Caribbean
Public Health
Agency

CARPHA

Preventing disease
Promoting and protecting health

CARPHA DRUG TESTING LABORATORY

- HISTORY
- FUNCTIONS
- PROGRAMMES
- STANDARDS
- PROPOSED CARIBBEAN REGULATORY SYSTEM FOR MEDICINES

HISTORY

- FORMERLY CARIBBEAN REGIONAL DRUG TESTING LABORATORY
- AGREEMENT SIGNED IN 1974
- COMMENCED OPERATIONS IN 1980
- LABORATORY SITUATED IN JAMAICA ADJOINING THE LABORATORY OF THE GOVERNMENT CHEMIST
- THE GOVERNMENT CHEMIST OF JAMAICA SERVED EX OFFICIO AS DIRECTOR OF THE LABORATORY

FUNCTIONS

- Perform microbiological and pharmacological tests
- Perform biological availability tests
- Investigate the stability of drugs under the condition of storage prevailing in the region
- Establish liaison with appropriate agencies interested in drug testing and provide information and advisory services to support the activities of drug control officials in the region

PROGRAMME OF WORK

- Surveillance of quality of drugs used in the region
  - Priority list determined by the Technical Advisory Committee
- Pre-registration or pre-tender evaluation
- Investigation of questionable efficacy or adverse events
- Investigation of suspected mislabeling, or counterfeits
- Analysis of products in development
- Additional technical support as requested

PROGRAMME OF WORK

- Tests conducted
  - Assays by HPLC, UV/Vis Spectrophotometry, Titrimetry, Fluorometry
  - Disintegration
  - Dissolution
  - Identification: IR, TLC, etc.
  - Uniformity of Dosage units
  - Water content
  - Loss on drying
  - pH
  - Specific gravity
  - Sterility
  - Microbiological examination of non-sterile products
  - Microbial Assay (Cylinder Plate method)

REFERENCES AND STANDARDS

- BRITISH PHARMACOPOEIA
- UNITED STATES PHARMACOPOEIA
- INTERNATIONAL PHARMACOPOEIA
- EUROPEAN PHARMACOPOEIA
- MANUFACTURER MONGRAPHS
- REFERENCE STANDARDS
  - Primary standards obtained from the pharmacopoeia commissions
  - Secondary standards from Sigma
  - ATCC

QUALITY MANAGEMENT SYSTEM

- BASED ON WHO GOOD PRACTICES FOR PHARMACEUTICAL QUALITY CONTROL LABORATORIES, 2010 and ISO/IEC 17025:2005
- Participate in WHO Quality Assurance Assessment Scheme, PAHO/USP External Quality Control Programme and Interlaboratory Comparison programme organized by CNCC
- Applied for prequalification under the WHO prequalification programme for medicines quality control laboratories
- Currently working to complete corrective actions
- Microbiology laboratory will require major redesign
- Plans underway for installation of LIMS

SELECTED DATA

Reasons for Submission

Year	Routine	Pre-Registration/ Pre-Tender	Product in Development	Regulatory Investigation	Other
2004-2005	157	44	7	6	**3**
2005-2006	145	73	9	8	**4**
2006-2007	259	83	1	4	**2**
2007-2008	147	130	8	11	**4**
2008-2009	100	178	0	2	**5**
2009-2010	148	157	1	10	**16**
2010-2011	51	206		6	**29**
2011-2012	**53**	**131**	**1**	**7**	**8**

SELECTED DATA

Percentage of Products Found to be Out-of Specification

Year	Routine	Pre-Tender /Registration	Product in Development	Regulatory Investigation	Other
2002-2003	18%	23%	31%		
2003-2004	17%	21%			
2004-2005	8%	2%	57%	17%	
2005-2006	10%	3%	22%	25%	
2006-2007	11%	5%		75%	
2007-2008	17%	16%	12%	45%	**25%**
2008-2009	16%	9%		50%	
2009-2010	13%	4%		30%	**10%**
2010-2011	20%	6%			**14%**
2011-2012	**9%**	**10%**		**14%**	**12%**

CHALLENGES

- Staffing
- Infrastructure
- Costly certified reference standards
- Lengthy procurement timeframes
- Declining compliance with surveillance programme

