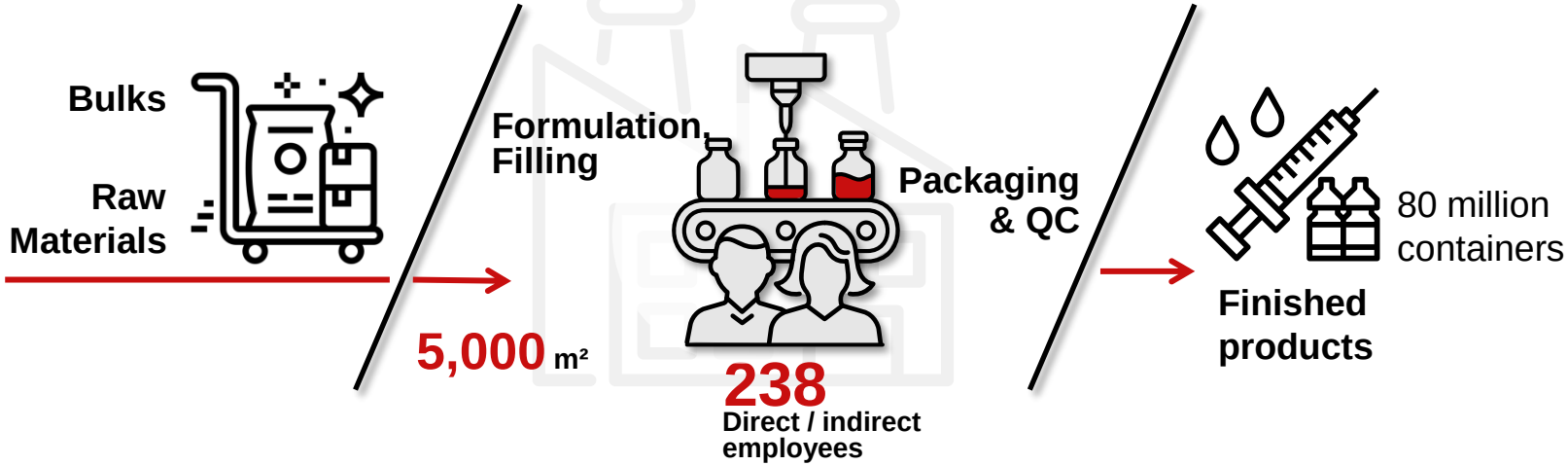
- Leverage economies of scale
- Leverage existing investment and infrastructure on the continent

* Refer to annex 1 for the African market vaccines demand; refer to annex 2 for the F/F factories capacities

Part 1 - Facility design for a model greenfield F/F CMO

- Process assumptions
- Capex and Opex estimates

The model F/F factory used for the baseline financial model includes 4 filling lines & three filling technologies (liquid vaccines in glass vial, freeze-dried vaccines in glass vial and oral vaccines / diluents in BFS tube)*



Key project **parameters:**
Medium F/F factory:

CAPEX
89 million EUR

Project Management & Tech Transfer expenses
up to 35 million EUR
for 16 vaccines & diluents

TIME
5 years
to first commercial production

*** Note**: see annex 3 for F/F factory lay-out & process flows chart; see annex 4 for F/F factory project planning; inputs and assumptions can all be changed and tested in the model .

Part 2 – Costing simulation tool

- Simulation calculator for operating the facility, including ability to enter variable data points for Capex and Opex
- Costing stimulation for various vaccines from different origins to fill capacity
- High level comparative import costing calculation for same vaccines, including freight

The Excel financial simulation model has been constructed in a flexible way based on inputs and assumptions which can be changed to test multiple variables and sensitivities*

CapEx inputs (EUR, +/-25%)

- Engineering studies, assumed to be supplied by a mix of India based and Europe based experts.
- Construction & black utility costs estimated per m² based on various investments executed
- Clean utility & process equipment costs based on quotations from renowned European suppliers or cost estimations from internal experts
- Contingencies +15%, transport +10%, import duties +0%, Qualifications +15%, based on industry experience

PM / Tech Transfer expenses & OpEx inputs (EUR)

- Project Management & Tech Transfer support based on industry experience
- Tech Transfer raw materials & consumables based on industry experience
- F/F factory Org Chart, headcounts and number of expatriates based on industry experience; baseline salaries as per Kenya' data
- General & Admin expenses based on industry experience

Raw Materials inputs (EUR)

- Filling raw materials from Indian suppliers' quotations
- Packaging raw materials based on industry experience
- Single use systems, formulation (except bulks) and QC materials based on industry experience

Financial parameters' outputs

- Net Present Value, Internal Rate of Return, Cumulated Free CashFlow and Payback period
- F/F costs per container / dose

*** Note:** see annex 5 for the Excel financial model' instructions and financial parameters definition

The baseline financial model shows only a modestly positive net present value (NPV), before incentives or CapEx subsidies for that model factory

Assumptions

- **Factory location:** medium factory, East Africa
- **F/F capacities:** 80 million containers per year, 4 F/F lines, 9 SKUs
- **CMO F/F costs:** + 5% markup
- **WACC:** 11.33 %
- **Time period:** 2024 to 2040

- **Project costs:**
  - CAPEX: 89 million EUR
  - Investment expenses: 35 million EUR
- **Annual operational costs:**
  - Raw Materials at cost
  - Salaries: 6.5 million EUR
  - Energy: 1.5 million EUR
  - G&A: 2.3 million EUR

Financial parameters*

CONCLUSION: Net Present Value estimated at + 449 K EUR

Internal Rate of Return	Payback period	Cumulated Free Cash Flow
11.48%	16 years	42 million EUR

*** Note**: refer to annex 5 for financial parameters' definition

There are four main profitability drivers with very high impact on the NPV: capacity utilization, cost of raw materials, salaries and cost of capital investment*

Capacity utilization

IF vaccines volumes down by -18% (to 68 million containers)

