Country presentation
MAURITIUS

GALVmed/OIE Stakeholder Workshop On The Harmonisation Of The Registration Of Veterinary Medicinal Products

JOHANNESBURG

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STATUS OF REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINES IN MAURITIUS

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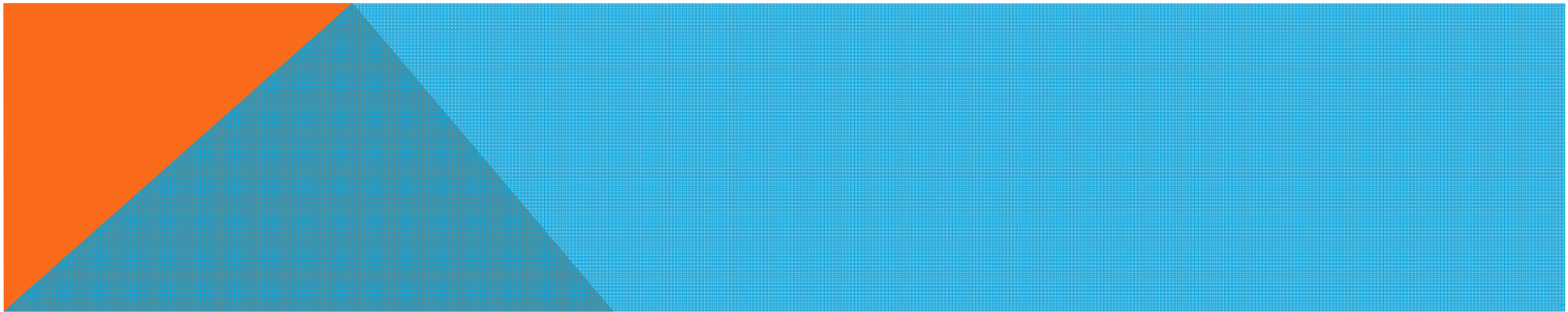


Country Overview

The Republic of Mauritius is located in the Indian Ocean off the east coast of Madagascar

COUNTRY OVERVIEW

- **Small Island Developing State (SIDS)**
  - **Manufacturing(export oriented)**
  - **Tourism**
  - **Agro industry**
  - **Financial & business services**

- **Emerging sectors**
  - **ICT- Business Process Outsourcing, software development**
  - **Hospitality and Property Development (commercial malls, luxury villas, and international flagship hotels)**
  - **The Seafood and Marine Industry- (fish farming, tuna fishing and canning, and seafood processing)**
  - **The Biomedical Industry- (medical devices, pharmaceutical products, multi-specialty hospitals)**

Key Economic Indicators

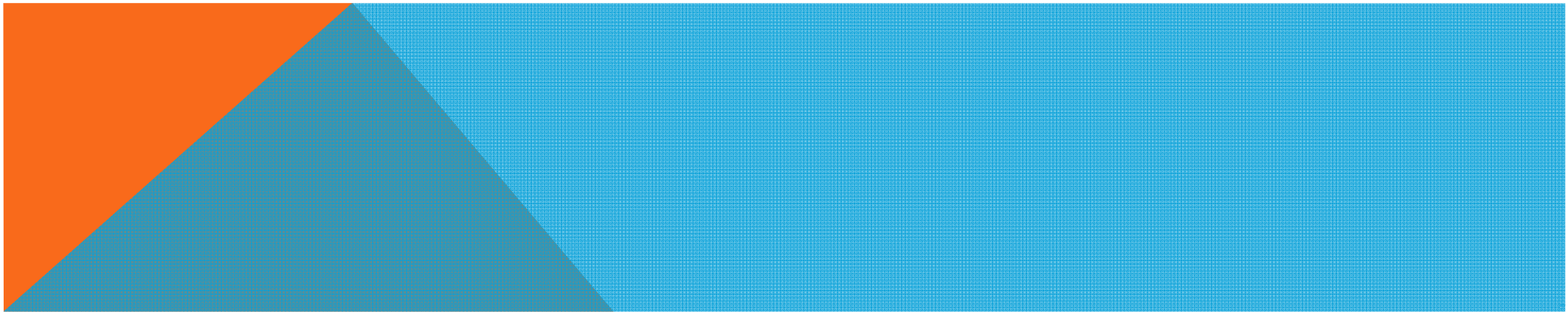
Total Land Area	2040 km^2
Population	1.26 million
Economic Growth Rate	3.0 %
GDP	US$ 11.6 Billion
Per Capita Income	US$ 9,234
Unemployment rate	7.9%
Literacy Rate	98.1%
Inflation Rate	1.3%

