KISAKYE INDUSTRIES LIMITED

PHARMACEUTICAL MANUFACTURING INDUSTRY

LUGALA – BUSEGA
KAMPALA
UGANDA

Local pharmaceutical manufacturing in Uganda

Private Health Sector Convention

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Introduction

- Kisakye Industries is a limited company registered in Uganda in the year 2000. It is fully owned by Ugandans with Mr. Benjamin B. Kitumba as the Managing Director.

- The company started as a small scale pharmaceutical industry in small premises on plot 13 William Street in 2000, and then shifted to plot 6 Wilson Lane, third floor in 2001 later on moved to Lugala in Busega as plans for expansion to a bigger production site were required of us.
- We mainly manufacture Oral Liquid Preparations and Topical/External preparations with Guidelines and Guidance from the Uganda National Drug Authority (NDA).

- At the beginning our production capacity was of 1000 bottles a day but currently we produce up to 10,000 bottles a day with semi automate machines.
- With the new high tech facility under completion, we hope to boost our annual production capacity to 9,400,000 bottles, 200,000,000 capsules and 1,900,000,000 tablets.

List of products we currently produce:

Liquid Oral Preparations

- Betalinctus (Cough Linctus)
- Magnant (Magnesium Trisilicate Mixture)
- Mpa Mirembe (Cough Expectorant)
- Haem Tonic (Herbal Blood Tonic)
- Anycof (Cough expectorant)

External Preparations

- Belamine lotion (Calamine Lotion)
- Belamine Ointment (Calamine ointment)
- Benoxide (Hydrogen Peroxide 6%)
- Universal Liniment
- Gentian Violet solution
- Glycerine of Borax
- Spiritant (Antiseptic solution)
- Benosept (Antiseptic Solution)
- Rayodine (Tincture Iodide)

OVERVIEW OF HEALTHCARE IN AFRICA

- ❖ 17% of the world’s population
- ❖ 30% of the world’s disease burden
- ❖ 3% of the world’s total health expenditure
- ❖ 75% of the world’s HIV/AIDS cases and 90% of the deaths due to malaria.
- ❖ other infectious diseases that cause substantial morbidity and mortality.

OVERVIEW OF THE PHARMACEUTICAL INDUSTRY IN AFRICA

- Africa has emerged as world's fastest growing economic regions over past 2 decades
- Pharma industry of Africa projected 9.8% annual growth rate between 2010 & 2020
- Africa market will be worth USD 40 billion to USD 65 billion by 2020
- Africa GDP rising to USD 3.9 Trillion by 2020
- New Regulatory Agency & efforts to augment economic growth, will positively contribute to growing pharma sector & attract foreign investments
- In many African countries, generic drugs are gaining market share at the expense of over-the-counter and branded products
- The continent overall has roughly 375 drug makers, most in North Africa and South Africa
- Nigeria has roughly 200 registered pharmaceutical manufacturers, South Africa has roughly 30, Ghana 20, Kenya, Algeria 30 and Tunisia 20. Other countries such as Uganda, Tanzania, Zambia and Zimbabwe have relatively between 5 to 10 companies. There are also countries such as Cameroon, Namibia, Swaziland, Lesotho, Malawi and others that have just 1 or 2 manufacturers.

EAC Healthcare Expenditure

- Average annual health expenditure per capita:
  - Africa: US$ 222
  - EU: US$ 2,214
  - America: US$ 3,873
  - (Atlas of African Health Statistics, 2016)
- Average of US$ 98 per capita across Sub-Saharan Africa
- Around 7% of GDP spent on health, which is far from reaching the Abuja target of 15%.
- Over 30% from out-of-pocket payment (opportunity of the private sector)

