



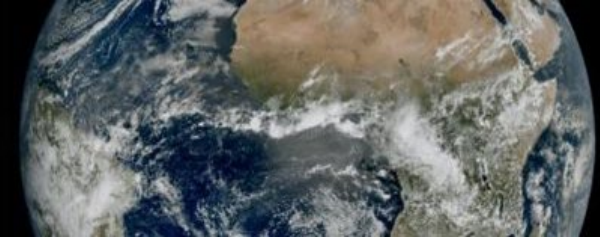
Global Health
Supply Chain Summit

[ABSTRACT #01]
[TRACK #12]
[14/11/2024]

LAGOS, NIGERIA ~ NOVEMBER 12-15

2024

**VALUE CHAIN INNOVATIONS FOR UNIVERSAL HEALTH
COVERAGE**

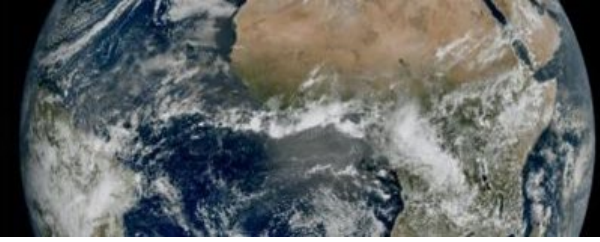


Building self sustainability for Health Products and Technologies (HPT): Enhancing Local Manufacturing in Kenya

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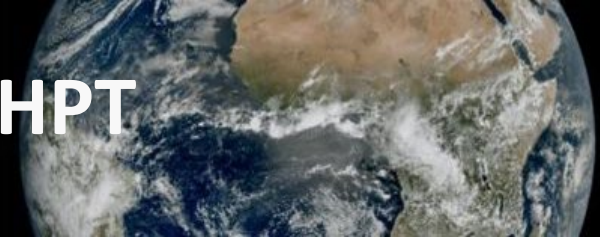


INTRODUCTION



- Essential medicines are those that satisfy the priority healthcare needs of the population. The key factors considered in selection of essential medicines include
 - Public health relevance
 - Evidence of efficacy and safety and Quality
 - Comparative cost-effectiveness and equity
 - Local suitability/appropriateness
 - **Local production for improved availability**
 - Local registration & availability
 - Human resource & infrastructure capacity
- The President pronouncement in October 2023
 - **At least 50% of health products and technologies in essential lists should be produced locally by 2026**

CAPACITY ASSESSMENT FOR LOCAL PRODUCTION OF HPT



Rationale/Problem statement

1. Mismatch between market demand and supply
2. 85% of essential meds not manufactured locally
3. Imports account for 70% of the total Kenya Pharma Market Size
4. 20% of the total health expenditure for HPT are from imports which accounted to KES 76 bn in 2020

Objectives of the assessment

1. To understand the profile and current scope of the local pharmaceutical industries in Kenya
2. To assess the extent to which essential medicines are currently manufactured locally
3. To gather market intelligence on current markets served
4. To evaluate the prevailing local manufacturing capacities
5. To identify challenges faced by local manufacturers
6. To identify proposed solutions by the local manufacturers to inform strategies for increasing local production of medicines



METHOD



Sampling

- Sampling frame of 41 local manufacturers was obtained from the regulator (Pharmacy and Poisons Board).
- 30 sites were identified for the assessment

Data Collection Process

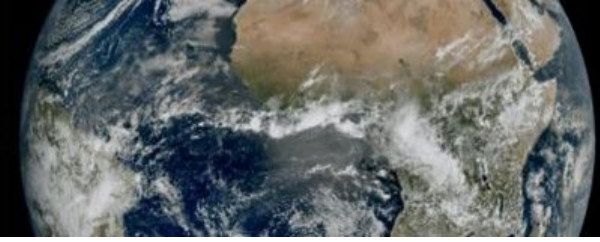
- Assessment done from 5th February to 16th Feb 2024
- Team composition: 3 to 4 members drawn from DHPT,ARC,KHF and HPA. Team- Leads from DHPY
- Consent and confidentiality forms were signed by both parties; A copy was to retained on site

Data collection tools

- Online tool was filled on Kobocollect app (using tablets)
- Excel template were filled and submitted to the Team leads