THEN NPV down by -14 million EUR

Raw Materials costs

IF Filling Raw Materials costs down by -10%

THEN NPV up by +10 million EUR

Salaries

IF salaries up by 20%

THEN NPV down by -9 million EUR

Capital Expenditure

IF process equipment costs down by -15%

THEN NPV up by +3 million EUR

IF process equipment costs up by +15%

THEN NPV down by -3 million EUR

WACC

IF WAAC up to 15%

THEN NPV down by -8 million EUR

CONCLUSION

- F/F capacities utilization should be optimized
- Global purchase contracts should be negotiated to reduce raw materials prices
- Salaries budget should not be underestimated
- Pool orders of process equipment across several factories to bring discount on CapEx
- Lower costs of capital / loan to reduce WACC

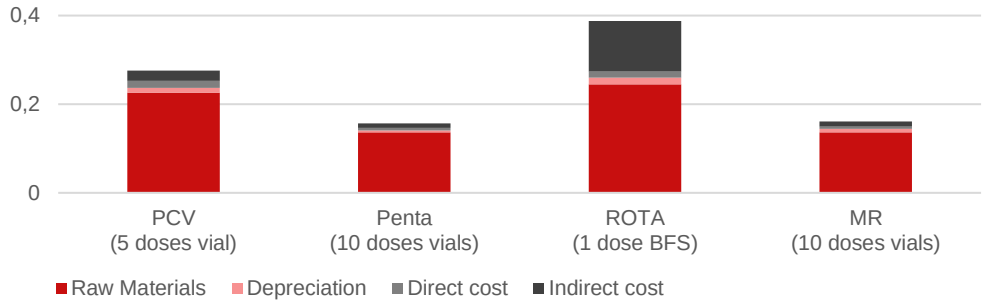
*** Note:** refer to annex 6 for simulations summary' table

The financial model provides the vaccines F/F costs estimations in the model factory, for 18 vaccines and 2 diluents clubbed into 9 presentations*

Assumptions

- **F/F factory' CAPEX:**
  89 million EUR depreciated on 20 years for building and 10 years for equipment
- **PM Tech Transfer expenses:**
  35 million EUR spread over 6 years
- **Annual Operational Expenditures:**
  10.3 million EUR (Kenya' salaries and energy costs)
- **Raw materials:**
  Fill / Pack from India, others from Europe
- **F/F capacities:**
  80 million containers, used at 90% for glass vials, 50% for BFS
- **NPV:**
  +449 K EURO

Estimated F/F costs of four main vaccines presentations (EUR per dose)



CONCLUSION

- F/F costs impacted at +/- 85% by raw materials and half with Filling raw materials
- Indirect costs represent +/-10%
- Direct costs and depreciation with minor weights

*** Note:** Annex 9 includes a detailed F/F costs summary table

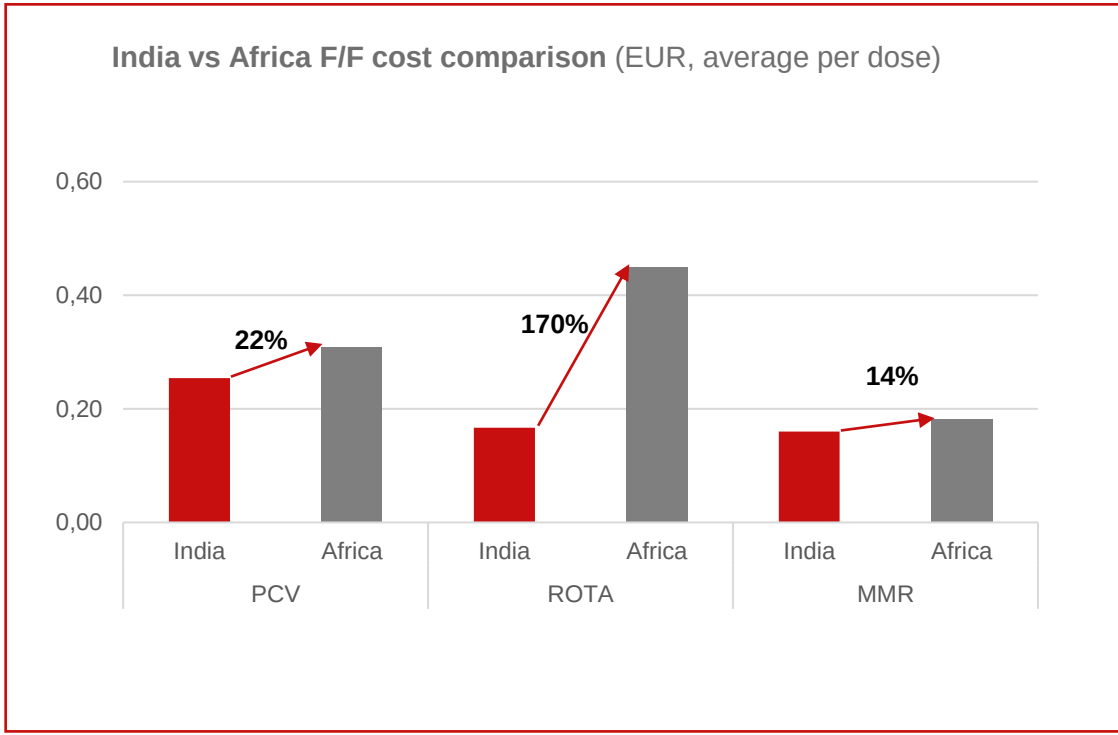
Based on these estimations from the model factory, vaccines F/F costs in Africa remain higher than in India, before considering transport costs or any CapEx subsidy

Assumptions

Indian F/F costs estimated based on intelligence data, vaccines industry experience and F/F costs extrapolated from the UNICEF vaccines' procurement prices*:

- **PCV 10 antigens** (5 doses vial): Y2023 price = 2,9 USD per dose; F/F costs from to 7,5 to 10%
- **ROTA 1 antigen** (1 dose BFS): Y2023 price = 0,95 USD per dose; F/F costs from 15 to 20%
- **MMR 3 antigens** (10 doses vial): Y2023 price = 1,70 USD per dose; F/F costs from 12 to 15%