Countries	THE (USD Million)	THE (USD Per Capita)	Funding (%)		Buyers (%)			% of population covered by some kind SHP mechanism
			Govt.	Donors	Govt.	Household	Other	
Kenya	3,500	78	72	28	61	26	13	32
Burundi	233	22	50	50	53	21	26	65
Rwanda	595	52	54	46	38	28	34	95
Uganda	2,000	52	N/A	N/A	25	41	34	<1
Tanzania	2700	52	64	36	46	23	30	15
South Sudan	358	30	58	42	42	54	4	N/A

Source: WHO country profiles and Global health expenditure database
http://apps.who.int/nha/database

Uganda Pharmaceutical Sector Market Data

- The market size of Uganda is about **US$500m**.
- Compound Annual Growth Rate **12%** *(2018 IMS Health reports)*
- Market share of locally produced pharmaceutical drugs (% of overall market)* - **20% ,** Imports make up **80%**
- Market segments: **80%** Generics , **20%** Branded drugs
- Number of local pharmaceutical manufacturers: **9**
- Large scale manufacturers: **4**
- Population: **40.8 million** *(July 2018 estimate)*
- Population annual growth rate: **3.18%** *(July 2018 estimate)*

WHY THE NEED FOR THE PHARMA SECTOR GROWTH

❑High infectious disease burden:

- Africa accounts for the bulk of the global infectious disease burden with about 75% of the HIV/AIDS pandemic, 90% of the malaria cases and deaths.
- According to the World Health Organization (WHO), 90% of child deaths in Africa are attributable to neonatal causes, pneumonia, diarrhoea, measles and HIV and AIDS.

❑Growing chronic and non communicable disease burden:

- The common types of Non Communicable Diseases are:
  i. Diabetes
  ii. Cancers
  iii. Cardiovascular diseases (like heart attacks and strokes)
  iv. Chromic respiratory diseases (such as chronic obstructed pulmonary disease and asthma)
  v. Sickle cell Anaemia
- These are projected to increase dramatically in Sub Saharan Africa due to improving social conditions and rapid urbanisation; environmental issues like air pollution; and an increase in the consumption of alcohol and tobacco products.

❑Inadequate distribution infrastructure:

- A percentage of donated or imported drugs expire on shelves in medical stores without ever reaching the areas of greatest need in rural clinics and hospitals. Conversely, there is a body of evidence that suggests that locally manufactured products are more readily available in the remote rural parts than imported products.
- This is also due to inadequate distribution of pharmacists and pharmacy outlets which are mainly centrally located making Uganda have a low pharmacist to population ratio as WHO recommends 1 pharmacist :5000 people; there are about 1200 pharmacists and about 1650 pharmacies to serve a population of about 40million in comparison to a developed state like France with about 25,000 pharmacies and around 54,000 pharmacists for a population of 65 million.

❑Limited access to essential medicines:

- This is due to various factors, like the lack of local production capacity, weak institutional or regulatory capacity and poorly regulated supply chain systems that enable sub-standard products (locally produced and imports) to reach patients, and the surge of counterfeit drugs.
- Local production will lead to increased access to affordable quality medicines, sustainable supply of essential medicines and will have a positive impact in promoting public health outcomes, industrial and economic development.

❑ Growing population and rise in the middle class population seeking to pay for better treatment:

- With the population of Uganda at around 40.8 million and growing annually at a rate of 3.18%, there's need to promote the health sector and ensure the availability of essential drugs for the people.
- Furthermore, the rise in the middle class population seeking to pay for better quality treatment creates room for investment in health service delivery and local production to sustain the demands of the population without delays as is the case with importation.

❑ New models of care like the Health Insurance program and Public Private Partnerships:

- Various health insurance programs are coming that will require the support and growth of the local pharmaceutical manufacturing sector to provide them with affordable, safe, efficacious and quality drugs for their insurance policies.

❑ Promote research and development in traditional or herbal drugs:

- A large percentage of the rural population depend on herbal drugs to combat various infections. The abundance of herbs in Uganda creates room for research and improving the use of herbals to meet international norms.

