Opportunities to Improve Access and Quality of Pediatric Cancer Meds

Charles Preston, MD, MPH

Advisor, Regulatory Systems Strengthening for Medicines and Other Health Technologies

PAHO/WHO

Pan American Health Organization
World Health Organization
Regional Office for the Americas

PAHO

Outline of Presentation

- Regulatory systems and how they ensure access to quality meds
- Data from region
- PAHO approach to regulatory strengthening
- Caribbean Regulatory System/ Medicines Quality Control and Surveillance Department

“If you think compliance is expensive – try non-compliance.”

Former U.S. Deputy Attorney General Paul McNulty

Regulatory Systems for Medicines and Health Technologies

- Critical but undervalued part of health system (often taken for granted)
- National government system that ensures safe, effective, **quality** products
- Can speed access to medicines with shorter approval times
- Can improve affordability with access to lower cost generics
- Monitor medicines in the market
- **When regulatory systems fail, people can be injured or die!**

PRINCIPLES Independence | Equity | Transparency | Ethics | Code of conduct | No conflict of interest | Risk management | Accountability | Regulatory science

CROSS-CUTTING ELEMENTS

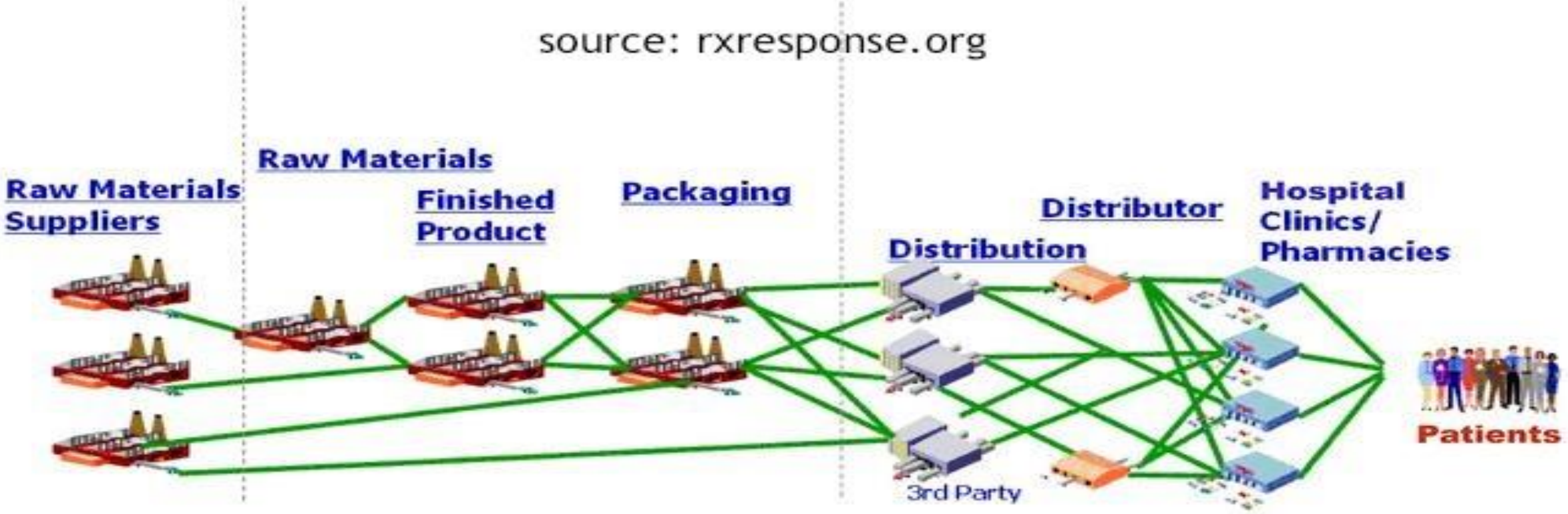
- Legal bases
- Standards, guides, specs. & procedures
- Resources (inc. finances)
- Quality assurance
- Workforce
- Information system