LEGAL FRAMEWORK

CURRENT LEGAL PROVISIONS IN FORCE :

THE PHARMACY ACT 1983

THE DANGEROUS DRUGS ACT 2000

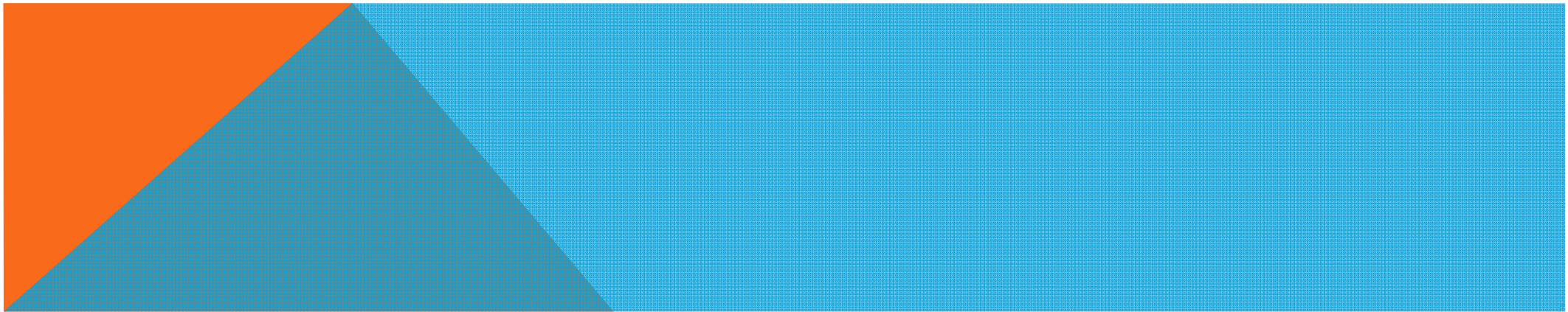


THE PHARMACY ACT 1983

TO CONTROL AND REGULATE:

MANUFACTURE, IMPORTATION, SALE, DISTRIBUTION AND POSSESSION OF ANY PHARMACEUTICAL PRODUCT.

THE PHARMACY TRADE .



THE DANGEROUS DRUGS ACT 2000

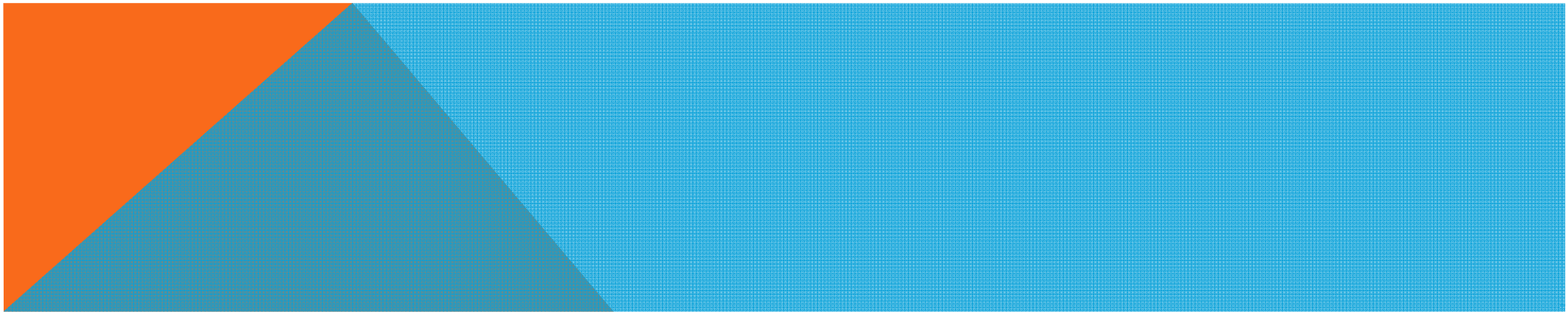
CONTROL OF DANGEROUS DRUGS.

NARCOTICS

PSYCHOTROPIC SUBSTANCES.

PRECURSOR CHEMICALS.

