

A hand is shown placing a red puzzle piece into a larger red puzzle piece. The background is a grey surface with a grid of puzzle pieces, some of which are missing, creating a pattern of interlocking shapes. The lighting is dramatic, highlighting the red pieces and the hand.

# Migrating from Routine to Risk Based Inspections

Optimizing the Human Resources in Post Pandemic

By: Alfred Athill, DPS  
Antigua & Barbuda

# Agenda

01



Introduction

02



Pharmaceutical Sector Regulation

03



Reliance

04

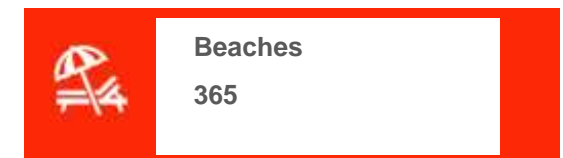
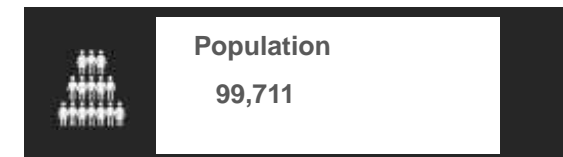
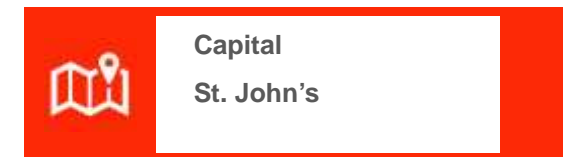
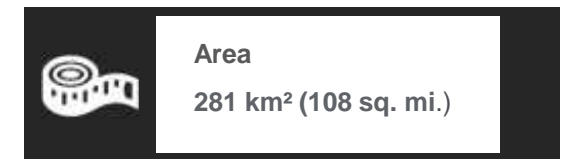