Proposed Establishment of a Caribbean Regulatory System for Medicines

- **2009 Health Research for Action (HERA) conducted a Regional assessment of Drug Registration and Regulatory Systems in CARICOM Member States and the Dominican Republic found weaknesses in many areas**
  - Inadequate legislative frameworks
  - Few countries had National Medicines Policies
  - Few countries had medicines registration system
  - Weaknesses in Inspection and Surveillance
  - Human resource constraints
  - Institutional constraints

Proposed Establishment of a Caribbean Regulatory System for Medicines

- RECOMMENDATIONS
  - Establish network for cooperation among NRAs
  - Harmonization of medicines regulation
- HARMONIZATION STRATEGIES
  - Member states commit to support all areas of medicines regulation
  - Only medicines assessed for safety, efficacy and quality will be allowed to be marketed
  - Assessment process based on harmonized requirements and guidelines
  - Joint support provided for MS without registration system
  - Shared resources

Proposed Establishment of a Caribbean Regulatory System for Medicines

- CRITICAL STEPS TOWARDS HARMONIZATION
  - Formulation of a CARICOM Regional Medicines Policy
  - Adoption of the policy by member states
  - Establishment of a harmonization Secretariat (formerly at PAHO CPC but recommended to be established at CARPHA)
  - Development of strategic and annual workplan for policy implementation
  - Securing funding for workplan implementation

Proposed Establishment of a Caribbean Regulatory System for Medicines

- STATUS
  - Caribbean Pharmaceutical Policy and Expanded Technical Advisory Committee on Pharmaceutical Policy (TECHPHARM) approved by COHSOD in 2011
  - Proposal developed for a Caribbean Regulatory System (CRS)
  - System will be a combination of sub-regional and national functions
  - Regulatory unit to be established at CARPHA, building on the existing DTL
  - Regulatory unit will coordinate the system
  - Mutual collaboration among entities in the system
  - Legislative provisions to be developed
  - Funding options: quotas, fee for service, grants (free from conflict of interest)
  - Road map for implementing the CRS developed

Proposed Establishment of a Caribbean Regulatory System for Medicines

- Proposed Regulatory Functions
  - Issuing guidelines, standards, regulations
  - Regulation of clinical trials
  - Evaluation and registration of pharmaceuticals
  - Lot Release (vaccines)
  - Inspection (manufacturers, distributors, pharmacies)
  - Licensing (manufacturers, distributors, pharmacies)
  - Quality control labs
  - Pharmacovigilance (surveillance of safety, quality and efficacy)
  - Medicines information and promotion
  - Health technologies assessment

Proposed Establishment of a Caribbean Regulatory System for Medicines

- Stakeholder Consultation held in July 2014
- Key implementation principles agreed
  - CRS will become a regulatory unit within CARPHA
  - Scope will include Medicines and Health Technologies
  - Registration of Medicines to be the first regulatory function implemented
  - Non-binding registration recommendations to be made
  - Registry of products to be established
  - Registration information to be used to bolster post-market surveillance

Proposed Establishment of a Caribbean Regulatory System for Medicines

- Key Objectives
  - Improve access to safe, quality assured medicines and health technologies
  - Improve market control of medicines and health technologies
  - Improve regulatory efficiency
  - Build regulatory capacity
  - Streamline regulatory processes and timely access to markets for industry

Proposed Establishment of a Caribbean Regulatory System for Medicines

- Next Steps
  - Presentation to COHSOD
  - Set up of the registration system
  - Implementation of the registration system

PAHO SUPPORT

- PAHO has played and continues to play a significant role in the development of proposals and strategies for the regulatory system
- PAHO through the Good Laboratory Practices working group has also contributed significantly to the training of analysts at the DTL and national quality control laboratories of the region
- Provided significant training and support for the implementation of Good Laboratory Practices at DTL
- Developed project for strengthening Official Medicines Control Laboratories in Caribbean Countries, funded by the Government of Argentina, implemented in 2013.
- Funded training workshop for OMCLs, delivered by CARPHA DTL, August 2014

Thank You!

Caribbean
Public Health
Agency

CARPHA

Preventing disease, promoting and protecting health