



“Fostering Private sector engagement to improve health commodities availability in Tanzania””

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DOUBLE TREE BY HILTON HOTEL,

DAR ES SALAAM

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Introduction Pharma & Medical Devices Manufacturing Facilities

- 14 domestic pharmaceutical manufacturers have been registered
 - 11 - Human medicines
 - 2 - Veterinary medicines
 - One (1) device manufacturing facility
- Most companies manufacture narrow range of products
 - mainly generics
- No Active Pharmaceutical Ingredients (API) manufacturing facilities
- No packaging materials manufacturing facilities
- No excipients manufacturing facilities
- Only two (2) CROs for BE studies



Existing manufacturing facilities

1. Shelys Pharmaceuticals Ltd –oral solids and liquids for human use
2. Zenufa Laboratories Ltd - oral solids, liquids and dry powders for suspension for human use
3. Tanzania Pharmaceutical Industries (1997) Ltd - oral solids and liquids for human use
4. TPI ARVs Ltd – dedicated facility for anti-retrovirals (manufacturing is planned)
5. Keko Pharmaceutical Industries (1997) Ltd - oral solids and dry powders for suspension for human use
6. Prince Pharmaceuticals Ltd –external preparations and oral liquids for human use



Existing manufacturing facilities

7. Mansoor Daya Chemicals Ltd - oral liquids for human use
8. Farmers Center Ltd - oral liquids and powders for suspension for veterinary use
9. A.A. Pharmaceuticals Ltd - external preparations
10. Sri Balaj Ltd - external preparations
11. S.G Star Pharmaceuticals Ltd - external preparations
12. Population Services International (PSI) – re-packaging of finished products (over-branding)
13. Tanzania Vaccines Institute - veterinary vaccines
14. Msagara Investment Ltd – cutting and packaging of medical devices (absorbent cotton gauzes)
15. Muhimbili - Institute for Traditional Medicine-herbal/traditional medicines



Factories Under construction

1. Kairuki pharma

500ml IV solution namely Ringers lactate, Dextrose saline, Normal Saline, Dextrose water 5%. Small volume parenteral of 100ml namely Paracetamol Infusion, Fluconazole infusions.



2. Bahari pharma

3. IPP pharma





PHARMACEUTICAL PRODUCTION TANZANIA

Year	Percentage
2006	33
2009	21
2012	12
2015	11

The market share of locally produced products reduced from 30% in 2007 to almost 10-12% to date



TOP TEN PHARMACEUTICAL PRODUCTS



	PRODUCT DESCRIPTION	UOM	ANNUAL DEMAND QTY
1.	AMOXICILLIN CAPSULES 250MG	1000 CP	2,200,000
2.	CO-TRIMOXAZOLE TABLETS 400 MG/80 MG	1000 TB	450,000
3.	SULPHADOXINE 500MG +PYRIMETHAMINE 2.5MG (10X10) TABS	100 TB	275,000
4.	SODIUM LACTATE COMPOUND (HARTMANN'S),500MLS	24 BT	300,000
5.	PARACETAMOL TABLETS 500 MG	1000 TB	2,275,000
6.	AMPICILLIN 250mg + CLOXACILLIN 250mg Capsules	100 CP	600,000
7.	CO-TRIMOXAZOLE SUSPENSION 200/40MG/5ML, 100MLS	24 BT	200,000
8.	FERROUS SULPHATE 200MG +FOLIC ACID 2.5MG (10X10) TABS	100 TB	1,700,000
9.	ERYTHROMYCIN 250MG (10X10) TABLETS	100 TB	655,000
10.	CIPROFLOXACIN TABLETS 500MG	100 TB	350,000