Conclusion



# Introduction

# Antigua & Barbuda



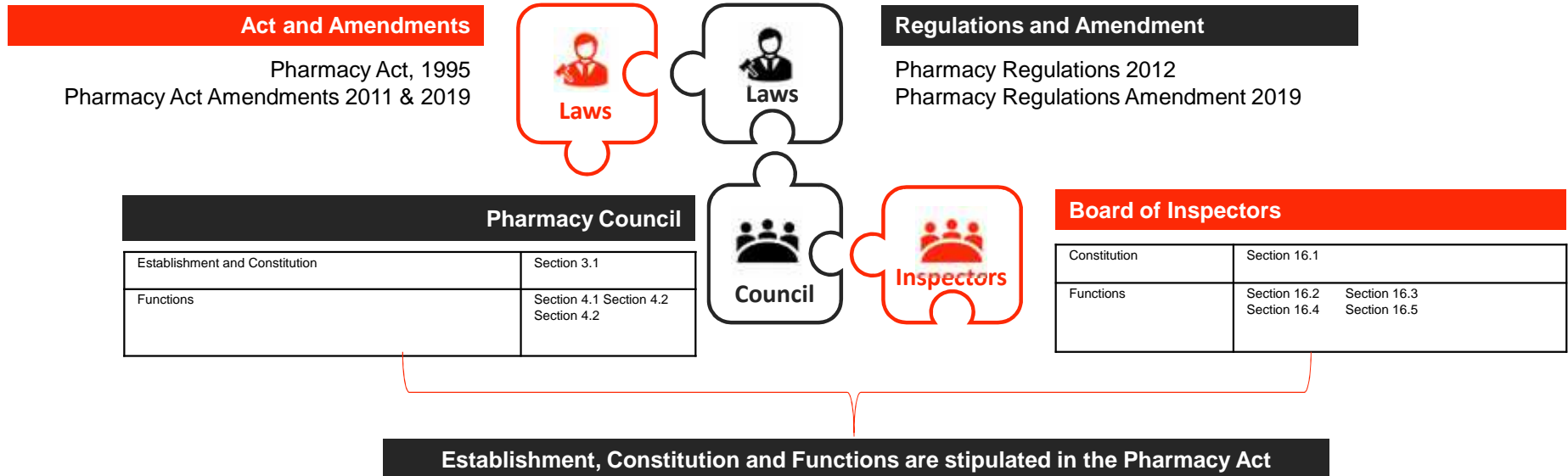
*The Beach is just the beginning!*



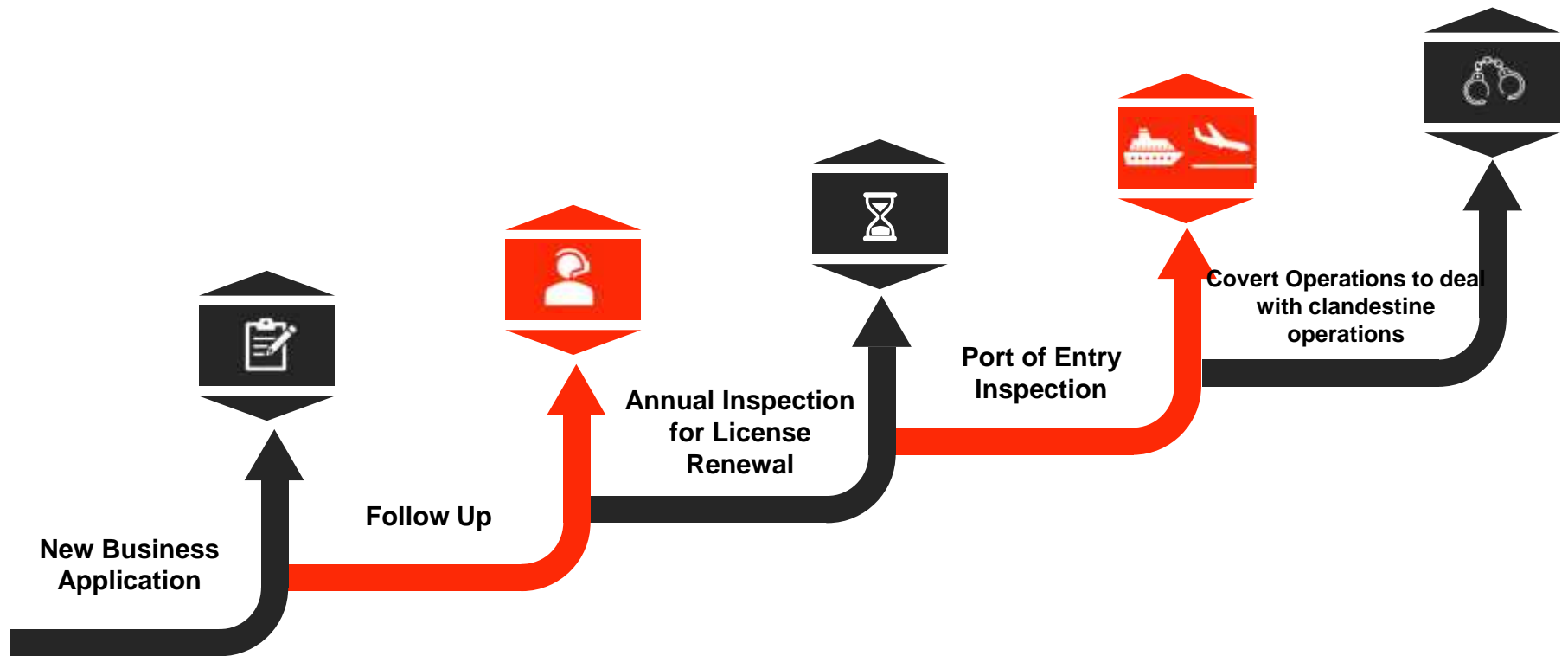
# Pharmaceutical Sector Regulation

# How the Pharmaceutical Sector is Regulated

The Pharmaceutical Sector in Antigua & Barbuda is Regulated by the following:



# Types of Routine Inspections Performed





**Reliance**



# Risk Based Inspector Approach

01

Technology

Particularly with an entity that has been consistently compliant.

