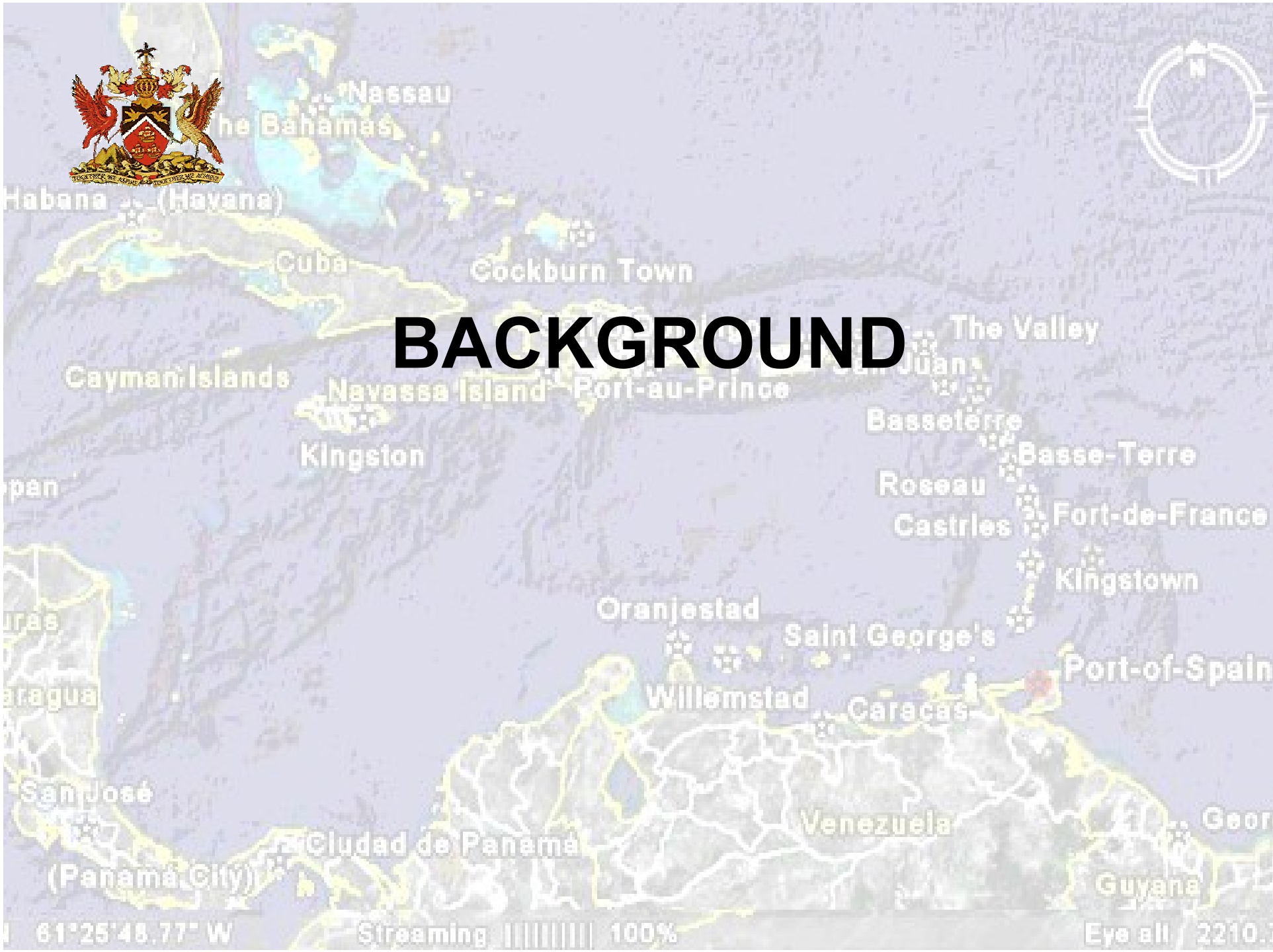
Trinidad and Tobago

Requirements for Drug Registration

Deoraj Ramcharan
Ministry of Health


Nassau
Habana (Havana)
Cuba
Cockburn Town
The Valley
Cayman Islands
Navassa Island
Port-au-Prince
Basseterre
Kingston
Basse-Terre
Roseau
Castries
Fort-de-France
Kingstown
Oranjestad
Saint George's
Port-of-Spain
Willemstad
Caracas
San José
Venezuela
Ciudad de Panamá
(Panama City)
Guyana
61°25'48.77" W
Streaming 100%

BACKGROUND

Where is Trinidad and Tobago?