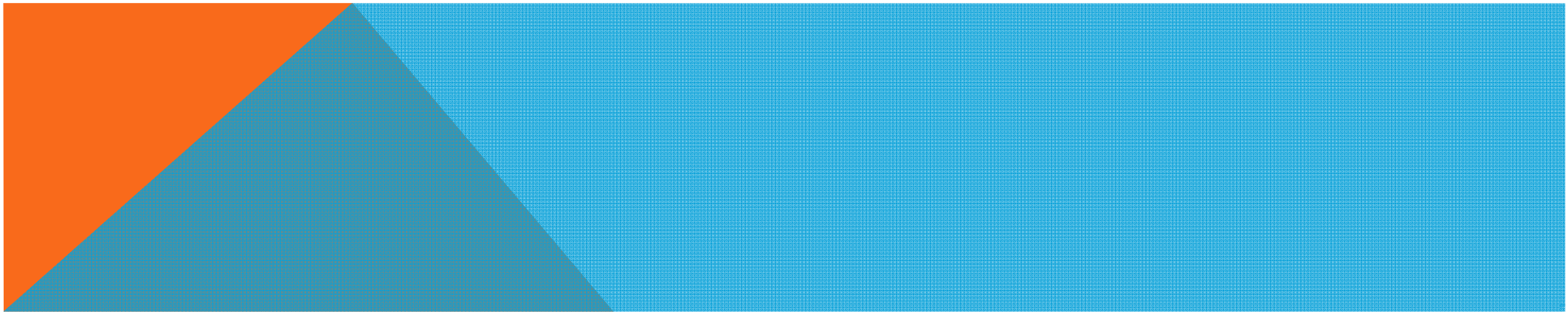
IN CONFORMITY WITH INTERNATIONAL CONVENTIONS (1961,1971,1988), TO WHICH MAURITIUS IS A SIGNATORY AND AN ACTIVE PARTY.



DEFINITION

Medicine as defined in the Pharmacy Act,1983:

A chemical product, preparation, biological product or other substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of any ailment, infirmity or injury affecting a human being or an animal or for dental treatment.



REGULATORY CONTROL

❖ THE PHARMACY BOARD

- ❑ The Pharmacy Board is the regulatory body established under the Pharmacy Act,1983
- ❑ History>50 years
- ❑ Mandate
  - control over medicines
  - inspection
  - grant licences/permits/certificates
- ❑ It operates under the aegis of the Ministry of Health and Quality of Life

REGULATORY CONTROL

❖ REGISTRATION PROCESS

- All medicines and pharmaceutical products must be registered with the Pharmacy Board prior to import and marketing in the country.
- Pharmaceutical products can only be imported by registered wholesale pharmacies under the supervision of pharmacists.
- They also hold a trading licence from the local authorities. Pharmaceutical products are being registered since 1985.
- Up to now ,only pharmaceutical products for human use are subject to the registration process.
- Fees for the registration of pharmaceutical products have been introduced since 2016.

REGULATORY CONTROL

❖ REGISTRATION PROCESS

- Approval of new pharmaceutical products is carried out through a registration process which involves examination the product's characteristics
- Any Marketing Authorization Holder or its local Technical Representative who wishes to register an imported pharmaceutical product shall make an application, in duplicate, to the Board in the prescribed form.
- The application form will be accompanied by the corresponding registration Dossier, containing all the technical information and specifications in the Common Technical Document(CTD) Format.

REGULATORY CONTROL

❖ REGISTRATION PROCESS

- The Pharmacy Board will refer the application to the Trade and Therapeutics Committee, set up under the Act, for assessment and recommendations, to the Board which may either approve or reject the application.
- The Board will then register the pharmaceutical product and issue to the applicant a certificate of registration on such conditions that it may determine.
- Since last year, a Marketing Authorisation is also being issued to the applicant.
- Duration for the processing of an application: Around 6 months

REGULATORY CONTROL

❖ LICENSING PROCEDURE APPLIED FOR THE IMPORT OF PHARMACEUTICAL PRODUCTS

- Certain specific category of medicines and pharmaceutical products as well as chemicals requires a licence for their import and export. These include:

- Antibiotics, vaccines and any therapeutic substance, listed in the Sixth Schedule of the Pharmacy Act,1983.
- Dangerous drugs as defined under Section 3 of the Dangerous Drugs Act 2000.

REGULATORY CONTROL

❖ PURPOSE AND COVERAGE OF LICENSING.

- The licensing process is a mandatory requirement governed by the provisions of the Pharmacy Act,1983 and Dangerous Drugs Act 2000:

  - intended to exercise control over import as per international requirements to ensure that the goods are destined for legitimate use (medicinal, scientific, educational),and