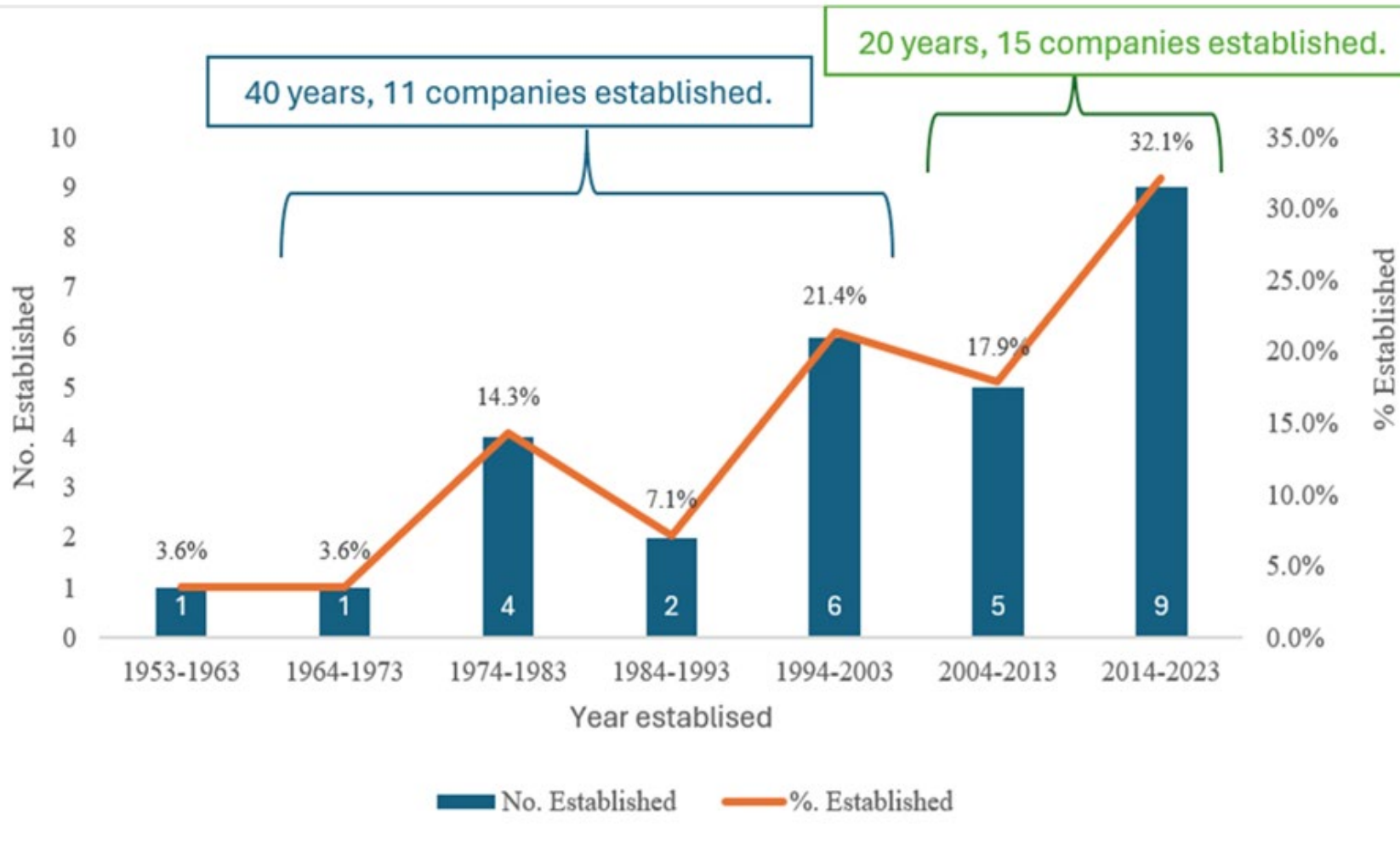
FINDINGS



- Company profiles
- Product ranges and volumes
- Capacity utilization and technology
- Markets served
- Challenges



ESTABLISHMENT OF PHARMA LOCAL MANUFACTURERS IN KENYA



Key Findings

N=28

Increasing trend of establishment;

- 9 in the last decade
- 1 pre-independence
- 11 companies within 40 years ago
- 50% within 20 years
- 9 in the last 10 years



LOCATION OF LOCAL MANUFACTURING SITES



Key Findings

N=28

Most of the companies are in Nairobi and surrounding counties except 1 in Nakuru County

