The Caribbean Regulatory System Copenhagen 2017
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Purpose of This Presentation

- Orient industry to a new regulatory mechanism in the CARICOM block of countries
- May be a good business opportunity
- Combines many of the elements industry says it wants:
  - Harmonization
  - Reliance
  - Accelerated processing
  - Accountability
  - Transparency
*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
The CRS is a centralized regulatory mechanism intended to speed marketing authorizations/legal sale of quality essential medicines in CARICOM. It helps CARICOM states perform assessments of essential medicines/vaccines for legal sale, and 2) monitors medicines in the market. It is physically a regulatory unit, with small # staff, based at CARPHA, with technical cooperation by PAHO/WHO, funded by Bill and Melinda Gates Foundation. Derives from Caribbean Pharmaceutical Policy and endorsement by CARICOM Ministers of Health in 2014. Small countries struggle with individual regulatory capacity but have strong history of cooperation and goal of common market. The mechanism is voluntary and is not meant to replace national systems.
Eligibility: CRS Mechanism

To use the mechanism, medicine must be:

- Essential medicine listed on WHO list (2017) (innovators and generics)
- Be approved in 1/10 PAHO designated authorities of reference: Argentina, Brazil, Canada, Chile, Colombia, Cuba, European Union, Mexico, United States, and WHO Prequalification
Process: CRS Assessment

- Company prepares a dossier based on same procedure WHO uses to prequalify products already approved by SRAs
- Manufacturer signs cover letter saying product is same
- Focus of CRS assessment is verification that the product is the same
  - Takes about 6-8 weeks to assess
  - Much faster than current situation in many countries
Broadly, these include the following:

- Cover letter that product is the same as in reference country; demonstration of marketing authorization certificate; 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

- Don’t require CPP, product samples, or pre-testing
Can accept prior documentation submitted to reference authority, e.g. CTD, other summary formats

Happy to try different approaches as long as basic requirements are met
  * Want to reduce burden on company

No user fees right now

Uses WHO collaborative procedure for medicines and vaccines
If CRS assessment/verification is favorable, CRS recommends the product to all of CARICOM for marketing authorization/import permit/procurement

- 6 countries have marketing authorization for products: Belize, Guyana, Haiti, Jamaica, Suriname, Trinidad and Tobago
- OECS has a regional procurer called OECS/PPS
To accompany recommendation, CRS issues an Assessment Report to CARICOM governments
- Government decides whether to grant approval
  - **Target is 60 calendar days**
- General in-country uptake process
  - Fill out local administrative forms (regulatory info covered by Assessment Report)
  - Pay local user fee
  - Identify local importer
CARPHA/CRS Assessment Process

In-Country Process (MOH) (Target: 60 calendar days)
- Fill out local administrative forms
- Pay local user fee
- Identify a local importer

CarPHA/CRS Assessment/Verification (30-60 days)

Eligibility for CRS Assessment
- Essential/priority med +
- Approved by RA

Other opportunities, e.g. accelerated qualification for procurement, etc.
After only a year and a few months of staff on the ground, the CRS initiative is progressing well!

- It has recommended 11 essential HIV products to CARICOM governments
  - Other products in the queue including for NCDs
- CRS is building a portfolio of essential medicines that governments can grant marketing authorization/import permit and procure
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<th>#</th>
<th>CARPHA/CRS: CRS/022017/HA001; WHO: HA 291</th>
<th>Lamivudine/Zidovudine</th>
<th>HIV/AIDS;</th>
<th>Strides Shasun Ltd, Strides house, Bilekahali, Bannerghatta Road, Bangalore, 560 076, India</th>
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<td>2</td>
<td>CARPHA/CRS: CRS/032017/HA002; WHO: HA 535</td>
<td>Tenofovir Disoproxil Fumarate</td>
<td>HIV/AIDS; Hepatitis B</td>
<td>Strides Shasun Ltd, Strides house, Bilekahali, Bannerghatta Road, Bangalore, 560 076, India</td>
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<td>3</td>
<td>CARPHA/CRS: CRS/042017/HA004; WHO: HA 524</td>
<td>Lamivudine, Nevirapine and Zidovudine USP [150/200/300mg] Tablets</td>
<td>HIV/AIDS;</td>
<td>Strides Shasun Ltd, Strides house, Bilekahali, Bannerghatta Road, Bangalore, 560 076, India</td>
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<td>4</td>
<td>CARPHA/CRS: CRS/0517/HA005; WHO: HA 552</td>
<td>Emtricitabine/Tenofovir Disoproxil Fumarate [200/300mg] Tablets</td>
<td>HIV/AIDS;</td>
<td>Strides Shasun Ltd, Strides house, Bilekahali, Bannerghatta Road, Bangalore, 560 076, India</td>
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List of regulatory assured medicines that governments can use for marketing authorization/import permit and procurement
Other Achievements

- Drug safety and monitoring
  - Launched regional mechanism for pharmacovigilance and post market surveillance (VigiCarib)
  - Country focal points report adverse and substandard/falsified medicine events to CRS for analysis and recommendations to Member States
  - Leverages regional CARPHA lab for risk based drug testing
Other Achievements

- Helping to reorient country regulatory approaches
  - Memorandums of understanding with Anguilla, Guyana, OECS PPS, Suriname
  - Guyana and Jamaica initiated fast-track process for CRS recommended products- close to approval in Guyana, 5 tentatively approved in Jamaica
  - Accelerated qualification for procurement in Barbados, OECS
Challenges

- Still implementing country uptake
- Invite industry and distributors to be patient, advocate for governments to use this mechanism
  - Eligible products are all those on EML, including innovators (something for everyone)
- Nature of effort will look like small incremental gains in short term, but will add to major advances in medium to long term → needs long term political commitment
Summary: Why CRS?

- Major industry opportunity with this mechanism
  - Harmonization, reliance, accelerated review, accountability, and transparency
  - New to market; want to launch new product quickly; want to expand to other markets, etc.
  - No user fees now, want to stabilize the system
  - Wide variety of products to submit, will participate in WHO Collaborative Procedure pilot with biosimilars (can consider products not on EML if need)
  - Will help you obtain volume, pricing information
Thank You

* For more information, visit the CARPHA/CRS webpage: http://carpha.org/What-We-Do/Laboratory-Services-and-Networks/CRS
* Additional information and submission inquiries can be requested from the below:
  * CRSregistration@CARPHA.org