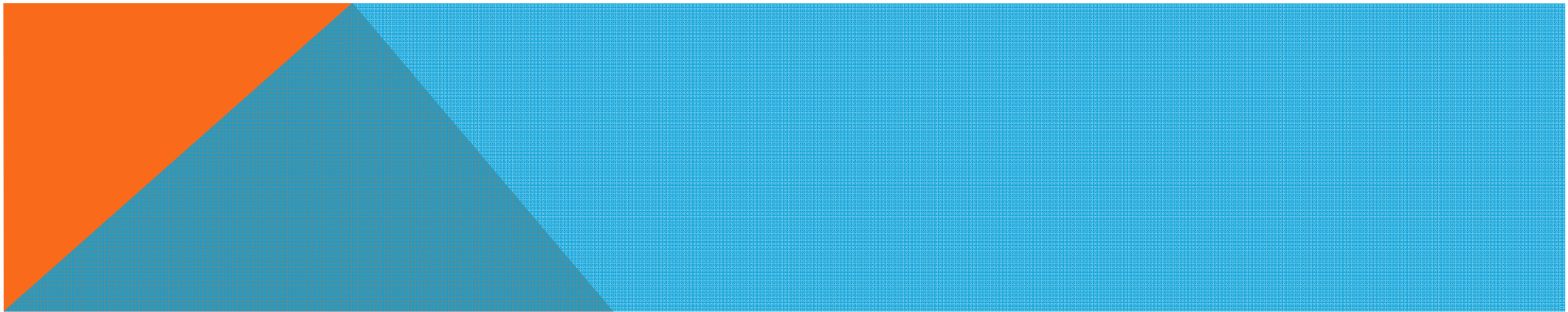
  - It applies to goods coming from any country.

REGULATORY CONTROL

❖ PURPOSE AND COVERAGE OF LICENSING

❑IMPORT OF THERAPEUTIC SUBSTANCES:

- **An import permit is for each consignment of a therapeutic substance imported (antibiotic, vaccine, corticosteroid).**
- **The importer(Pharmaceutical Wholesaler) is required to submit an application for a permit as specified under Sections 25 &30 of the Pharmacy Act indicating the name of the product(s) and quantity in respect of each product being imported.**