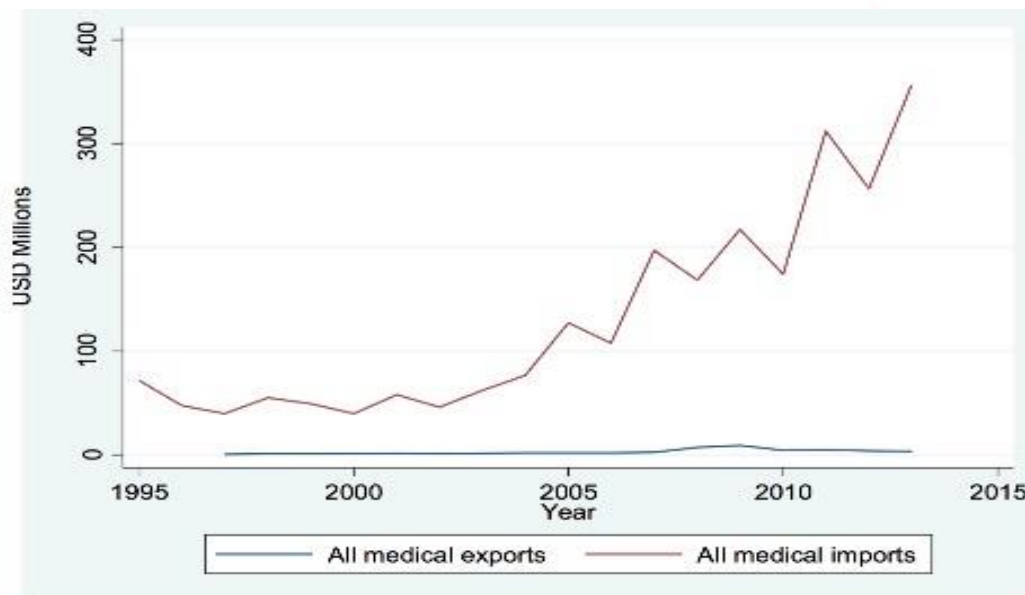


3. TOP TEN MEDICAL DEVICES & SUPPLIES

	PRODUCT DESCRIPTION	UOM	ANNUAL DEMAND QTY
1.	GAUZE ABSORBENT BPC 90 CM X 100 M	1 RL	290,000
2.	GLOVES EXAMINATION LATEX NON-STERILE DISPOSABLE MEDIUM	50 PR	2,000,000
3.	GLOVES SURGICAL LATEX RUBBER STERILE SIZE 7.5	50 PR	700,000
4.	DELIVERY KIT - SUPERIOR QUALITY WITH SELF STERILIZATION TRAY	1 KT	2,775
5.	SYRINGE AUTO DISABLE 5cc WITH NEEDLE	100 PC	345,000
6.	MATTRESS FOAM 200X 95 X 12 CM (WITH PVC WATER PROOF COVER)	EACH	17,800
7.	BED HOSPITAL WITHOUT CASTORS	EACH	10,000
8.	SYRINGE AUTO DISABLE 2ML	100 PC	300,000
9.	BLOOD BAG SINGLE 450ML	5 PC	125,000
10.	GLOVES EXAMINATION LATEX NON-STERILE DISPOSABLE LARGE	50 PR	1,000,000



Pharmaceutical Industry in Tanzania



Source: Comtrade data, <http://comtrade.un.org/data/>, downloaded

1. From 107 million USD in 2007 the pharmaceutical market rose up to almost 450 million USD in 2017



PHARMACEUTICALS & HEALTHCARE FORECASTS (TANZANIA 2015-2021)

Year	2015	2016	2017f	2018f	2019f	2020f	2021f
Pharmaceutical sales, USDbn	0.442	0.457	0.497	0.532	0.573	0.628	0.696
Pharmaceutical sales, % of GDP	0.99	1.03	1.04	1.03	1.01	1.00	1.00
Pharmaceutical sales, % of health expenditure	18.10	18.10	18.00	17.90	17.80	17.80	17.80
Health spending, USDbn	2.436	2.532	2.765	2.974	3.214	3.526	3.908

1. f = forecast, Source: National sources, WHO, UN Comtrade, BMI
2. Forecasts of pharmaceutical industry as projected by BMI (Business Monitor International) Research. The market is expected to grow from 450 million USD in 2016 to almost 700 million USD in 2021



POLICY AND LEGAL FRAMEWORK

Tanzania Development Vision, 2025

Transform the economy from a low productivity agricultural economy to a semi-industrialized one

Sustainable Industrial Development Policy 1996-2020(SIDP)

Phase the public sector out of production activities and let the private sector be the principal engine for economic th.

