The Caribbean Regulatory System Initiative

VIII Conference of the PANDRH

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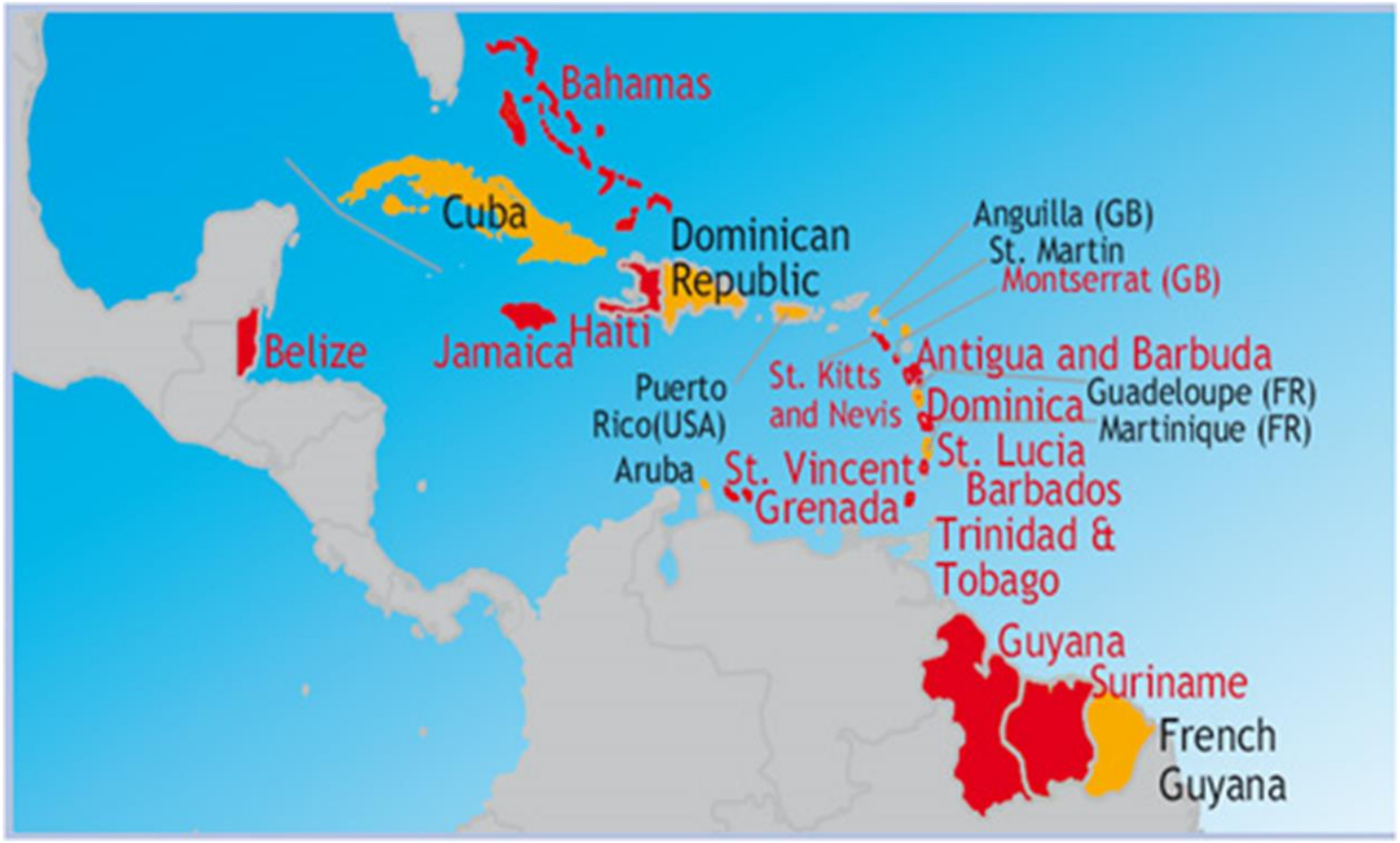
Presentation Outline

- Background of the Caribbean Regulatory System (CRS) Initiative
- Recent developments
- Proposed Next Steps

CARICOM Countries



Background on the CRS Initiative

- Limited regulatory capacity in CARICOM countries
  - Poor capacity in core functions including marketing authorization, pharmacovigilance and post-marketing surveillance
  - Inadequate legislation
  - Resource constraints

Background on the CRS Initiative

- Caribbean Pharmaceutical Policy (CPP) adopted in 2011
  - Endorsed regional approach to address regulatory matters
  - Created advisory body (TECHPHARM) to oversee implementation
  - Proposed establishment of a regional regulatory system for medicines