❑ Local pharmaceutical production is becoming a national security concern:

- The future will likely see a reduction in the level of donations in support of our healthcare systems due to various global financial and political factors. Therefore, it is imperative that we implement a plan for developing our industry so that we can ensure access to quality affordable medicines independent of donations.

❑ The need to improve the quality of products to which our people are exposed across the Essential Medicines List (EML):

- There is a significant penetration of sub-standard and counterfeit products in our markets.

  In Dar es Salaam, Tanzania's Food and Drug Administration seized $8,300-worth of counterfeit medical products, including antibiotics and antimalarial tablets, while in Zimbabwe, police seized 5,700 counterfeit tablets.

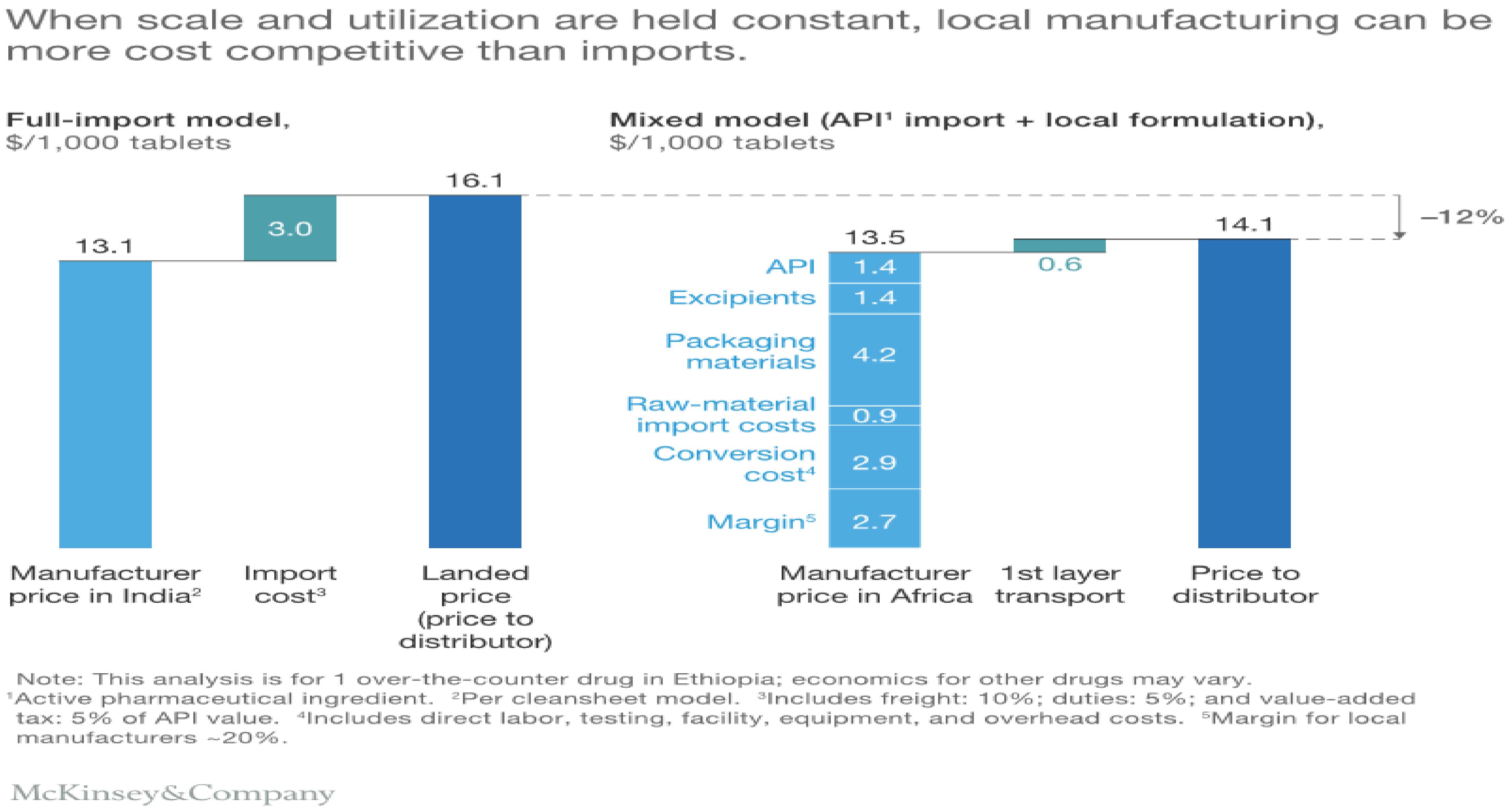
  According to a 2018 report funded by the European Union, counterfeit medicines account for up to 30% of the global market. The EU estimates that fakes may cause up to 158,000 deaths a year on the continent from malaria alone.

