Implementing a Regional Approach to Pharmacovigilance and Post Market Surveillance in CARICOM

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Caribbean Public Health Agency CARPHA

Pan American Health Organization

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CARICOM Map

*Member States are:
Antigua and Barbuda, Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St. Vincent and the Grenadines, Suriname, and Trinidad and Tobago

*Associate Member States are:
Anguilla, Bermuda, British Virgin Islands, Cayman Islands, and Turks and Caicos Islands

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Regulatory Capacity in CARICOM

* The current state of regulatory capacity is limited due to resource constraints in the many small, mixed- GDP/capita, states of CARICOM
  * Many governments do not have medicines regulatory authorities, some have only procurers
  * 5/20 governments carry out reviews of safety, efficacy, and quality of medicines and vaccines to determine legal authorization for marketing and sale
  * Some countries have backlogs of products that go back years, with challenges in transparency and accountability
  * Few systems to monitor drug safety and quality, including for substandard and falsified medicines

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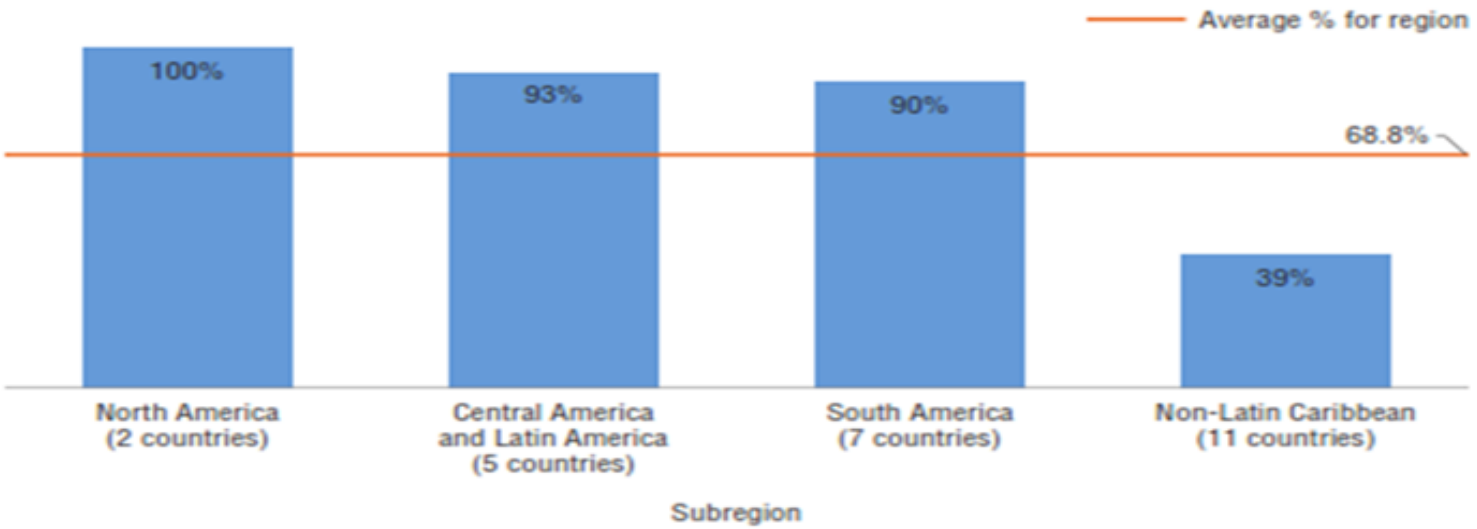
Regulatory Capacity in CARICOM

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



Source: Data from (14).
[a]PAHO: Pan American Health Organization.

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What Is Being Done?

* Setting up a regional mechanism to strengthen capacity for regulation of medicines and vaccines in CARICOM
  * Caribbean Pharmaceutical Policy approved by CARICOM Ministers of Health in 2011 and operationalized in 2014 as Caribbean Regulatory System (CRS);
  * Pools resources and leverages cooperation platforms to augment and support MS

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How Does CRS Work?

* Managed by CARICOM's regional public health agency, CARPHA
  * Partners PAHO/WHO, NRA/RR of region, BMGF
  * Advised by Member State representatives called TECHPHARM
* Focused on strengthening 2 key functions:
  * 1) Marketing authorization- reliance on reference authorities for fast-tracking high quality essential meds
  * 2) PV and PMS

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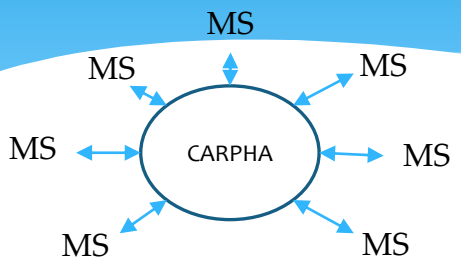
Product Recommendations

CARPHA/CRS List of Medicines Recommended for Marketing Authorization in CARICOM States