Background on the CRS Initiative

- Initiative to establish the CRS approved by CARICOM Ministers of Health in 2014. Reaffirmed each year since then
- Funding received from Bill and Melinda Gates Foundation in 2015, with funding for subsequent years if performance goals met
- Funding support also received from US FDA and Health Canada at earlier stages
- Additional support provided by NRA/RR including technical support from COFEPRIS

Background on the CRS Initiative

- The CRS is to be implemented as a regulatory unit within CARPHA in close technical collaboration with PAHO
- The CRS will perform 2 key regulatory functions
  1. It will carry out an accelerated review of priority generic medicines, using reliance on PAHO-designated Reference Authority (equivalent to a registration procedure), and
  2. Coordinate pharmacovigilance of these medicines in concert with CARPHA Drug Testing Lab, and national authorities
- Focus will be on priority medicines, including from WHO EML and/or priorities from countries
- Only products already registered by reference authorities will be eligible for evaluation by the CRS

Background on the CRS Initiative

- The CRS will recommend products for which there has been a positive review outcome to CARICOM Member States
- Member States will be provided with an assessment report, and relevant dossier information will be shared to facilitate understanding of the rationale for the CRS decision
- CRS review should be done in 180 days; the Member States are then responsible for issuing Marketing Authorizations, ideally within 60 days of communication of the CRS decision
  - Will put in place legal arrangements (MOUs) to accomplish this

Note on CRS Accelerated Review Procedure

- The CRS uses a WHO procedure that was developed to be accelerated for products undergoing prequalification that have already been approved by a reference authority
  - 14 requirements
    - Cover letter that product is the same as in reference authority country; copy of marketing authorization; summary product characteristics; labelling; GMP certificates from reference authority; batch certificate of analysis; finished product specifications; proof of therapeutic equivalence; stability studies; periodic safety update report; portions of quality information summaries

Recent Developments

- Staffing the CRS Initiative
- Development of policies, procedures and communication mechanisms
- Fostering engagement with Member States and other partners
- Fostering engagement with industry.

Recent Developments

- Staffing the CRS initiative
  - Technical Officer engaged for CRS unit at CARPHA HQ
  - PAHO Advisor in Port of Spain, Trinidad

Recent Developments

- Development of policies, procedures and communication mechanisms
  - CRS operational policies developed
  - Dossier submission requirements established
  - Website launched
  - EOI published

Recent Developments

- Member State engagement
  - Working to get strong engagement at all levels of Ministries of Health
  - Strong engagement and input from the TECHPHARM
  - Focal point network being established (9 of 15 Member State focal points nominated to date)
  - MOU drafted and being circulated to Member States
  - Discussions being held with National Authorities regarding backlogs of products awaiting registration

Recent Developments

- Engagement with Industry
  - Numerous conversations with company representatives to build awareness of the CRS and generate interest in submission of dossiers
  - General interest in the initiative however, since registration is voluntary, difficult to make business case
  - Strategy
    - Continue work to put MOUs in place to provide assurance that CRS recommendations will be recognized. One country has already signalled intent to sign

Recent Developments

- Engagement with Industry (cont.)
  - Continue engagement with National regulators to identify qualifying products in their backlog and reach out to industry sponsors to submit those products for evaluation by CRS
  - Continue gathering and analysing market information including procurement volumes and pricing information (data in respect of 10 medicines already collected from 5 countries)
  - Engagement with public procurement agencies to acknowledge CRS recommendations

Proposed Next Steps

- Continue stakeholder engagement including industry
- Encourage submission of dossiers
  - Target 15 medicines and 1 vaccine in year 1
- Convene group review with experts from reference authorities, member state authorities, CRS
- Sign MOUs with member states
- Continue collection and analysis of market data to help sharpen strategic focus (procurement volumes, pricing, registration timelines etc.)
- Begin conceptualization of pharmacovigilance strategy

CRS Benefits to CARICOM

- Benefits of the CRS will include:
  - Improved access to, and affordability of, priority medicines that are safe, quality and effective for populations
  - Regulatory assured products to procure from
  - Reduced regulatory burden on governments, for example with backlogged registrations
  - Decreased health system costs through generic competition
  - Strengthened human resources capacity in regulation
  - Central portal with one set of requirements for access to CARICOM markets (17 million people), faster marketing authorization, and better access to procurement markets

Thank You

- CARPHA/CRS webpage: http://carpha.org/What-We-Do/Laboratory-Services-and-Networks/CRS