ESSENTIAL REGULATORY FUNCTIONS

1. National systems
2. Registration & mkt authorization
3. Licensing
4. Mkt surveillance & control
5. Vigilance
6. Clinical trials oversight
7. Regulatory inspections
8. Lab testing
9. NRA lot release

Pharmaceutical Supply Chain

source: rxresponse.org



Raw Materials Sourcing → Manufacturing → Distribution and Dispensing Logistics → Dispensing

What Do We Know About Children's Cancer Medicines in Caribbean

- We do not have good info on what is in the market
- Have to use procurement data to see availability and quality issues

Availability of Quality Priority Childhood Cancer Medicines by Procurers in Trinidad and Tobago and OECS PPS

EML INN by Formulation	Manufacturer Procured by TT (Origin)	Maufacturer Procured by OECS PPS (Origin)
Asparaginase injection	None	None
Cyclophosphamide injection	Celon Laboratories (India)	Baxter (?)
Cyclophosphamide tab	Baxer (?)	Baxter (?)
Mercaptopurine tab	Heumann Pharma (?)	GlaxoSmithKline (?)
Vincristine injection	Neon (India)	Celon (India)
Rituximab injection	Dr. Reddy's (India)/ Hoffman LaRoche (?)	None

National Procurement of Total Childhood Cancer EML by Formulation for TT and OECS/PPS

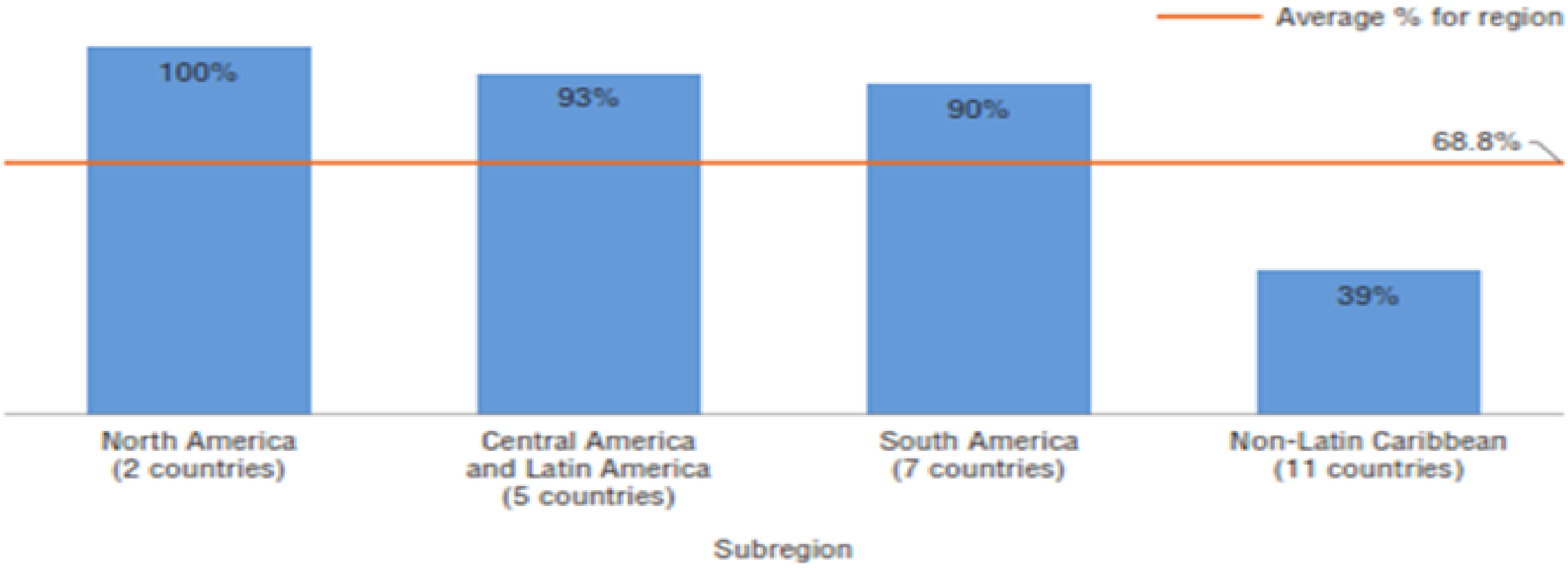
- TT = **31/46 (67%)**
- OECS/PPS = **12/46 (26%)**
- Are these quality versions??? How are these products regulated?