* From UNICEF Supply Division, Vaccine price data in USD, from Indian suppliers



Disclaimer: The figures presented in this slide are tentative estimations

Imported bulks (rather than finished packed vaccines) bring substantial shipping cost savings (preliminary conclusion, deeper logistics analysis to be done)

TODAY

- Large volumes of finished packed vaccines* shipped from India to UNICEF' distribution hubs
- UNICEF caring of logistics to African countries

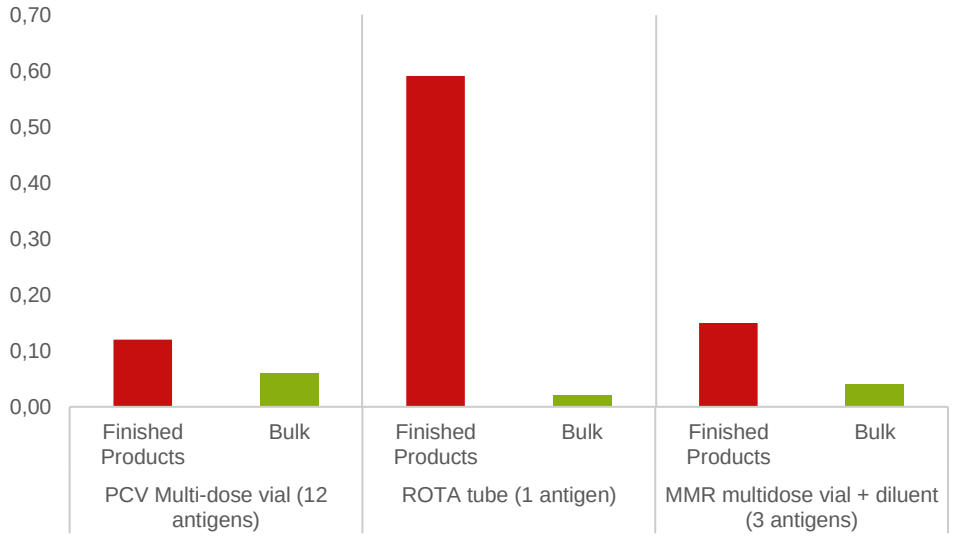
CONCLUSION

Smaller volumes of vaccines' bulks* shipped from India to African CMO factory:

- **PCV** (12 antigens / bulks):
  5x less volumes (than 5 doses vial)
- **ROTA** (1 antigen / bulk):
  44x less volumes (than 1 dose BFS)
- **MMR** (3 antigens / bulks):
  6x less volumes (than 10 doses vial + diluent)

African CMO factory to supply to local Health Ministry and local airport; UNICEF caring of logistics to regional countries

Estimated shipping costs of finished vaccines vs bulks (EUR per dose)

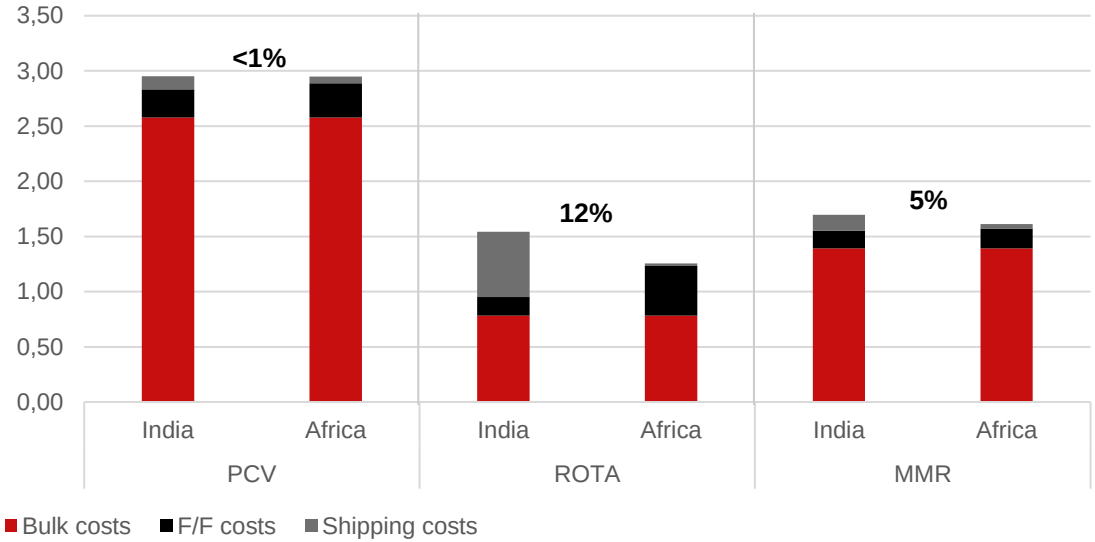


* Shipping costs in passive cooling pallet (+2+8°C for finished vaccines & -25°C for bulks) as per current air freight tariffs + insurances – based on quotation from one shipping company

Disclaimer: The figures presented in this slide are tentative estimations

Vaccines produced by the African CMO F/F factory could be cost competitive to UNICEF once shipping costs are considered

Estimated total costs to UNICEF (EUR, average per dose)



Vaccines produced by African CMO F/F factory would bring to UNICEF net costs savings **thanks to lower bulks shipping costs off-setting the higher F/F costs**