- *21 in Nairobi county*
- *3 in EPZ (Machakos County)*
- *2 in Kiambu county*
- *1 in Kajiado County*
- *1 in Nakuru*

No state –owned (Biovax was not assessed as it is still in the set-up stage)



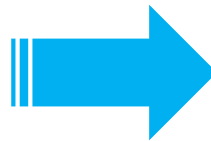
PRODUCT RANGE

- 1. What ranges of medicines are currently produced in Kenya?**
 - Range of products by therapeutic categories
 - What are the % of locally produced medicines that are in the KEML
- 2. Are these products aligned to the Disease Burden in Kenya?**

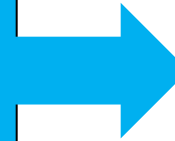


THERAPEUTIC CATEGORIES VS. DISEASE BURDEN

- 1 Anti-infective medicines
- 2 Cardiovascular medicines
- 3 Dermatological medicines (topical)
- 4 Medicines for pain and palliative care
- 5 Medicines for endocrine disorders
- 6 Anticonvulsants/antiepileptics
- 7 Medicines for mental and behavioural disorders
- 8 Antiallergics and medicines used in anaphylaxis
- 9 Medicines for correcting water, electrolyte and acid-base disturbances
- 10 Medicines affecting the blood
- 11 Ophthalmological preparations
- 12 Disinfectants and antiseptics
- 13 Gastrointestinal medicines
- 14 Anaesthetics, pre- & intra-operative medicines and medical gase
- 15 Diuretics
- 16 Ear, nose and throat medicines
- 17 Vitamins and minerals
- 18 Immunomodulators and antineoplastics
- 19 Medicines for wound care
- 20 Antidotes and other substances used in poisonings
- 21 Antiparkinsonism medicines
- 22 Blood products of human origin and plasma substitutes
- 23 Medicines for reproductive health and perinatal care
- 24 Medicines for rheumatology
- 25 Antimigraine medicines
- 26 Diagnostic agents
- 27 Dialysis solutions
- 28 Immunologicals
- 29 Medicines acting on the respiratory tract
- 30 Medicines for alzheimer's disease and dementia
- 31 Medicines for benign prostatic hyperplasia (bph)
- 32 Medicines for osteoporosis
- 33 Muscle relaxants (peripherally acting), cholinesterase inhibitors and anticholinergics
- 34 Nuclear medicine (radiopharmaceuticals)
- 35 Preparations for clinical nutrition management



- Kenya faces a triple burden of disease; **communicable illnesses, non-communicable conditions, and injuries.**
- 54% of deaths stem from communicable diseases, maternal and neonatal causes, 39% from non-communicable diseases (NCDs), and 7% from injuries.



