CRS Status, Main Challenges, Future Outlook

Dr. Virginia Asin
Director Surveillance, Disease Prevention and Control

Caribbean Public Health Agency
CARPHA

Preventing disease, promoting and protecting health

Pan American Health Organization
World Health Organization
PAHO

DNM

PANDRH

Inherent Regulatory Challenges in CARICOM

- Limited regulatory capacity in small states of CARICOM:
  - Small populations mean few staff and technical capacity
- Small market challenges
  - Business incentives to comply decreased bc small volumes
  - Lots of intermediary actors in the market (importers)
    - Not familiar with, or used to, regulation
  - Decreased appetite to pay user fees
  - => Caribbean Pharmaceutical Policy and Caribbean Regulatory System CRS: Small regulatory unit at CARPHA

CRS Results

- ~50 dossiers submitted since April of 2017
- 21 products recommended (HIV, cholera vaccine, reproductive health)
  - All WHO Prequalified generic essential medicines
  - ~60 days average time
- 31 products registered/tentatively registered in Guyana, Jamaica
  - Guyana requires CRS as one pathway for imported products
- 1 product procured by Trinidad and Tobago (7 offered)
- OECS will require CRS recommendation for HIV tenders in 2019
- Sparking regulatory reforms across CARICOM
- Over 160 PV/substandard and falsified (SF) med reports received thru VigiCarib, with reports being entered into WHO global databases for PV and SF, including resulting in action
  - Unregistered/falsified biosimilar in Guyana→ prosecution

Offered CRS Products in T&T in 2017 Procurement Cycle
5/7 Products Cheaper Than Lowest Cost Version in Last Cycle While Maintaining High Quality (All WHO Prequalified)

Medicine	Dose	Price Per Unit Now (Last Procurement Cycle TT$)
Tenofovir Disoproxil tab	300MG	1.65 (from 1.94/3/4.49) 15% reduction in price
Emtricitabine/Tenofovir tab	200MG/300MG	4.95 (from 5.37/7.05) 8% reduction in price
Lamivudine/Zidovudine cap	150MG/300MG	0.91 (from 0.87)
Efavirenz cap	600MG	1.00 (from 1.08/1.35) 8% reduction in price
Efavirenz/Emtricitabine/ Tenofovir tab	600MG/200MG/300MG	5.95 (from 7.97/10.74) 25% reduction in price
Lamivudine/Zidovudine/ Nevaripine tab	150MG/300MG/200MG	1.30 (from 1.53) 15% reduction in price
Nevirapine tab	200MG	0.39 (from 0.33)

Persistent Implementation Challenges

- Member State uptake
  - Countries at different stages of implementation
    - Sovereignty
  - Some procedures/requirements hamper efficiency
    - e.g. requirement for importers, samples, CPP
- Industry uptake
  - Business case in small markets
    - Need to improve incentive variables (mandatory, timelines, more/larger procurement)

Overarching Vision

- An overarching vision and mandate for regulatory systems is outlined in Sustainable Development Goal (SDG) # 3.3.8, which states that United Nations member states should, "*Achieve… access to safe, effective, quality and affordable essential medicines and vaccines for all*". In other words, all governments should have in place, or be working to put in place, systems that can assure everyone has access to quality medicines.

Future Vision for CRS:

Increased access, reduced cost, easy for industry, through a shared approach to regulatory capacity building, appropriate to CSME

- Smart, value-added service implemented in partnership with MS
  - Lean, smart, sustainable enterprise
- Quality versions of all WHO EML meds registered via fast-track
- Regulatory action via VigiCarib on post market surveillance improving quality of medicines in market
- Systematic risk based testing by Medicines Quality Control lab
- Procurers advantaging/requiring CRS recommended meds
- Platform for training and applied research; building regulator pipeline

Caribbean Public Health Agency
CARPHA

Preventing disease, promoting and protecting health

Pan American Health Organization
World Health Organization
PAHO

DNM

PANDRH

THANK YOU

Caribbean Public Health Agency
CARPHA

Preventing disease, promoting and protecting health

Pan American Health Organization
World Health Organization
PAHO

DNM

PANDRH