Disclaimer: The figures presented in this slide are tentative estimations

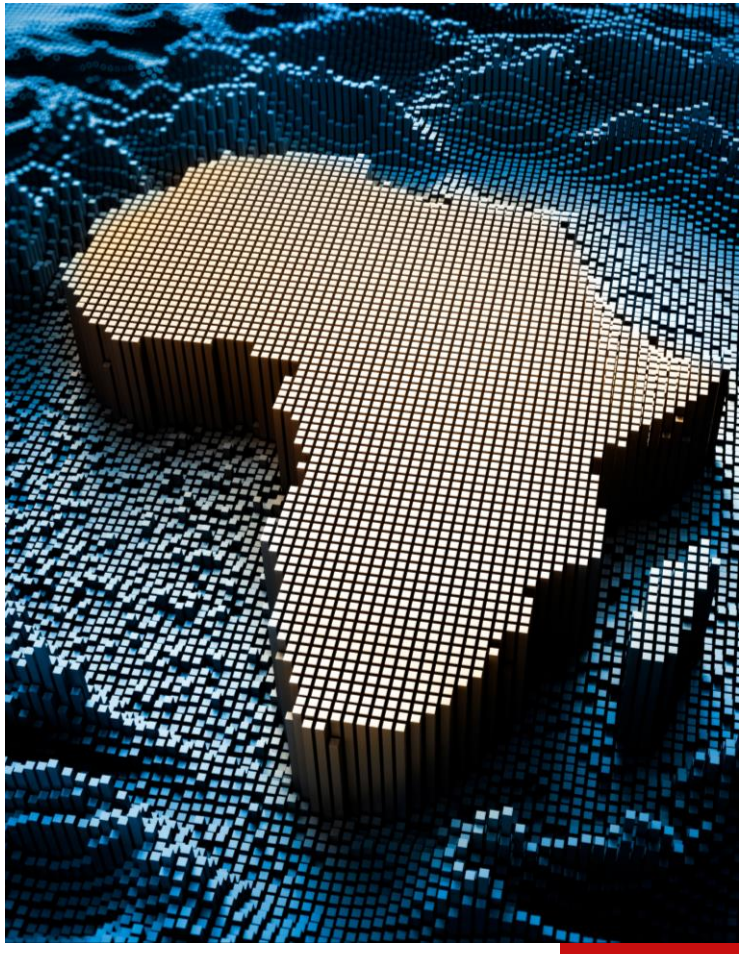
Conclusions from the study

- Fill/Finish costs in Africa are higher than in India, but difference could be compensated by savings in **intercontinental shipping costs**
- Ambition of 60% Vaccines manufactured in Africa by 2040 **could be achieved**
  - Requires top-down approach with at least **5 small and medium factories,** either new or leveraging existing F/F capacity *
  - **89 million EUR** (CapEx) + **35 million EUR** (OpEx & Tech Transfer) for one medium-sized greenfield factory
- Executing this strategy must build on existing and already planned Drug Product infrastructure in Africa to avoid over-capacity.
- Optimized greenfield factory design includes 2 glass vial filling lines, 1 BFS tube filling line, and 1 filling & freeze-drying line
- Lead time to commencing GMP production = **5 years**
- **Raw materials** (specifically containers) account for **85%** of F/F costs
- Base case simulation leads to a **modestly positive NPV**
- Profitability mainly influenced by **capacity utilization**, **raw material costs**, **capital investment**

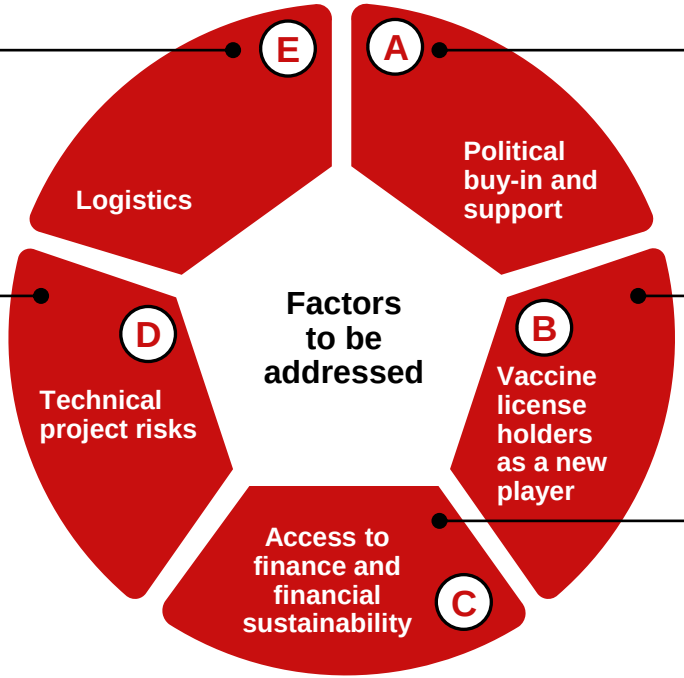
* See Annex 11, PATH / CHAI report about existing vaccines F/F capacity in Africa

Part 3 - Recommendations and strategic advice for sustainable CMO plants in Africa

- Optimal capacity and product mix, including mono vs multi product lines
- Optimal technology choice Glass vs BFS
- Optimal number of CMO sites based on financial viability



Multiple factors must be addressed pro-actively to enable success of an investment in an African Vaccines Fill/Finish facility



- Ensure reliable and efficient supplies of raw materials
- Close gaps in cold chain transportation networks

- Strong willingness to continuously support local biomanufacturing
- Building competence of local regulatory authorities
- Providing access to local talent – education programs

- Complexity of vaccine manufacturing and modern factories requiring thorough competence and project execution
- Ability to demonstrate successful transfer

- Leveraging well established international networks
- Proven quality standards, certified through WHO prequalification
- Become a new CMO with proven credibility

- Access to funding at low interest rates, long payback periods
- Government incentives to compensate for higher manufacturing cost
- Long-term advance purchase commitments

Use facility to manufacture other biopharmaceutical products to ensure high capacity utilization rate and improve profitability

Biotherapeutics,
Insulins,
Small volume parenteral

- **Biotherapeutics:**+/- 5 million vials free capacities on glass vials F/F lines
- **Insulins:** no free capacities unless vaccines demand reduced
- **SVPs:** +/- 42 million free capacities on BFS F/F line

- Minor investment in additional filling format
- Tech transfer costs

- Biotherapeutics: additional net revenues, NPV up to >1,5 million EUR
- Insulins: prevent revenue drop in case of reduced vaccines demand
- SVPs: additional net revenues, NPV up to >5 million EUR