National Symbols

Official seal

Hummingbird

Chaconia *Warszewiczia*

Anthem

Forged from the love of liberty
In the islands of hope and prayer
With boundless faith in our destiny
We solemnly declare
Side by side we stand
Islands of the blue Caribbean sea
This our native land
We pledge our lives to thee
Here every creed and race
Find an equal place
And may God bless our nation.

Cocrico
Ortalis ruficauda

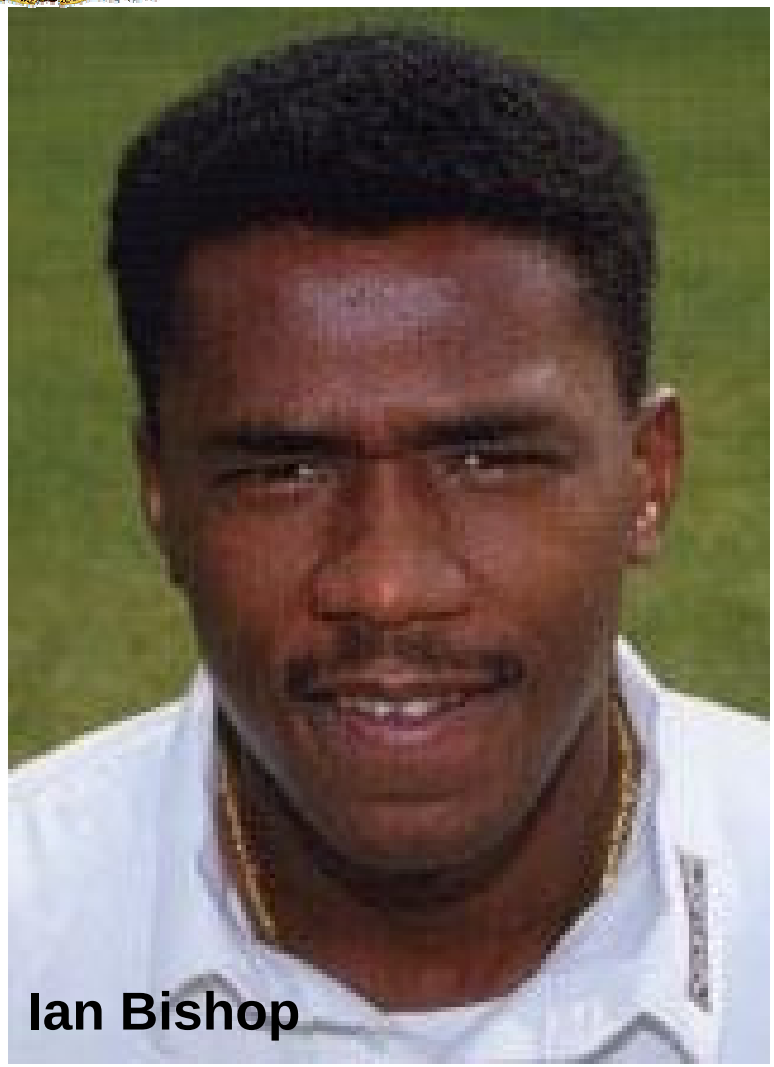
Scarlet ibis
Eudocimus ruber

Famous beauties

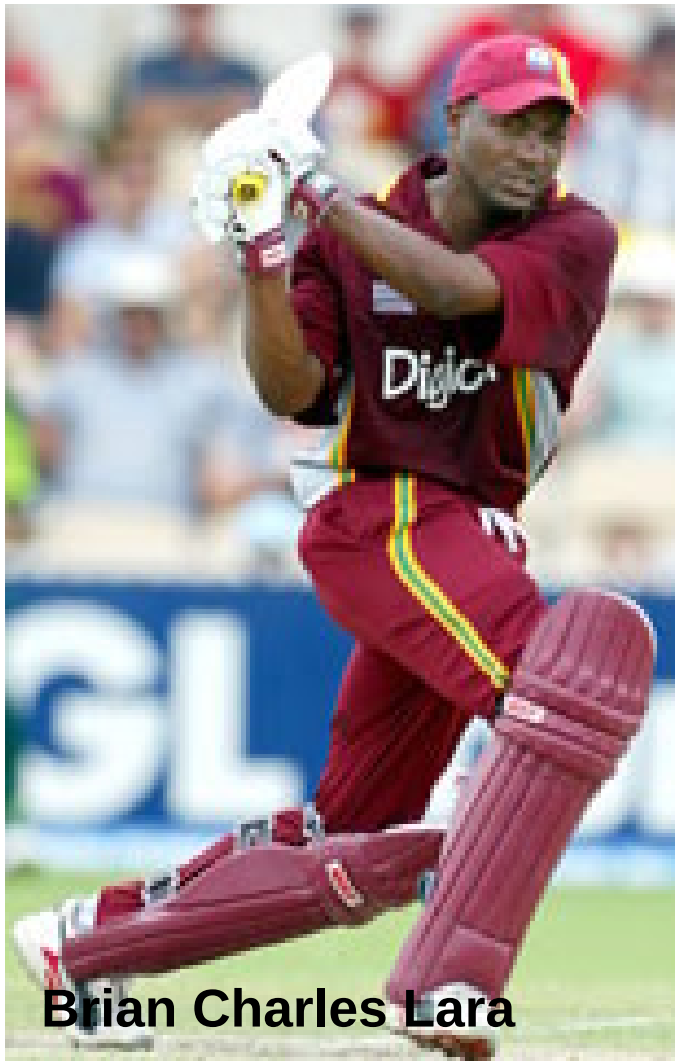
Janelle Commissiong
Miss Universe 1977

Giselle La Ronde
Miss World 1986

Sportsmen



Ian Bishop



Brian Charles Lara

Economy

- Based on petroleum, natural gas.
  - 40% of world's asphalt
  - 58% of ammonia
  - Largest exporter methanol
  - Largest LNG plant
- GDP earners
  - Services 54%
  - Manufacturing 44%
  - Tourism 3%
  - Agriculture 2%

Health

- Free medical care
- Free pharmaceuticals
  - Chronic Disease Assistance Program CDAP
- Free admissions, out-patient clinics
- Decentralized
- Pre/post-natal care, obstetrics, pediatrics, dentistry, ophthalmology, …….

CURRENT DRUG IMPORTATION

Statistics

- Total pharmaceutical imports (2006) - $765M
  - $75.7M from India
- Total formulations registered – 7924
  - 845 from India
- Over 300 pharmaceutical suppliers registered
  - 77 from India

Statistics

- Total formulations supplied to CDAP - 763
  - 218 of Indian origin
