PHARMACY AND MEDICINES REGULATORY AUTHORITY

Quality Medicines for Malawi

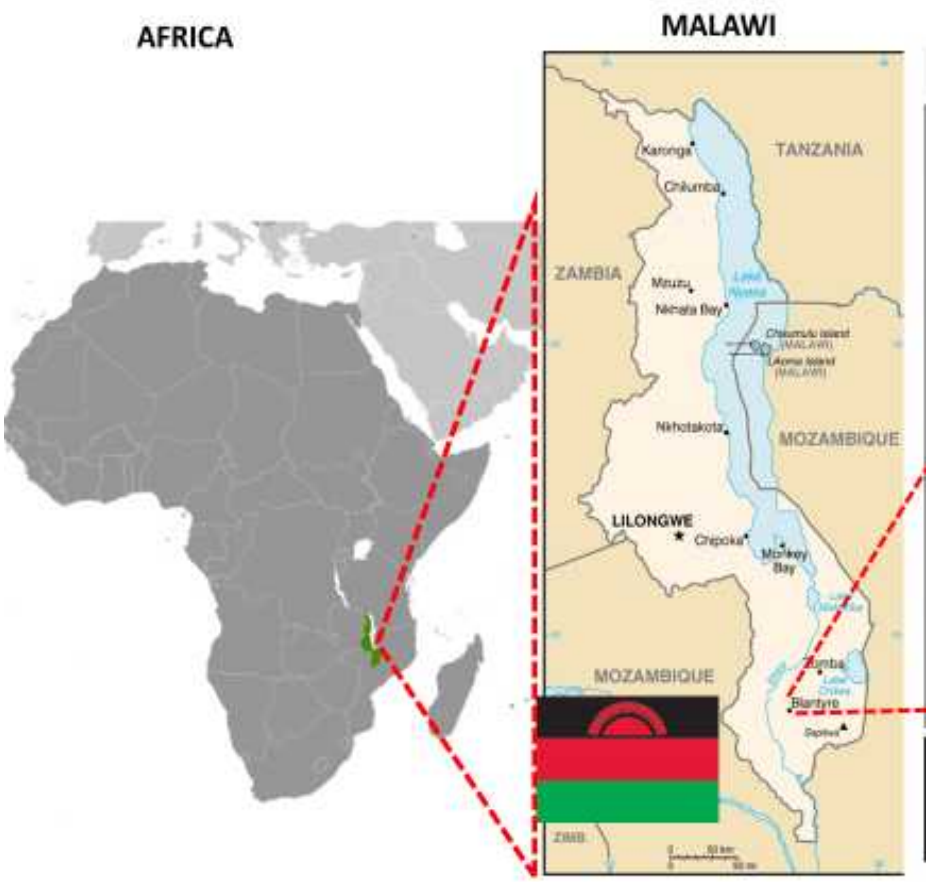
INDIA SOURCED GENERIC DRUGS - GLOBAL EXPECTATIONS

SESSION 7 – MALAWI

Outline

1. Malawi's Medicines Regulatory Landscape
2. Expectations from Malawi

GEOGRAPHICAL LOCATION AND DEMOGRAHICS



- Located in Southern Africa, and shares a border with Mozambique, Zambia and Tanzania.
- Population: > 20 Million (UN Estimates, 2022).
- Area: 119,000 KM^2 with a population density of 129 people per M^2 (World Bank, 2019).
- Health services are provided by: Ministry of Health (60%), Faith based institutions (37%).

Medicines Regulatory Landscape

MANUFACTURERS

1. Total Manufacturers on Register: 209 (74% Indian)
2. Active Manufacturers: 105 (50%)
3. Pending GMP Inspections: 41 (20%) Vs 8 Inspectors

PRODUCTS

1. Total Products on register: 4, 200
2. Active Products (annual average): 2000
3. Pending Dossier Assessment: 170 Vs 8 Assessors

Picture indicative of increased work load – Need for reliance/ work sharing arrangements with other regulators.

THE PHARMACY AND MEDICINES REGULATORY AUTHORITY ACT, 2019

PART XI—HARMONIZATION OF REGULATION OF MEDICAL PRODUCTS AND INTERNATIONAL COOPERATION

Harmonization and international cooperation

123. The Authority may participate and cooperate with any regional or continental medical products regulatory agencies and take such measures to share summary evaluation and inspection reports in order to—

(*a*) provide for harmonization of the data requirements for evidence of quality, safety, and efficacy of medical products;

(*b*) harmonize registration of medical products, inspections, quality management system, information management systems, joint evaluations, joint inspections and any other regulatory activities as may be appropriate; and

(*c*) provide for the use of accredited quality control laboratories within the harmonization framework.

MEDICINES REGULATORY LANDSCAPE (cont')

Key gate keeping responsibilities (PMRA Act, 2019)

1. Product Assessments and MA (Section 62)

2. Quality Control testing (Section 79) & Establishment of the National PV System (Section 72)

2. The requirement of an import permit (Section 58)

With these gate keeping responsibilities coupled with efficiencies from harmonization efforts (SADC-ZAZIBONA & WHO CRP members)

Need for complimentary efforts from Indian regulators

EXPECTATIONS FROM MALAWI

1. As world's largest manufacturer/supplier of generic products, strengthen regulatory framework i.e.
   - *Oversight over BE study & pharm development submissions,*
   - *Provide understanding on contract manufacturing, loan licenses, exports requirements.*

2. Explore collaborations (technology transfer & Trainings) with manufacturers in importing countries, help the world reach pharma commodity security. *(Local Govt's preferential procurement from local manufacturers)*

3. Compliance to mandatory submission of Periodic Safety Updates by manufacturers as required by Law *(Medical representatives more focused on marketing than quality and safety issues)*

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THANK YOU