*__Note:__ refer to annex 7 for other revenues' summary & pandemic readiness

Engage in the development of Blow-Fill-Seal (BFS) presentations for injectable vaccines to enable substantial cost reduction in the longer term

CURRENT SITUATION

- Injectable vaccines use glass containers
- Cost mainly driven by raw materials (glass vials, stoppers)
- Oral vaccines in BFS have drastically lower manufacturing costs driven by raw materials
- Feasibility of BFS presentation shown for multiple vaccine types

OPPORTUNITY

- **Blow-Fill-Seal technology:** container formed by injection of LDPE resins at high temperature into a mold, then product filled, and container closed
- **Development of multi-dose BFS containers** to be completed
- **Development pathway:**
  - Confirm feasibility for each type of vaccine
  - Confirm user acceptance
  - Development cost per vaccine: 1.5 million EUR
  - Time to launch: 3 to 4 years

RECOMMENDATION

- Engage vaccine license holders
- Seek support of global health authorities e.g. WHO and other stakeholders
- Development of BFS technology to be sponsored by supranational organizations

CONCLUSION

- Higher CAPEX to fill liquid vaccines in BFS but,
- NPV increased to + 3 million EUR
- F/F **costs multi doses BFS reduced by +/- 40%**

Avoid too much complexity and limit risks: Focus initial efforts on a mid-size facility with optimized conditions

- Allocation of resources to one F/F factory to limit complexity and risks
- Integration of existing local F/F capability and capacity, if available
- Use of a business-led approach with focus on financial sustainability
- Facility designed to be flexible
  - Ability to manufacture variety of different products enables to cope with demand variability
  - Ensuring high-capacity utilization
- Concept optimized for profitability and financial sustainability
    - Product mix: Liquid products offer better return than freeze-dried products
    - Location: West Africa provides a lower energy and salary cost than most other regions in Africa
    - Drive for reduction of raw material cost through purchase agreements and/or local sourcing
    - Drive for reduction of CapEx

Disclaimer

This report has been prepared based on Unizima's contract with GIZ for a study on Sustainable Vaccines Manufacturing in Africa – Business Case Simulation for Fill & Finish Contract Manufacturing Operations (project: 20.2155.8-015.00).

The study had the following objectives only:

1) Capex and Opex of a CMO Vx Formulation, Fill & Finish (FF/F) factories for both glass and BFS vials

2) Costing simulation tool to assess financial viability and compare local production to import

3) Provide recommendation and strategic advice for sustainable CMO plants across Africa

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Abbreviations

BFS: Blow-Fill-Seal
BLA: Biologic License Applications
CAPEX: Capital Expenditures
CMO: Contract Manufacturing Organization
EUR: Euro
F/F: Fill & Finish
FCF: Free Cash Flow
G&A: General and administrative expenses
GMP: Good Manufacturing Practices
LDPE: Low-Density-PolyEthylene
LMIC: Low and Middle Income Countries
mAbs: Monoclonal Antibodies
Mio: millions
NCDs: non-communicable diseases
NPV: Net Present Value
OPEX: Operational Expenditures
PM: Project Management
QC: Quality Control
QA: Quality Assurance
SKU: Stock-Keeping Unit
WACC: Weighted Average Cost of Capital

Annexes

Note: for further details, refer also to the detailed Word study “Sustainable vaccines manufacturing in Africa” and the attached Excel financial model

Annex 1 – African market vaccines demand (1/2)

1 Vaccines prioritized to calculate market demand and manufacturing capacity

- **Partnership for African Vaccines Manufacturing (PAVM) Framework for Action**
- **GAVI**'s 2022 publication titled **Sustainable Vaccines Manufacturing in Africa**

LEGACY

- Pentavalent
- Tuberculosis
- Measles-Rubella
- Yellow fever
- Oral cholera vaccine
- Typhoid
- Meningococcus A Conjugate
- Polio
- Tetanus Diptheria

EXPANDING

- Human papillomavirus
- Pneumococcal conjugate vaccine
- Rotavirus
- Malaria
- HIV
- Multivalent meningococcal vaccine

OUTBREAK

- Ebola
- Influenza
- Chikungunya
- Rift Valley
- Lassa fever
- Disease X
- Covid-19

ADDITIONAL*

- Rabies
- Dengue
- Varicella

*Added based on Unizima expert analysis

KEY TAKEAWAY

2.1 billion doses would be required annually by 2040 **to meet 100%** of the estimated vaccines' demand in Africa (excluding outbreak vaccines)

Annex 1 – African market vaccines demand (2/2)

2 Container volumes

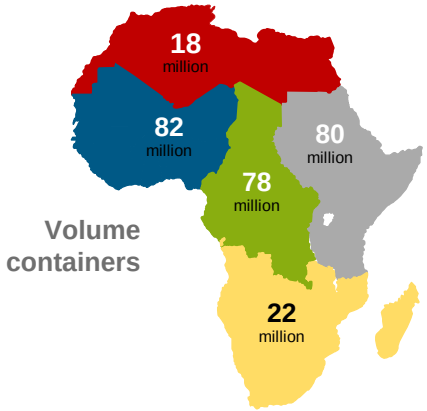
The baseline assumption is that vaccines would be supplied as per PAVM presentations: liquid with 1, 2, 4, 5 or 10 doses; freeze-dried with 1 or 10 doses; oral with 1 dose and diluents with 1 or 10 doses

Containers volumes (million - 2040)	**Liquid vaccines in glass vials**	**Oral vaccines & diluents in BFS tubes**	**Freeze-dried vaccines in glass vials**	**Total containers volumes**
Total (100% vaccines demand)	215	200	51	**466**
Total (60% vaccines demand)	129	120	31	**280**

3 Regions

Proposal for one F/F factory in each of the 5 regions:

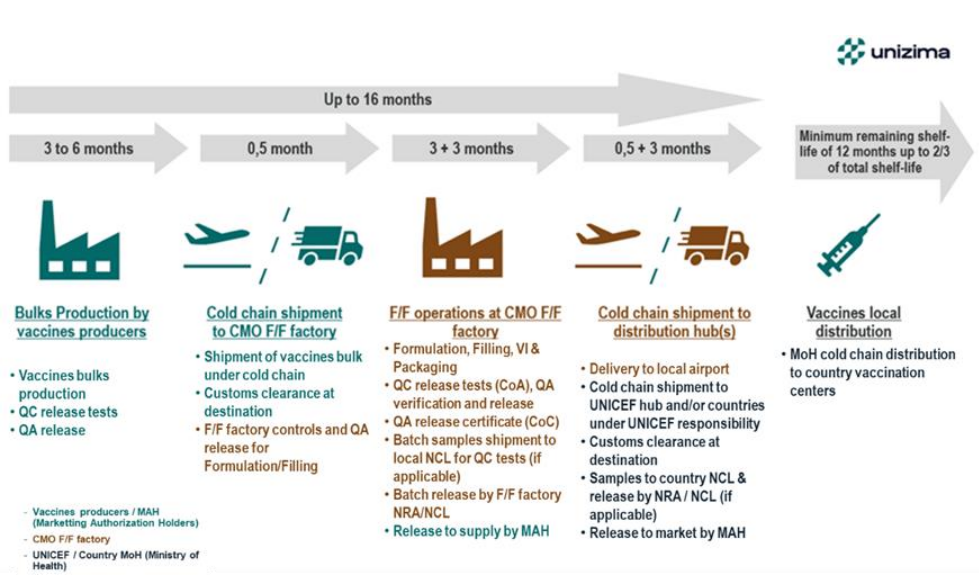
- Manufacturing all vaccines for the local/regional market (except for vaccines with low demand)
- Medium size F/F factory to combine economy of scale with limitation of risks and complexity
- Medium size F/F factory in the East and two in the West (one for Central markets)
- Smaller F/F factory leveraging existing F/F capacities in North and South Africa

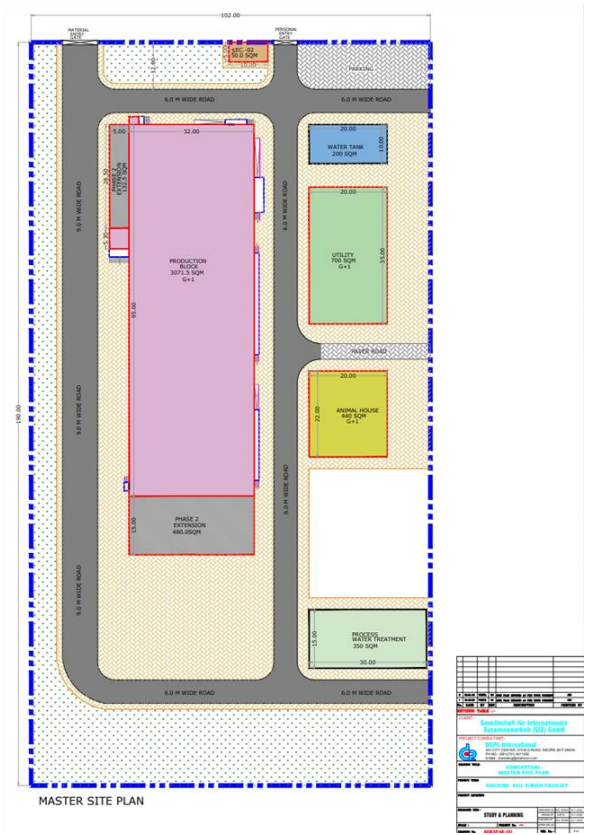


Annex 2 – F/F factories capacities as per African market demand

	African markets demand in Y2040 - Volumes allocation to the five F/F factories assuming 60% - million containers		Central Africa market with West region factory nr1	East Africa market with East region factory	North Africa market with North region factory	South Africa market with South region factory	West Africa market with West region factory nr2	Total Africa
1	Demand liquid vaccines		at 60%	at 60%	at 60%	at 60%	at 60%	at 60%
		Total liquid vaccines demand	20,28	41,62	13,83	11,70	41,62	129,04
	Demand allocation per factory	Penta - 10 doses vial	1,49	3,09	1,29	1,10	3,09	10,06
		IPV - 10 doses vial	0,93	1,92	0,80	0,68	1,92	6,24
		TD - 10 doses vial	0,75	1,54	0,65	0,55	1,54	5,03
		PCV - 4 doses vial	3,20	6,60	2,77	2,34	6,60	21,51
		HIV - 10 doses vial	0,99	2,05	0,86	0,73	2,05	6,67
		HPV - 1 dose vial	3,24	6,70	2,81	2,38	6,70	21,82
		MenCWY - 1 dose vial	4,77	9,86	4,13	3,50	9,86	32,12
		Typhoid - 5 doses vial	2,34			1,66		4,00
		Malaria - 2 doses vial	12,96			8,64		21,60
	Total liquid vaccines demand allocated per factory		30,66	31,75	13,31	21,57	31,75	129,04
2	Demand freeze-dried vaccines		at 60%	at 60%	at 60%	at 60%	at 60%	at 60%
		Total freeze-dried vaccines demand	3,98	10,08	3,03	3,04	10,37	30,51
	Demand allocation per factory	BCG - 20 doses vial		1,93			2,31	4,24
		MR - 10 doses vial		5,88			7,03	12,91
		Rabies - 1 dose vial			4,24			4,24
		Varicella - 1 dose vial	2,18					2,18
		YF - 10 doses vial	3,21					3,21
		MenA - 10 doses vial	3,18					3,18
		Dengue - 10 doses vial			0,54			0,54
	Total freeze-dried vaccines demand allocated per factory		8,57	7,81	4,78		9,34	30,51
3	Demand BFS oral vaccines and diluents		at 60%	at 60%	at 60%	at 60%	at 60%	at 60%
		Total BFS vaccines + diluents demand	21,20	36,58	14,53	9,63	38,11	120,06
	Demand allocation per factory	Rota - 1 dose BFS tube	11,25	33,00			31,50	75,75
		Cholera - 1 dose BFS tube	13,80					13,80
		Diluent 20/10 doses BFS tube	11,57	5,84			7,37	24,78
		Diluent 1 dose BFS tube (Rabies / Va	1,78	1,97			1,97	5,72
	Total BFS vaccines demand allocated per factory		38,41	40,81			40,84	120,06
		Total F/F demand per factory	77,64	80,37	18,10	21,57	81,93	279,60