❑ Over reliance on imported products that are hard to regulate by the limited manpower of Regulatory Authorities:

- It is estimated that the continent imports between 70 and 90% of the drugs it consumes, compared to 5% for China and around 20% for India.
- The continent only has around 375 drug makers, mostly in the North Africa region, South Africa, Nigeria and Kenya.
- By contrast, China and India are thought to have around 5,000 and 10,500 manufacturers respectively.
- This makes it expensive and hard for a regulatory body with limited manpower to keep oversight of over 15,000 factories spread all over the world than to oversee a couple of factories in its proximity within a nation.

❑ Locally made products can be cheaper than imported products:

- McKinsey report estimates that tablets, capsules and creams produced in Ethiopia and Nigeria tend to be about 5 to 15% cheaper than the landed price of imports from India, which are subjected to freight costs, duties and VAT.



CHALLENGES OF THE LOCAL PHARMA MANUFACTURING SECTOR

1. Lack of access to investment capital

- Investment capital for the sector is essential if companies are to be able to make the significant investments required to reach and maintain international standards.
- In 2011, UNIDO *(United Nations Industrial Development Organization)* conducted some research into the capital requirements of companies and the availability of different types of funding
- From a demand perspective, most companies in SSA (outside South Africa) wanting to invest in upgrading facilities required long term capital (5+ years) to the tune of multi-million dollar sums (specific cases vary dramatically but typically US$5mn as a bare minimum).
- This research established that traditional bank debt financing was problematic given the high interest rates involved (15% to 30+% depending on the country).
- It also found that loans in excess of US$3mn were rarely available and that the term was usually less than five years.

2. High costs of operation e.g Power, Utilities, Infrastructure

- Power costs in Uganda are as high as US$15 cents per kwh compared to US$5 cents per kwh for India or China that are awarded to large scale manufacturers.

3. Limited availability of skilled human resources

- Traditional universities offer various science, engineering and technology degrees relevant only to the extent of providing solid grounding in scientific theory which is crucial for industry.
- However, they lack industry applicability and practicality. It takes up to three years to train a new recruit who has a basic qualification in the various relevant disciplines and to convert him/her into a skilled pharmaceutical operator.
- More skilled labour is needed in formulation and product development

4. High market competition with imported products

- In India, local manufacturers receive substantial government assistance to promote exports including:
    - Duty free imports of equipment and raw materials for export products
    - Ten year tax holidays
    - Export credits
    - Low utility rates
    - Working capital credits
    - Enhanced depreciation allowances

  More additional tax exemptions or low taxes on their imports as incentives given by African governments to importers.
- This lack of a level playing field poses a genuine threat to the sustainability of high quality pharmaceutical production in Africa and limits the ability of companies to make the investments required to upgrade their plants.