Integrated Industrial Development Strategy 2025(IIDS)

Provide strategy to implement the SIDP under the current business environment and extend SIDP to 2025.

Five Year Development Plans (2011-2026)

FYDP I: Removal of growth constraints (hard and soft infrastructure, electricity and markets).

FYDP II: Nurturing Industrial development

FYDP III: promote competitiveness of the manufacturing sector

Pharmaceutical Sector Strategy – final stages



POLICY INITIATIVES:

1. Sustainable Industrial Development Policy (1996 - 2020)

- The policy promotes investments of all Industries including pharmaceutical sector
- The private sector will be the principal drivers in carrying out direct investments in industries including Pharmaceuticals.
- The government will provide conducive environment for the promotion of all industrial sectors



STRATEGY

INTEGRATED INDUSTRIAL DEVELOPMENT STRATEGY 2012 – 2025

- The strategy set the pharmaceutical sector among others as the priority sector



FYDP II 2020/21

INTEGRATED INDUSTRIAL DEVELOPMENT STRATEGY 2012 – 2025

- The FYDP II centered to boost industrialization and productivity growth across the economy targeting light manufacturing and resource based industries
- One of the initiative is to increase local production of pharmaceuticals and Medical Equipment's



IIDS TARGETS BY 2025

INTEGRATED INDUSTRIAL DEVELOPMENT STRATEGY 2012 – 2025

- Manufacturing sector growth
Average annual growth from 8.4% to 15 % p.a.
- Manufacturing sector contribution to GDP
From 6.59% to 23% by 2025
- Manufactured Value Addition (MVA)
to US\$16.8 billion by 2025
- Manufacturing Goods Export \$ 6.6 billion by 2025



Pharma and Medical Equipment Manufacturing Opportunities

Single Window : A single window for import clearance of goods to simplify the process.

Tax Incentives: There are no taxes (including VAT) and duties on ALL raw and packaging materials, pharmaceutical manufacturing equipment as well as spares. Corporate tax has been reduced to 20% from 30% on all new investments.

Permanent policies : All Policies (Tax, Industrial as well as Health) have been and are being rationalized and synchronized in order to avoid incoherence.

A GROWING MARKET IN THE COUNTRY & REGION



Pharma and Medical Equipment Manufacturing Opportunities

6. Introduction of “Positive List” : This is the Government initiative to promote the local pharma industries by discourage importation of essential medicines that domestic manufacturers have the capability to produce and supply sufficiently for the entire country's requirement. (Best Practice Ghana)

Positive List

- 1 Paracetamol Tablets/Syrup
- 2 Co-trimoxazole Tablets/Syrup
- 3 Amoxicillin Capsules/Syrup
- 4 Ciprofloxacin Tablets
- 5 Erythromycin Tablets/Suspension
- 6 Penicillin VK Tablets/Syrup
- 7 Quinine Tablets/Syrup
- 8 Ampicillin+Cloxacillin Capsules/Syrup
- 9 Metronidazole Tablets/Suspension
- 10 Artemether+Lumefantrine Tablets/Syrup



Pharma and Medical Equipment Manufacturing Opportunities

7. **Price Preference** : A preferential margin of 15% applied.
8. **Re-introduction of local tenders** : Exclusive Local tenders have started to be given to domestic manufacturers by MSD for all products that can be produced locally, through Frame-work Contracts.
9. **Government campaign** to promote use of local pharmaceutical products
10. **Technical Assistance-** UNDP, UNIDO , GIZ



Pharma and Medical Equipment Manufacturing Opportunities

Promote Business Linkages : Business linkages between domestic manufacturers/Investors and international companies are being promoted through dialogue and special incentives. These have begun to bear fruit. (There are 50 expressions of interest, 7 of whom have applied for permits to start construction , 3 Construction Started i.e Kairuki, Bahari , IPP pharma

12. There is now more close Collaboration with Training & Research Institutes(**MUHAS Pharm R & D Lab., St. Lukes Foundation, COSTECH**).

