PHARMACEUTICAL REGULATION OPPORTUNITY FOR TRADE IN JAMAICA

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OVERVIEW

- Objectives
- Brief epidemiological trend impacting health status
- Drug Regulation in Jamaica
- Drug Registration process

OBJECTIVES

- To provide a brief introduction on the geography of the LAC Region
- To provide a brief description of the drug regulatory framework in Jamaica.
- To discuss the drug registration requirements/process in Jamaica.

Bird's eye view of LAC/JAMAICA

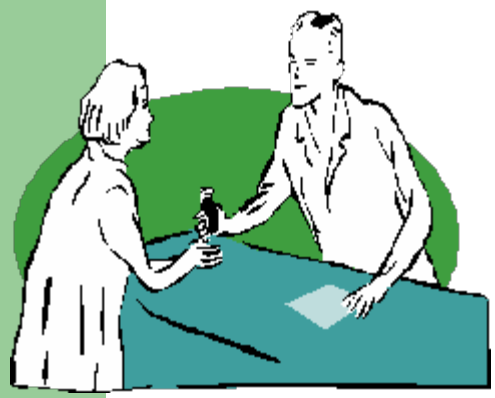
English Speaking CARICOM – Brief Overview

- Fifteen Countries
- Population (excluding Haiti) just over 5.3M with >50% females
- Country Size:Guyana> Jamaica> Trinidad & Tobago> Barbados
- Population of Jamaica- 2,641,600
- Average Population per registered Pharmacy in Jamaica is 7,584

Population Health Status

- Ageing population
- Demand for drugs driven by disease prevalence.
- Chronic Disease prevalence:
  - Hypertension
  - Diabetes
  - Arthritis
  - Glaucoma
  - Respiratory
- Incidence of sexually transmitted infectious diseases unacceptably high HIV/AIDS

Population Health Status



- Various Government supported initiatives help improve affordability & equitable access to healthcare and essential drugs.
- **TAC** provides regional network to ensure drug quality and safety.
- **RABDAT**
  - Harmonisation

Market Structure:

- Public Sector
- Private Sector
- Legislation & policies established centrally
  - applicable to both
- Systems operate separately
  - Products offered
    - National Formularies Vs. essential drug lists e.g.. VEN List
  - Pricing structure
    - Drug Tenders price driven

JAMAICA – MARKET STRUCTURE

- Private Sector
  - Six private hospitals
  - Three Hundred & Fifty-six private pharmacies
  - Fifteen major Distributors
  - Six Manufacturers

JAMAICA
MARKET STRUCTURE

- **Public Health Sector:-**

  Four Regional Health Authorities comprising

  - Twenty-three public hospitals
  - Three Hundred & Forty-eight health centres
  - Ten Drug Serv Pharmacies

DRUG MARKET in JAMAICA

- 22% growth in import market for drugs & related products from 1997 – 2002
- Value of market in 2002 was US$82M
- Factors contributing to growth include:
  - Trade climate
  - Government programmes for provision of drugs
  - Social and health status
- Government is single largest importer- estimated at 25% of total import – implication for Generic drug importation

ACCESS TO DRUGS

- **Access to essential drugs constitutes part of the human right to health. Therefore:-**
- **“Access to essential drugs is a human right”**

ROLE OF STATE

- Public health – state responsibility
- Provision of quality goods & Services
- Protection of state borders from fraudulent purveyors – good border controls
- Regulation (unbiased, transparent)
  - Monitoring, standard setting, auditing
- Integrity of individual choice
    - **Brand Vs. generic**
    - **Conventional Vs. Complimentary**

Drug Regulation

Mutual reinforcement of numerous activities all directed at promoting and protecting health. The activities vary from country to country in scope and implementation but usually include common functions. (WHO, **paraphrased)**

Drug Regulation

- **Well established drug regulatory system**
- **Legislative Framework**
- **Application of sound medical, scientific and technical knowledge**
- **Regulatory functions involve interactions with various stakeholders (manufacturers, traders, consumers, health professionals, researchers and governments)**

DRUG REGULATORY FUNCTIONS

Primary Drug Regulatory Functions

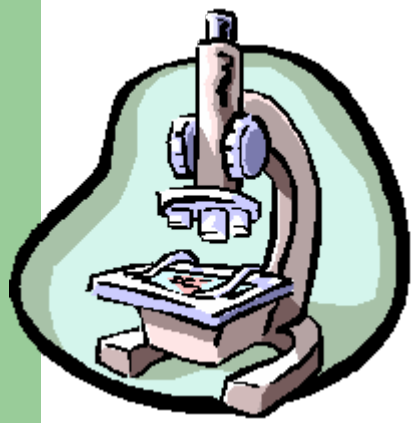
- Licensing (in Jamaica function is split)
  - Pharmacy Council
  - Ministry of Health
- Assessment (medicine safety, efficacy, quality)
- Marketing authorization
- Monitoring (inspection, surveillance of manufacturers, importers, wholesalers and dispensers of medicines
- Control promotion and advertising of medicines
- Monitoring adverse reactions to medicines
- Provision of independent information on medicines to professionals, public
- Guidance to policy directorate