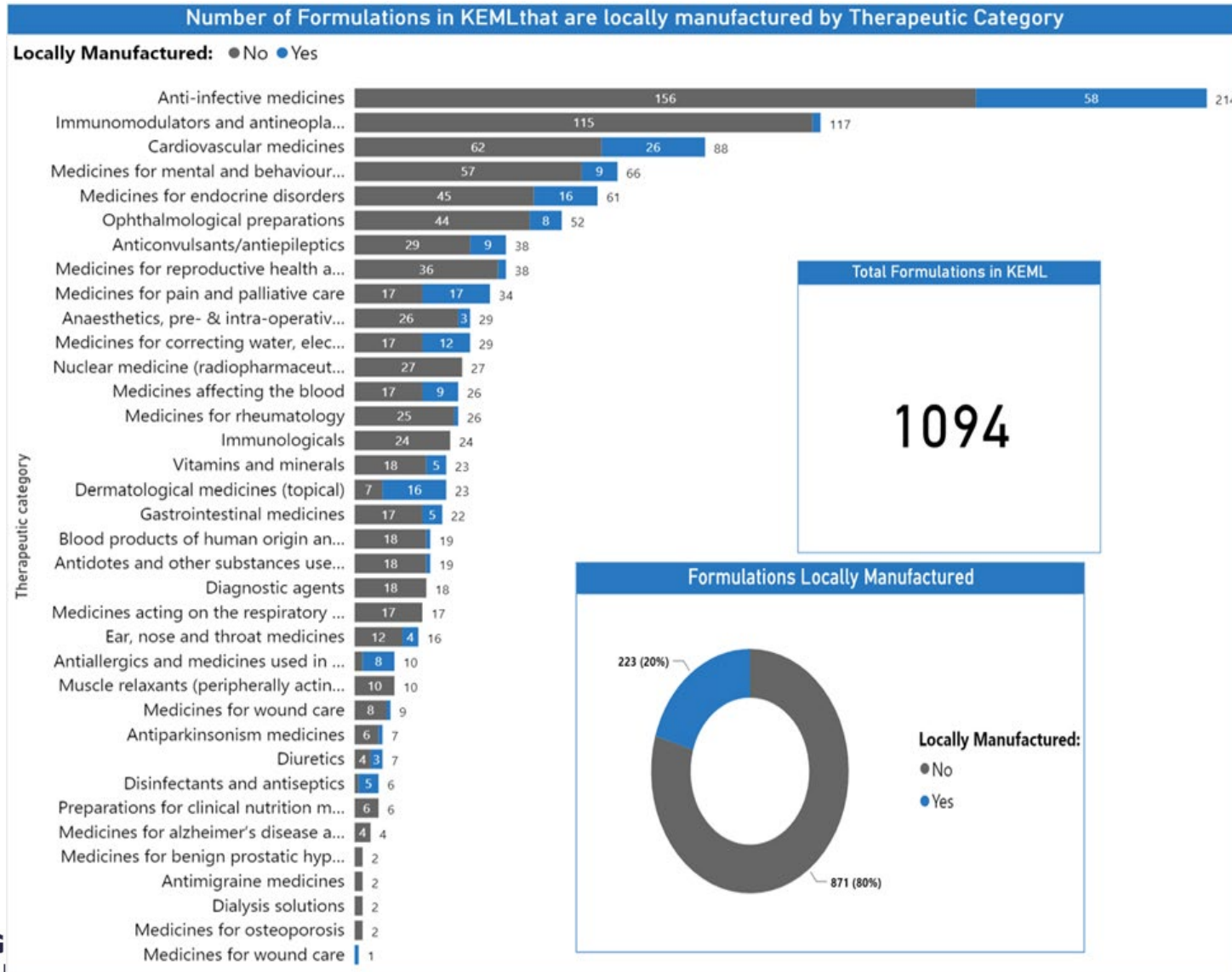
KEY FINDINGS

There are 35 Therapeutic Categories in the KEML 2023;