13. **TFDA Transforming itself from being purely a REGULATOR to being a NATIONAL FACILITATOR FOR PHARMA INDUSTRY DEVELOPMENT as well!**



Pharma and Medical Equipment Manufacturing Opportunities

14. **Pharmaceutical Sector Strategy Formulation** - Final Stages
15. **Establishment of the National Pharmaceutical Coordination Committee** – Oversee the Six pillars of EAC- RPMPOA
16. **Facilitation and provision of industrial plots** and parks for pharmaceutical production (Pharmaceutical Industrial Park – TAMCO Kibaha);
17. **Facilitation of fiscal regime for pharmaceutical industrial development;** and
18. **Facilitate long-term credit** to raise production capital (TIB).



Why you should invest

- Geographical location (8 countries borders Tanzania) - Potential for exportation of products to neighboring countries
- Population and prevalence of diseases
- Existence of MSD for bulk procurement
- MSD win tender for pooled procurement with SADC
- Existence of national health insurance scheme
- 89% of medicines are imported
- 100% of medical devices are imported
- Still existing facilities are not adequate to meet market demands (currently domestic companies can meet only 11% of the total demand)



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Non-medical Manufacturing

The following list of Non-medical supplies is another area of interest for investment to meet MSD requirements;

- Safety Boxes for Disposable Used Syringes,
- Bed Sheets,
- Packaging Boxes,
- Dispensing Envelopes,
- Color-coded Waste Bins,
- Prescription Forms A5,
- Patient Registers,
- Injection Registers,
- Ball-point Pens, etc.



Investors Who Have Shown Interest

17 Investors have expressed interest in investing in pharmaceutical & devices manufacturing:

1. **Biotech Ltd** – oral solids and liquids for veterinary use - construction started
2. **Novabi Ltd** – veterinary vaccines – construction started
3. **Tabora Textiles Ltd** – cotton based products
4. **Zinga Pharmaceuticals Ltd** – infusions and ARVs
5. **Guilin Pharmaceuticals (T) Ltd** – oral solids and liquids
6. **Simiyu Project** – infusions and cotton based products
7. **Bahari Pharmacy Ltd** – oral solids and liquids



Investors Who Have Shown Interest

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8. **Africables Ltd** – infusions
9. **Hester Pharmaceuticals Ltd** - veterinary vaccines
10. **Kairuki Pharmaceuticals Industry Ltd** – infusions - construction started
11. **Revital Healthcare Ltd** – medical devices
12. **Pharco Ltd** – oral solids
13. **Mohammed Enterprises Ltd** – infusions
14. **SUMA JKT** – infusions
15. **Subhash Patel** – oral solids
16. **Cure Afya Pharmaceuticals Ltd** – infusions
17. **Emedics Pharmaceuticals Ltd** – orals solids -construction started



Investors Who Have Shown Interest

17 Investors have expressed interest in investing in pharmaceutical & devices manufacturing:

- 18. Alfa Industries LTD (disposable Syringe and I.V infusions)
- 19. Medal Investments LTD (I.V fluids)
- 20. USA (Diaspora)
- 21. Decca Medics (medical devices)
- 22. E & E care industries (eye and Ear drops)
- 22. Moshi Paper bags (packaging materials)



Procedure for establishment of pharma and devices manufacturing facilities

Requirements;

- Certificate of Registration from **BRELA**
- Clearance on Suitability of the Site from **NEMC**
- A Copy of Certificate of Incentive from **TIC**, EPZA if registered by
- Schematic drawing of the proposed manufacturing plant
 - **After approval of drawings, construction can start followed by installation of equipment and production of trial batches**
- Submission of dossiers for registration of products to TFDA
- **Approval Process:**
- GMP inspection and quality audit of manufacturers
- Registration of products that meet quality, safety and efficacy requirements
- Marketing of products



Conclusion

Government will continue to create enabling environment and ensure a robust and vibrant domestic pharmaceutical industry that will contribute significantly to attaining National Self-sufficiency to local supply of essential medicines and Medical Equipment



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