- Total Government Imports (2006) - $255M
  - $28M from India

Top 10 Indian Suppliers (Formulations)

• CIPLA Ltd	116
• Meditab Specialities Pvt Ltd	75
• Ranbaxy Labs Ltd	60
• Cadila Pharmaceuticals Ltd	59
• The Himalaya Drug Co	46
• Dr. Reddy's Laboratories	42
• Dabur Pharma Ltd	25
• CIPLA Ltd (Lasmed Jamaica)	23
• Intas Pharm Ltd	20
• Glenmark Pharm Ltd	19

Top 10 Indian Suppliers (Value)

- Ranbaxy Labs Ltd
- Dabur Pharma Ltd
- Meditab Specialities Pvt Ltd
- Wockhardt
- CIPLA Ltd
- Gland Pharma Ltd
- Torrent Ltd
- Intas Pharm Ltd
- Nicholas Piramal India Ltd
- Dr. Reddy's Laboratories

LEGAL FRAMEWORK

A General

- No person shall import, sell or advertise for sale a new drug unless the Minister has issued a notice of approval in respect of the new drug to the manufacturer or importer.
  - [Section 2(b), Division 3 - New Drugs, Food and Drugs Regulations, 1965].

A General

- A Drug Advisory Committee is established by the Minister, in the interest and for the protection of public health to assist and advise him with respect to:
  - drug standards, schedule of drugs, conditions of sale of drugs, and any other matters connected therewith
  - [Section 26(1) (a), Food and Drugs Act,1960].

A General

- The Committee consists of persons with interest and expertise in
  - Allopathic medicine
  - Pharmacology
  - Veterinary medicine
  - Chemistry
  - Pharmacy
  - Human sciences
  - Complementary medicine.