DRUG REGISTRATION PROCESS

SCOPE OF PRODUCTS

- Foods
- Drugs
- Cosmetics; Chemicals
- Medical Devices
- Pesticides
- Precursor Chemicals
- Controlled Substances -Psychotropic drugs
  -Narcotics
  -Other Dangerous Substances

LEGISLATIVE FRAMEWORK



- Dangerous Drugs Act 1948
- Food & Drugs Act 1964
- Food & Drugs Regulation 1975
- Pharmacy Act & Regulations 1966*
- Precursor Chemicals Act 1999

*Administered by the Pharmacy Council

Passive process which involves scientific review of documentation provided by the applicant for a particular product and subsequent approval and issuance of a Certificate of Registration if established criteria have been clearly satisfied. Effective component of regulatory system to safeguard against unsafe/illicit drugs

PROCESS

1. Preparation of Dossier
   - **List of Requirements provided**
   - **Requirements prescribed in F& D Regulations**
2. Appointment with a Scientific Officer
   - **Submission of documentation with Fee**
   - **Initial review**
3. Detailed review by technical team

Process contd.

- **Presentation to Product Registration Committee with comments/ recommendations**
  - **Composition of committee**
  - **Sub committees**

- Expert Committee Review which may result in
  - **Acceptance → Approval → Licence issued**
  - **Request for further scientific review**
    - **Clinical consult**
    - **Veterinary Sub-Committee**
  - **Deferral**
  - **Refusal**

Basic Criteria-

- **Safety**
- **Quality**
- **Efficacy**

Pre-registration Activities

Quality

Product Integrity-

- **"Certificate of Analysis"**
  - **Conformity assessment for proper identity**
  - **Content verification**
  - **Purity (impurities- degradation prod., heavy metals, aflatoxins, moisture etc.)**
  - **Raw Materials (source etc. GSP)**
  - **GAP GCP GLP GMP**
  - **Product Stability**

Good Manufacturing Practice

WHO Certification Scheme – Quality

‘Free Sale Certificate’ replaced by “Certificate of A Pharmaceutical Product”-

Periodic inspection of manufacturing facility in keeping with WHO Guidelines

Good Clinical Practice

ICDRA recommends:

- Clinical trials should meet scientific & ethical requirements
  - **Informed consent especially with vulnerable populations**
  - **Appropriate guidelines must be followed**
    - **Biological samples for genetic studies**

Efficacy:-

- **Ability to support label claim**
  - Indications/mode of action
  - Pharmacological activity
  - Potency
  - **Bioavailability Vs Bioequivalence**
  - If combination, rationale
- Drug peculiarities which can affect therapeutic outcome –conditions which affect absn- pH, fat

Safety:-

- Toxicity – toxicological report
  - Acute
  - Mild, severe, reversible
  - Long term
- Reporting responsibility
  - Post market surveillance
- Drug interactions, contraindications
- Use in special populations

Further Technical Requirements

- **Certificate of Pharmaceutical Product**
  - Declaration regarding approval/use in country of origin
  - other countries
  - Authentication
- **Free Sale Certificate**

Drug Registration Lead Times

- New chemical moieties- 120 days
- Generics, Me- Too's - 90 Days
- Life saving drugs - 60 Days
- Other submissions - 60 to 90 Days
  - Vitamins
  - Herbal Preparations
  - Dietary supplements

Post Registration Activities

- Permit system
- Post market surveillance
  - Random collection of samples- Brand, Generic
  - Laboratory testing

Trade Considerations

- WTO/Trips
- Recognition of Patents
- Generic drug use

International Initiatives

- WHO
  - Certification Scheme for Pharmaceuticals Moving in International Commerce
  - Prequalification Scheme
    - Vaccines, drugs used in treatment of HIV/AIDS
  - Pharmacovigilance (Uppsala Monitoring Centre)
  - Guidelines for Regulation of Herbal Medicines
  - PANDRH
  - ICDRA
- ICH Guidelines
- OAS/CICAD
- International Standard Bodies-ISO etc.
- International Conventions and Treaties - INCB

CONCLUSIONS

- Access to safe drugs is a human right and a state responsibility
- Drug registration is an essential component of Jamaica's drug regulatory system
- The criteria for safety, efficacy and quality must be satisfied in order to obtain marketing authorisation for new drugs in Jamaican.

THANK YOU!