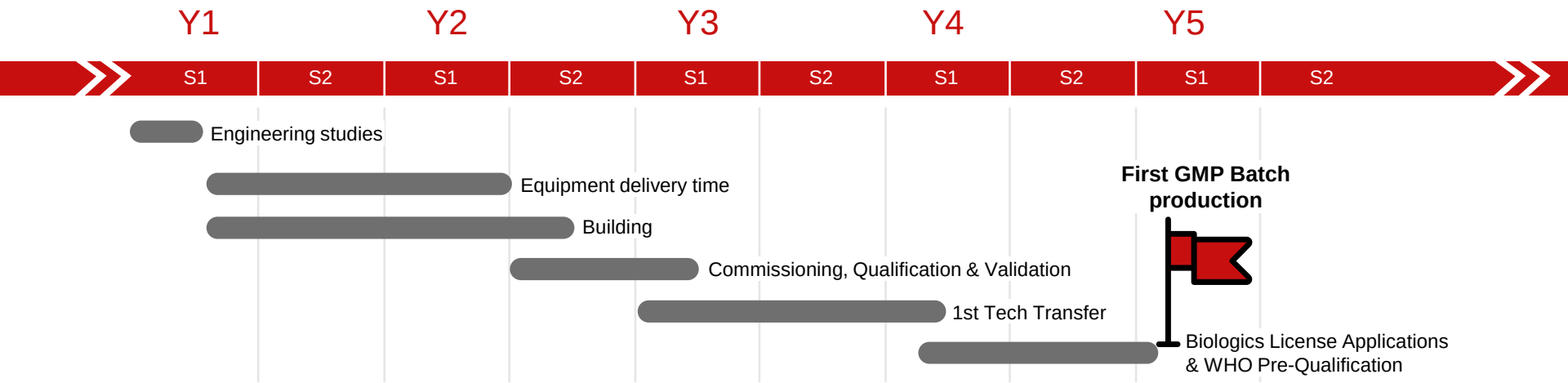
Annex 3 – F/F factory process flows chart & conceptual lay-out &





- **Medium F/F factory**: green field, +/- 5000 sqm, 4 F/F lines, 80 millions containers per year, 89 million EURO Capex
- **Smaller F/F factory**: brown field, 2 F/F lines added to existing facilities (1 liquid glass vials and 1 freeze-dried glass vials or 2 liquid glass vials), leveraging existing QC labs, warehouses, packaging, …), 22 to 26 million containers per year, 32 million EURO Capex

Annex 4 – F/F factory project planning (medium factory)



- **Medium F/F factory**: 3 to 4 Tech Transfers per year, up to Y8 for last one
- **Smaller F/F factory**: expected to be one year faster, depending on building / equipment available in existing facilities

Annex 5 – Excel model instructions and financial parameters' definitions

Excel inputs' tabs

Tab "1.1 Pilot sheet" to select the F/F factory and the F/F lines

Tab "1.2 Pilot sheet details" and tabs "5.1 to 5.7" to change the F/F factory key parameters

Excel results' tabs

Tab "2.1 FinPlan" with the four main financial parameters: NPV, IRR, CashFlow and Payback period

Tab "2.2 FF costs per SKU" with estimated F/F costs per container / dose

Financial parameters

Net Present Value: assess the current value of future earnings using a specific discount rate (WACC)

Internal Rate of Return: discount rate that makes the NPV of a project equal to zero

Payback Period:

number of years until the factory cash position becomes positive

Cumulated Free Cash Flow: sum of all free cash flows calculated in the model throughout the years of the model

Annex 6 – Simulations' summary table
(5 F/F factories, East F/F factory, West nr2 F/F factory)

	Vaccines F/F factories - Key financial parameters	Baseline	Simulation 1 Vaccines volumes down by about 18% (no HIV and MenCWY)	Simulation 2 Project implementation extended by one year	Simulation 3 No freeze-dried vaccines	Simulation 4 HC and/or salaries costs increased by 20%	Simulation 5 Energy costs increased by +50%	Simulation 6 vials filling raw materials costs decreased by -10%	Simulation 7 Process equipment costs down by 15%	Simulation 8 Liquid injectable vaccines in multi-doses BFS tubes
		5 factories: 332m EUR Capex, 280m containers -- 1 factory: 89m EUR Capex, 80m	5 factories: 332m EUR Capex, 240m containers -- 1 factory: 89m EUR Capex, 68m containers	same as baseline	5 factories: 261m EUR Capex, 250m containers -- 1 factory: 75m EUR Capex, 72m containers	same as baseline	same as baseline	same as baseline	5 factories: 296m EUR Capex, 280m containers -- 1 factory: 80m EUR Capex, 80m containers	5 factories: 357m EUR Capex, 240m containers -- 1 factory: 97m EUR Capex, 80m containers
5 factories	NPV (6x EBITDA) -	28.028	(19.134)	1.880	31.395	(3.892)	17.828	62.367	38.702	35.905
East	K EUR	449	(13.590)	(6.708)	3.736	(9.737)	(3.993)	9.849	3.689	3.078
West nr2		14.301	2.673	7.713	13.376	6.685	13.172	23.695	16.898	17.386
5 factories	Profitable from -	2031	2031	2031	2031	2031	2031	2030	2031	2031
East	Year	2031	2032	2031	2031	2031	2031	2030	2031	2031
West nr2		2029	2031	2029	2029	2030	2030	2029	2029	2029
5 factories	Cumulated free	204.161	64.010	148.312	174.765	132.283	177.620	278.034	214.657	219.437
East	cash flow in	42.249	1.028	27.272	41.237	19.238	30.864	64.045	47.976	47.518
West nr2	Y2040 - K EUR	75.595	45.580	63.819	66.241	63.118	74.706	101.521	80.146	83.766
5 factories	IRR - %	14,48%	9,31%	11,67%	15,75%	11,12%	13,36%	18,26%	15,94%	15,47%
East		11,48%	6,51%	9,36%	12,85%	8,42%	10,06%	14,48%	12,58%	12,33%
West nr2		17,44%	12,95%	14,52%	18,79%	14,16%	16,91%	21,07%	18,85%	18,94%
5 factories	Pay-back period -	15	17	16	14	16	15	13	14	14
East	Years	16	18	17	15	17	16	14	15	15
West nr2		13	15	14	13	14	13	12	13	13

