Caribbean
Public Health
Agency

CARPHA

Preventing disease
Promoting and protecting health

Strengthening Medicines Regulation

Proposed Argentine Collaboration

Caribbean Public Health Agency
CARPHA

Preventing disease, promoting and protecting health

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

Proposed Areas of Work for Argentine Collaboration

- Establish a Medicines Regulatory Unit within CARPHA
- Strengthen the CARPHA Drug Testing Laboratory
- Strengthen Post-Marketing Surveillance of Medicines
- Support Development of a Pharmacovigilance System in Caribbean Countries

Establish Regulatory Unit within CARPHA

- Recruit Expert to direct unit – Secondment
- Develop policies, SOPs
- Train staff
- Provide necessary equipment etc. for the unit

Strengthen CARPHA Drug Testing Laboratory

- Upgrade facilities including redesigned Microbiology laboratory
- Upgrade Scientific Equipment
- Training to expand range of services available
- Enable continued support to OMCLs

Strengthen Post-Marketing Surveillance of Medicines

- Training in development of market surveys
- Support the conduct of surveys
  - Reference standards
  - Training in-country staff involved in planning and executing sample collection

Support Development of a Pharmacovigilance System

- Provide expert to assist in establishment of unit
- Provide essential equipment for unit
- Training staff
- Capacity-building within member states
- Public education
- Establish electronic reporting platform to facilitate submission of reports

Thank You!

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