B Summary of Product Characteristics

- Adequate enough to provide a general understanding of the data/information in the application.

C Basic Requirements- Dossier must contain:

1. A description of the drug:
   - Name of the drug
     - Proper (generic/chemical/INN etc.) name
     - Proprietary (trade) name
   - Pharmaceutical/Dosage form and strength
   - Therapeutic category
   - Name and Address of the Drug Manufacturer

C Basic Requirements- Dossier must contain:

1. A description of the drug:
   - Licensing status of drug manufacturer
     - Manufacturing site(s).
     - Manufactures dosage form (start to finish)
     - Packages and/or labels a dosage form manufactured by an independent manufacturer

C Basic Requirements Dossier must contain:

2. Statements about:
   - Route of administration
   - Indications
   - Dosage
   - Contraindications, warnings, precautions, overdosage, drug interactions
   - Use in pregnancy and other special groups
   - Adverse effects.

C Basic Requirements Dossier must contain:

3. Detailed description of packaging materials.
4. Detailed description of the ink and printing
5. Brief description of
   - manufacturing and packaging procedures
   - in-process controls.

C Basic Requirements Dossier must contain:

6. Labelling
   - Copy of approved labelling in country of origin
   - Copy of proposed labelling
7. Name and Address
   - Applicant
   - Importer
   - Agent
   - Distributor

D Key Technical Data- Dossier must contain:

1. Regulatory Status in Country of Origin
   - A Free Sale Certificate or a Certificate of Pharmaceutical Product certifying that the new drug
     - is approved for use in the country of origin and its manufacture therein,
     - does not contravene any known requirement of the laws of that country

D Key Technical Data- Dossier must contain:

2. Chemical data

- Quantitative formula and quality control specifications
  - Finished product
  - **All ingredients used** in the manufacture of the drug
    - whether or not present in the final dosage form
- Description of each ingredient
  - physical and chemical characteristics
  - purity and stability

D Key Technical Data- Dossier must contain:

2. Chemical data

- Validated analytical methods
  - Finished dosage form
  - each ingredient (as noted above)
- Results of batch testing with batch number and manufacturing date.

D Key Technical Data- Dossier must contain:

3. Stability data
   - Real time
   - Accelerated
   - Proposed shelf-life
   - Recommended storage conditions

D Key Technical Data- Dossier must contain:

4. Details of tests applied to control potency, safety and purity of the drug:
   - Non-clinical/in-vitro
   - Studies and/or data with respect to inactives not affecting the safety or efficacy of the drug
   - Studies with respect to the pharmacological and action of the drug in relation to its proposed therapeutic benefit/indication

D Key Technical Data- Dossier must contain:

5. Detailed reports of animal tests and/or clinical trials to establish safety and efficacy of the new drug
   - Clinical investigations (pharmacokinetic and bioavailability) in humans to assess/evaluate
     - Safety
     - Efficacy

D Key Technical Data- Dossier must contain:

- Studies/data with respect to the drug in animals:
  - Absorption
  - Distribution
  - Metabolism
  - Excretion
- Description of the analytical and statistical methods for each study

D Key Technical Data- Dossier must contain:

- Studies/data with respect to the effects of the drug in relation to the proposed indication(s):
  - toxicological
    - acute
    - subacute
    - chronic
    - carcinogenicity,

E Variations/Changes to the Original Approved Submission

- Supplementary submission required upon change(s) to
  - the conditions of use of the drug
    - indications for use
    - route of administration
  - labels
  - packaging
  - pharmaceutical form in which it is sold
  - dosage
  - strength, purity or quality
- [Section 5(1), Division 3 - New Drugs: Food and Drugs (Amendment) Regulations, 1987].

F Generic Drug Products

- Must conform to the same standards of:
  - quality
  - safety
  - efficacy
- Same basic and technical data required for the assessment
- Must shown to be pharmaceutically equivalent
  - data about the therapeutic equivalence may be required.

F Generic Drug Products

- Requirements to assess equivalence:
  - Comparative bioequivalence
  - Comparative pharmacodynamic studies in humans
    - (when the quantitative analysis of the API(s) and/or the metabolites in plasma, blood or urine cannot be made with a high degree of accuracy)
  - Comparative clinical trials
  - In vitro dissolution tests.