Annex 7 – Other revenues' summary & pandemic readiness

	Estimated market demand	F/F factory capacity impact	F/F factory CapEx impact	F/F factory OpEx impact	F/F factory revenues & NPV impact	Overall attractiveness
Biotherapeutics	Low	Low: use of free F/F capacities, +/- 5 million vials	-New change parts on existing F/F line(s) -Products' Tech Transfer costs	-No additional HC -Higher raw mat costs	-Revenues ++ -NPV ++	
Insulins	High	High: vaccines volumes to be reduced	-New change parts on existing F/F line(s) -Products' Tech Transfer costs	-No additional HC -Higher raw mat costs	-Revenues + -NPV +	
Insulin analogs	Low	Low: use of free F/F capacities				
Small Volume Parenterals	High	Low: use of free F/F capacities, +/- 42,5 million BFS	-New mold(s) on existing F/F line -Products' Tech Transfer costs	10 additional HC	-Revenues + -NPV+	
Pandemic readiness vaccine	Very high but rare	High: vaccines F/F to be stopped	-Product' Tech Transfer costs -Storage at ultra low temperature	High but temporarily	-Revenues = -NPV =	

F/F factory capable to manufacture common pandemic vaccine platforms

Pandemic vaccines supplied within few months, assuming F/F capacities re-allocated from routine to pandemic vaccines.

F/F factory to support the improvement of the pandemic preparedness on African continent

Annex 9 –
F/F costs summary table

GIZ project - Vaccines F/F factory - 2.2- Fill & Finish (F/F) costs estimation per SKU - EUR

SKU N°1					
Liquid vaccines in glass vial, 10 doses per vial Penta, IPV, Td, HIV	Units	31/12/2030	31/12/2035	31/12/2040	% per item
Total Production cost per vial	*(Eur)*	1,735	1,619	1,570	100%
Cost per dose	*(Eur)*	**0,174**	**0,162**	**0,157**	
SKU N°2					
Liquid vaccines in glass vial, 5 or 4 doses per vial Typhoid, PCV	Units	31/12/2030	31/12/2035	31/12/2040	% per item
Total Production cost per vial	*(Eur)*	1,562	1,431	1,379	100%
Cost per dose	*(Eur)*	**0,312**	**0,286**	**0,276**	
SKU N°4					
Liquid vaccines in glass vial, 1 dose per vial HPV, Men CWY	Units	31/12/2030	31/12/2035	31/12/2040	% per item
Total Production cost per vial	*(Eur)*	1,121	1,034	1,002	100%
Cost per dose	*(Eur)*	**1,121**	**1,034**	**1,002**	
SKU N°5					
Freeze-dried vaccines in glass vial, 10 doses per vial BCG, MR, YF, Men A, Dengue	Units	31/12/2030	31/12/2035	31/12/2040	% per item
Total Production cost per vial	*(Eur)*	1,850	1,666	1,611	100%
Cost per dose	*(Eur)*	**0,185**	**0,167**	**0,161**	
SKU N°7					
Oral vaccines in BFS, 1 dose per tube Cholera, Rota-virus	Units	31/12/2030	31/12/2035	31/12/2040	% per item
Total Production cost per vial	*(Eur)*	0,467	0,417	0,389	100%
Cost per dose	*(Eur)*	**0,467**	**0,417**	**0,389**	
SKU N°8					
Diluents in BFS, multi doses Diluent in BFS, 10 doses per tube	Units	31/12/2030	31/12/2035	31/12/2040	% per item
Total Production cost per vial	*(Eur)*	0,583	0,520	0,505	100%
Cost per dose	*(Eur)*	**0,058**	**0,052**	**0,051**	
SKU N°9					
Diluents in BFS, mono dose Diluent in BFS, 1 dose per tube	Units	31/12/2030	31/12/2035	31/12/2040	% per item
Total Production cost per vial	*(Eur)*	0,421	0,358	0,343	100%
Cost per dose	*(Eur)*	**0,421**	**0,358**	**0,343**	

Annex 10 –
3D layout of the F/F factory

unizima

PROPOSED 3D VIEW FOR GIZ-GERMANY.

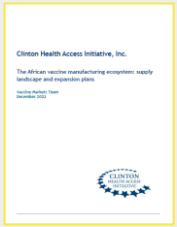
Doshi Consultants Pvt. Ltd
email: projects@doshicon.com

Annex 11 – PATH / CHAI studies about existing vaccines F/F capacities in Africa

This paper offers insights into the current African vaccine manufacturing landscape & plans to verify public pronouncements based on on-the-ground research

Reports based on public announcements

CHAI White Paper
Summarizing current landscape of African vaccine manufacturing and publicly announced expansion plans



PATH Report
Mapping the current state of vaccine production infrastructure in Africa

Wellcome Report
Perspectives from the African vaccine manufacturing industry on challenges and the need for support

Key questions still to be answered

- What is the accurate assessment of installed capacity on the continent? What portion is commercialized for vaccines?
- What plans for African Vaccine Manufacturers have been proposed? How realistic are these plans based on companies' technical and commercial capabilities?
- What challenges exist for manufacturers and how can they be addressed either bilaterally or through market shaping initiatives?