Regulatory Systems for Medicines and Health Technologies in the Caribbean

- Challenge is regulatory systems very limited in the Caribbean
- Small populations, small markets, limited financial resources
- Only 6/14 governments have regulatory systems
- Amongst those with regulatory systems, backlogs of products for approvals, long wait times, very limited monitoring of whats on the market, very limited labs

Regulatory Capacity in CARICOM

FIGURE 1. Average % of each of the 20 PAHO* basic indicators for regulatory capacity achieved by 25 selected countries, by subregion, Americas region, 2014



Source: Data from (14).
*PAHO: Pan American Health Organization.

Key PAHO Approaches to Strengthening Regulatory Systems in Caribbean

- Focus on critical functions of marketing authorization, market surveillance, lab
- Adopt efficiencies to do more with less
  - Work regionally/collectively
  - Use reliance on reference authorities
  - Share information
  - Pool markets/ 1 set of standards
  - Work electronically

Caribbean Regulatory System

- Regional regulatory mechanism for CARICOM (regulatory unit at CARPHA)
- Focused on helping countries with marketing authorization and surveillance (detection of adverse events/substandard and falsified medicines)
- Voluntary
- Requires products are approved and the same in a reference authority
  - Short verification review, if positive, electronic transmission of recommendation assessment to Member States
  - Same quality criteria and process as PAHO Strategic Fund
- Regional reporting system called **VigiCarib**
- Regional drug testing lab called **MQCSD**

CRS/VigiCarib/MQCSD Successes

- >75 essential medicines recommended including cancer medicines
- Timelines of anywhere between 4-8 weeks for process

- Public list of recommended products http://carpha.org/What-We-Do/Laboratory-Services-and-Networks/CRS

- Over 200 products reported, most of which are reported to WHO databases for adverse events and substandard/falsified medicines→ increasingly resulting in regulatory action

aribbean Regulatory

Not secure | carpha.org/What-We-Do/Programmes-and-Projects/CRS/Caribbean-Regulatory-System

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- Caribbean Regulatory System
- CARICOM Member State Engagement
- Operational Policy
- Stakeholder Information
- VigiCarib
- Latest News

Contact

For more information or submission of inquiries:

CRSRegistration@carpha.org

For more background and context, please see the recent

THE CARIBBEAN REGULATORY SYSTEM

The Caribbean Regulatory System (CRS) is an initiative of the Caribbean Community and Common Market (CARICOM) and is managed as a regulatory unit within CARICOM's regional public health body, the Caribbean Public Health Agency (CARPHA). It is supported by a number of partners, including the Pan American Health Organization/World Health Organization (PAHO/WHO), PAHO designated National Regulatory Authorities of Regional Reference (NRA/RR) (Argentina, Brazil, Canada, Chile, Colombia, Cuba, Mexico, United States), and the Bill and Melinda Gates Foundation (BMGF).

LEGAL AUTHORITY

The CRS derives its legal authority from CARPHA's Public Health Mandate, the Caribbean Pharmaceutical Policy, and va

Conclusions and Next Steps

- These programs can be important source of quality pediatric cancer medicines
- We can work on identifying manufacturers willing to supply reference authority approved versions of these products
- Use CRS/VigiCarib/MQCSD programs to report and test suspect meds in the Caribbean market

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Thank you

Questions/comments?

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