02

Other Regulatory and/or Procurement Agencies and Stakeholders

Reliance on other Regulatory and/or Procurement Agencies to ensure that only safe and effective medical products are distributed in the market.

CHARPA – CRS

01

OECS / PPS

02

Customs  
Ministry of Trade

03

# Caribbean Regulatory Systems (CRS)

## ABOUT



This is the regulatory unit within CARICOM's regional public health body - Caribbean Public Health Agency (CARPHA).

## MISSION



“ Through dedication to efficiency, transparency, resource-sharing, and capacity-building, we provide recommendations for market authorization, rational use, and quality and safety monitoring of medical products in the Caribbean. ”

## SUPPORT

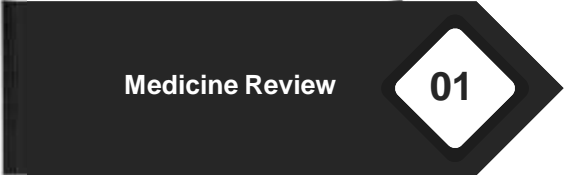


It is supported by several partners, including the Pan American Health Organization/World Health Organization (PAHO/WHO), PAHO designated National Regulatory Authorities of Regional Reference (NRA/RR) (Argentina, Brazil, Canada, Chile, Colombia, Cuba, Mexico, United States), and the Bill and Melinda Gates Foundation (BMGF).



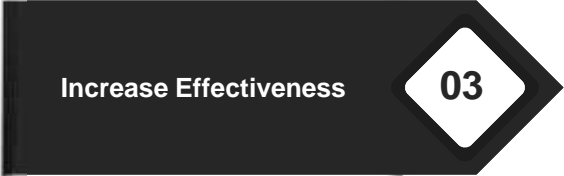
# CARPA-CRS Benefits to Member States

Reduce the number of resources needed to review medicines for market registration and/or import approval



Identify safety and quality issues that may need monitoring and action.

Realign staff functions to increase effectiveness and/or expand scope of work



# CARPHA-CRS Benefits to Industry

Apply for market entry among CARPHA Member State markets of over 17 million people.

Market Entry

01

02

Streamlined review process

Use a streamlined process for review, particularly for countries without a formal process.

Experience faster market access, particularly for WHO Prequalified medicines and vaccines.

Faster market access

03

04

Case Reports

Submit case reports of suspected adverse reactions and quality issues for countries without reporting systems.



Dr. Rean Extavour



[CRSRegistration@carpha.org](mailto:CRSRegistration@carpha.org)

O E C S / P P S

ORGANIZATION OF EASTERN CARIBBEAN STATES  
PHARMACEUTICAL PROCUREMENT SERVICE

This is a procurement agency that ensures the citizens of OECS Member States are guaranteed the best possible essential list of medicines at the lowest possible price.

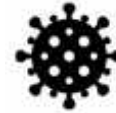
WHO prequalified medicines are given priority in the selection process.

 **Ms. Rosalyn Opel**

 **pps@oecs.int**



# Partnership with Stakeholder Customs / Ministry of Trade



Due to the COVID-19 pandemic and subsequent travel restrictions there has been an increased traffic of individual medicine importation.



Use of an electronic platform (whatsapp) to verify and approve the release of medications.



Use of Import license to regulate the importation of medicines and medical products.



**Conclusion**

# Conclusion

1

Antigua and Barbuda does not manufacture Pharmaceutical Products; hence inspections are focused on regulating other aspects of the sector.

3

Reliance is used to ensure that safe and effective medicines are marketed within our borders.



2

The Pharmacy Council and Board of Inspectors are mandated by Law to regulate the pharmaceutical sector to ensure the health and safety of the population.

4

Partnership/Stakeholder involvement is essential to accomplish some of the objectives of the regulatory process.





THANK YOU

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