1	CARPHA/CRS: CRS/022017/HA001; WHO: HA 291	Lamivudine/Zidovudine	HIV/AIDS;	Strides Shasun Ltd, Strides house, Bilekahali, Bannerghatta Road, Bangalore, 560 076, India	Tablet
2	CARPHA/CRS: CRS/032017/HA002; WHO: HA 535	Tenofovir Disoproxil Fumarate	HIV/AIDS; Hepatitis B	Strides Shasun Ltd, Strides house, Bilekahali, Bannerghatta Road, Bangalore, 560 076, India	Tablet
3	CARPHA/CRS: CRS/042017/HA004 WHO: HA 524	Lamivudine, Nevirapine and Zidovudine USP [150/200/300mg] Tablets	HIV/AIDS;	Strides Shasun Ltd, Strides house, Bilekahali, Bannerghatta Road, Bangalore, 560 076, India	Tablet
4	CARPHA/CRS: CRS/0517/HA005 WHO: HA 552	Emtricitabine/Tenofovir Disoproxil Fumarate [200/300mg] Tablets	HIV/AIDS;	Strides Shasun Ltd, Strides house, Bilekahali, Bannerghatta Road, Bangalore, 560 076, India	Tablet

CARPHA/CRS Regional Pharmacovigilance/Postmarket Surveillance System (VigiCarib)



* Key principles
  * Builds on networking concept, prior called "VigiCarib"
  * CARPHA/CRS serves as coordinator/hub
  * Asks CARICOM states/ focal points to report 1) adverse events and 2) suspected substandard/falsified on medicines and vaccines
  * Central database at CARPHA or in combo w MS
  * Leverages CARPHA drug testing lab, other WHO resources and systems e.g. WHO GSMS
  * Makes regulatory recommendations to MS

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Where To Start

* WHO recommends low resource NRAs start with spontaneous systems
* May need to be targeted- smart safety surveillance:
  * PV
    * Request reports on serious adverse events/therapeutic ineffectiveness
    * Request reports on higher risk products, e.g. new meds/vaccines
  * PMS
    * Request reports on SF medicines
    * Sample products that have not gone through strong regulatory scrutiny
    * Sample informal markets
  * Request reports/sample traditional/complementary meds
* →Determine pilot countries?

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Benefits of Regional Approach to PV/PMS

* Pooled data for analysis
* Information sharing/exchange on common products in similar populations
* More harmonized processes/standards
* Evidence generation for future approaches/ we do not know what we do not know
* Safer, higher quality medicines for patients

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Closing Thoughts

* Regional approach/networking is what many have said we need to do more of
* Successes and failures can be informative, example
* Much is riding on the success of these types of initiatives

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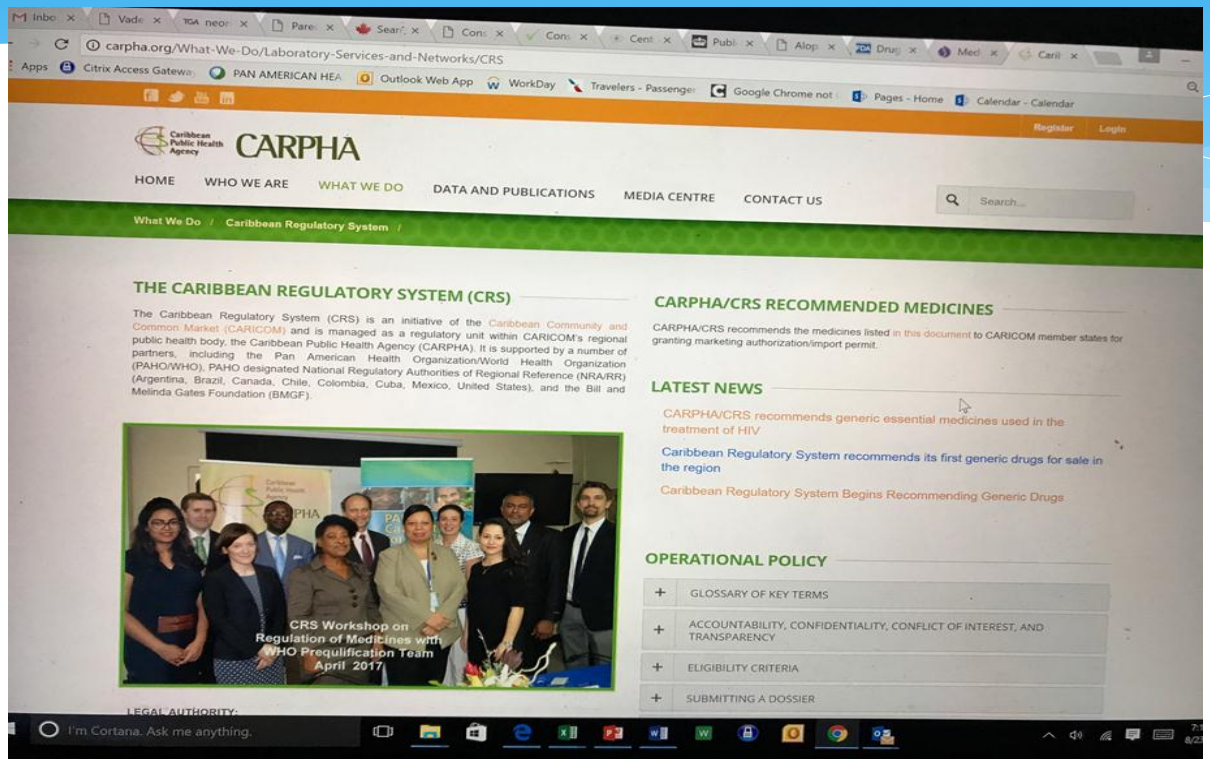
Links and Contacts



* For more information, visit the CARPHA/CRS webpage: http://carpha.org/What-We-Do/Laboratory-Services-and-Networks/CRS

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