- 664 medicines molecules
- 1,096 product formulations



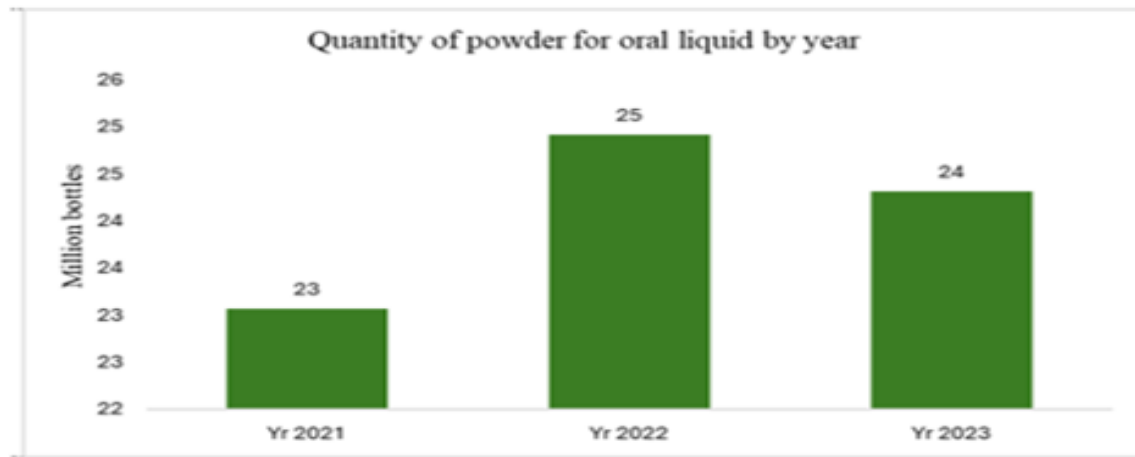
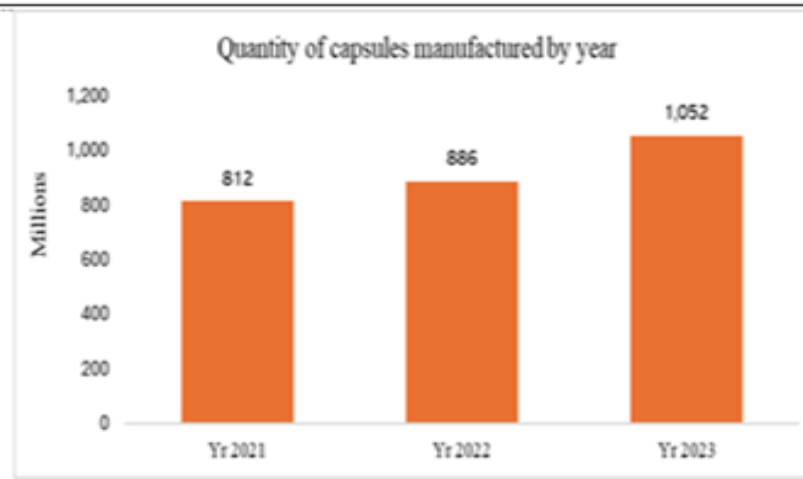
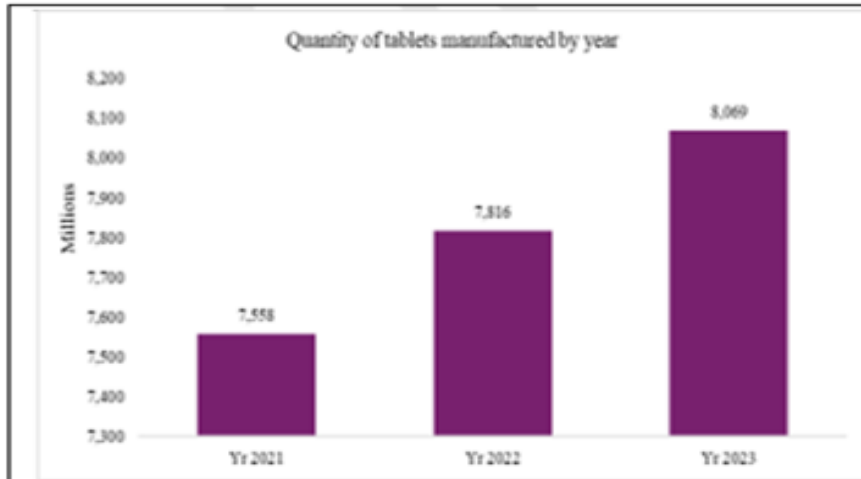
Formulations in KEML that are Locally Manufactured (by Therapeutic Categories)



KEY FINDINGS

- **22% (146)** of the 664 medicine molecules are locally manufactured
- **20% (223)** of the 1,094 product formulations are locally manufactured
- **68.6%** of the locally manufactured products are not in the KEML 2023
- **24 (of 35)** therapeutic categories had products produced locally
- **5 out of 6** products for disinfectants and antiseptics produced locally

TOTAL VOLUMES OF PRODUCTS BY DOSAGE FORM



KEY FINDINGS

N=26 (2 companies did not provide data on volumes produced)

Most common dosage forms are:

- Tablets: **24 Billion tablets over 3 years**
- Capsules: **3 Billion capsules over 3 years**

A general increase was observed for capsules and tablets, while there was a dip in 2023 for oral liquids and topical creams/ointments

Challenges Impeding Full Capacity Utilization

Lack of incentives by the government	20	71.43
Shortage of hard currency to procure inputs	16	57.14
Poor access to finance/loans to do additional investments	16	57.14
Erratic Supply of raw material supply (API, Excipients, reagents)	15	53.57
Inadequate utilities (water, power supply, etc.) to ensure its smooth operation	13	46.43
Lack of a conducive working environment (bureaucracy, corruption, tax, etc.)	13	46.43
Tight regulatory requirements	9	32.14
Others*	7	25
The staff lacked the requisite technical skills	6	21.43
Lack of market data and intelligence	5	17.86
Lack of market for medicines produced	4	14.29
Absence of in-house equipment maintenance capacity/Lack of such service providers	4	14.29
Inadequate physical infrastructure (building, room design, space, etc.)	4	14.29
Lack of local equipment calibration services	3	10.71
Shortage of workforce needed for the industry	3	10.71
Use of inappropriate technology	2	7.14

KEY FINDINGS N= 28

The major challenges that were reported were:

- Lack of

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