5. Poor corporate culture

The issues cited include:

- Businesses generally controlled by one shareholder or family
- Focus on retaining the business to pass on within the family
- Reluctance to view exits such as M & A (Mergers and Acquisitions) or a stock market listing positively
- Poor corporate governance
- Poor record and account keeping, lack of audited accounts and other records
- Poorly functioning Boards of Directors – lack of outside independent business experts
- Poor planning; lack of long term strategy and vision
- Personnel issues (e.g. family-owned companies hesitant to recruit external senior management)

6. Illicit trade in sub-standard and counterfeit products

- These account for up to 30% of the global market.
- This is due to insufficient regulatory oversight leading to substandard and counterfeit products taking the market share from domestic firms.

7. Under resourced and weak institutions (e.g Drug Regulatory Agencies, Civil Societies)

8. Lack of accurate and comprehensive market data

9. Unreliable supporting industries and necessary infrastructure

- Includes educational and training institutions, laboratories and research centers, suppliers of manufacturing equipment, legal & financial systems and affordable utility suppliers.

SUGGESTED SOLUTIONS

- **Procurement preferences in public tenders**
  - Brazil has a 25% price preference for local manufacturers.
  - Russia ensures that 70% of products procured by the state are locally manufactured.
  - South Africa has local production preference points in tenders and some designated products will be procured only from domestic producers.

- **Import restrictions of certain products**
  - They involve import prohibition on identified products as applied in Nigeria and Ghana. Until Ghana introduced a restricted list of 13 products, it had 5 local manufacturers and that today it has 22 active manufacturers.
  - In Algeria and Tunisia, once a locally manufactured generic is registered, the innovator is given two years in which to commence local production. Failure to do this, results in a ban on importation of the finished product and the market can then only be served through locally produced products.

- **Preferential payment terms - government**
  - Working capital credits, Letters of Credit

- **Subsidized credit and Interest subsidies**

- **Utility subsidies and Export incentives**

- **High tariffs on imported finished products (introduce a 25% import duty on selected products)**
  - India has tariffs for final formulations of up to 56%
  - Brazil has a 15% tariff for finished formulations
  - China has import tariffs of up to 37% e.g on Sulfamethoxazole (SMZ) imported from India
  - For Non-sensitive (not used in emergencies) products made locally, an import duty of 25% should be charged on similar imported products

- **Tax holidays for investment in new plants**

- **Human Resource Development**

- **Facilitate access to affordable long term investment capital sufficient to enable upgrading of facilities to international standards**

- **Regulatory systems strengthening & building regulatory capacity**

- **Facilitating market access & promoting intra-regional trade by Harmonizing registration requirements**

- **Facilitate partnerships, collaboration and business linkages**

- **Formation and strengthening of pharmaceutical trade associations**

- **Assistance to leading companies to achieve stringent regulatory approval**

- **Advise governments on the implementation of strategies for building the pharmaceutical sector by conducting extensive consultations all relevant key stakeholders**

- **Providing assistance to accelerate research and development into traditional medicines**

- **Corporate training programs in these core areas:**
  - Accounting and Financial Management
  - Pharmaceutical Business Environment
  - Business Law
  - Production and Operations Management in Pharma
  - Strategic Management in Pharmaceuticals
  - Pharmaceutical Sales Management
  - Marketing Management
  - Brand Management in Pharmaceuticals
  - Logistics and Supply Chain Management for Pharmaceuticals
  - Corporate Governance and Board Leadership

OVERCOMING THE PERCEPTION OF LOCAL GENERICS

➢Focus on quality improvement

The ‘quality’ of pharmaceuticals should touch all aspects of a product and its manufacturing process, for example:

- The level of active pharmaceutical ingredient (API) content
- Appropriate formulation impacting on the pharmaco-kinetics of the drug (e.g. peak concentration, dissolution profile of drug)
- Degradation factors of the product e.g poor storage
- Contamination of the product with other drugs, with impurities, or following the degradation of the API e.g during transportation or after formulation
- Correct labelling of products
- Microbial contamination control of a product

➢Sensitisation of the public and healthcare professionals

- Through medical representatives by holding seminars with healthcare professionals and sensitise them about their products
- Disseminate information via different media e.g brochures, talk shows, journals etc