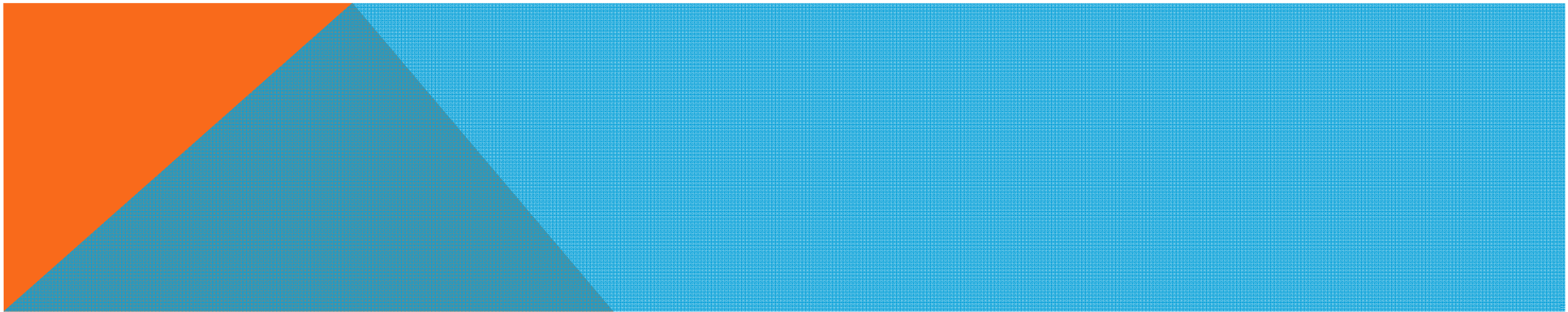


REGULATORY CONTROL

❖ PURPOSE AND COVERAGE OF LICENSING

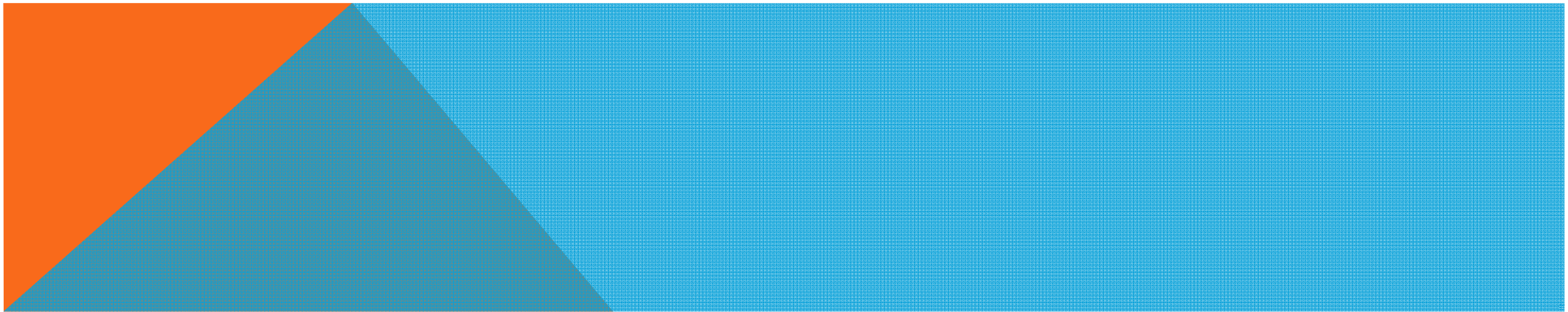
❑ DANGEROUS DRUGS

- It is mandatory under the International Conventions that a permit be issued by the regulatory authority for the import/export of substances listed in Schedule I, II, III &IV of the Dangerous Drugs Act 2000.



ADMINISTRATIVE CONTROL

DIRECTORATE PHARMACEUTICAL SERVICES IS THE REGULATORY AUTHORITY RESPONSIBLE FOR THE ADMINISTRATIVE CONTROL.



ADMINISTRATIVE CONTROL

❖ DUTIES & RESPONSIBILITIES OF THE REGULATORY UNIT

- **Verification of invoices against data base and approving release of consignments (100 daily).**
- **Issuing of import permits for Dangerous Drugs Sch. I.II,III IV.**
- **Issuing of permits for therapeutic substances-Antibiotics, Corticosteroids, Vaccines.**
- **Issue of authorisation /permits to import health supplements, Ayurvedic medicines**
- **Allocation of quota for Dangerous Drugs Sch.II &SCH III**

ADMINISTRATIVE CONTROL

❖ DUTIES & RESPONSIBILITIES OF THE REGULATORY UNIT

- **Issuing of import permits for Sch.I Drugs for scientific and research purposes to FSL and Police Dept.**
- **Reporting to the International Narcotics Control Board-Returns on imports of dangerous Drugs submitted on a quarterly and yearly basis.**
- **Examine registration dossiers for pharmaceutical products.**
- **Prepare files and documents for submission to Committees & Ph.Board.**

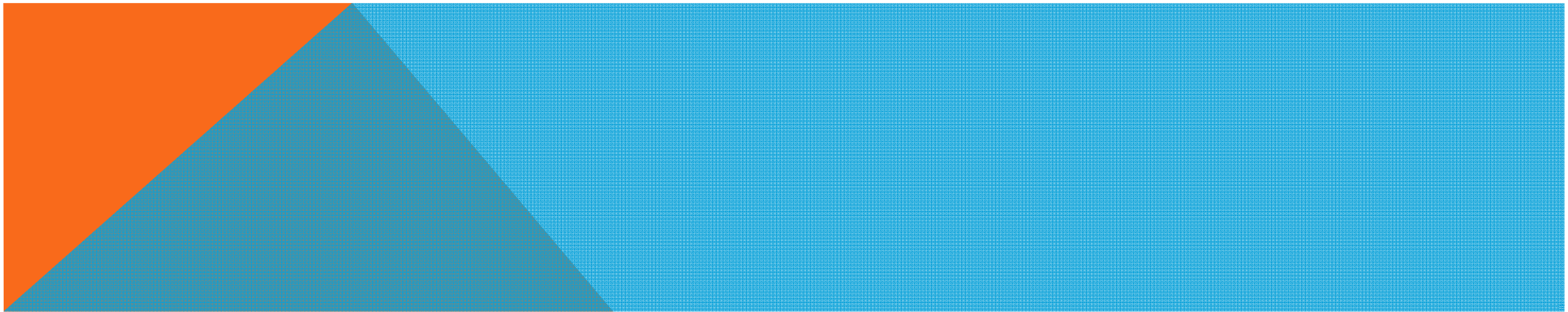
VETERINARY MEDICINES

- Except for the registration process, veterinary medicines imported into the country are subject to all regulatory and administrative control applicable to human medicines.
- Application to import veterinary medicines must be accompanied by their relevant Technical Data Sheet and approval by the Regulatory Authority of the country of origin.
- Prior approval from the Division of Veterinary Services of the Ministry of Agro Industry and Food Security is required for the issue of the import authorisation by the Directorate Pharmaceutical Services.
- Import authorisation is granted for a period of one year and is subsequently renewed.
- Import permits issued yearly(approx.):40(Antibiotics);80 (Vaccines); and 20 others.

WAY FORWARD

❑ NEW LEGISLATIVE FRAMEWORK

- **Establishment of a National Medicines Regulatory Agency**
- **Special provisions for veterinary medicines**
- **Product Registration Committee for veterinary medicines**



THANK YOU!