



**WORLD HEALTH ORGANIZATION
PAN AMERICAN HEALTH ORGANIZATION**



REGULATION OF PHARMACEUTICALS IN THE CARIBBEAN COUNTRIES

**BRIDGETOWN, BARBADOS
17-19 SEPTEMBER 2006**

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**REGULATION OF PHARMACEUTICALS
IN THE CARIBBEAN COUNTRIES**
Sub-regional meeting
September 17 – 19, 2006
Barbados

Background

On September 2004 national responsible professionals for national programs met to review and analyze the ACP project plan of work of the first year. That meeting took place in Barbados and as a result participants prioritize activities of the ACP project¹. Drug Regulation was identified to be a third priority to address, being the first two: drug access and drug supply². At the same time, CARICOM Secretariat informed at that meeting that they would be implemented a sub-regional study on Drug regulation and on implementing TRIPS legislation as separate study. At that meeting it was agreed that since CARICOM will implement such studies, the best decision to take was not to overlap and to focus ACP activities on other regulatory activities, as well as other areas of the ACP project.

The second phase of the ACP project was recently approved and the Expected Result # 6 refers to *Effective Drug Regulation in the Region*, being strengthening medicine registration in the Caribbean an important part of that component.

In order to review the current status of the registration process and activities carried out in the Caribbean region, PAHO/WHO organized this meeting. Since a special training on Pharmacovigilance for HIV products was being held the week of 11-16 September, it was decided to hold the meeting on Regulation of Pharmaceutical right after the training to better use the financial resources of the ACP project, since participants from MOH were the same to participate at the second meeting.

Rationale

It is recognized worldwide that National registration of pharmaceuticals is a primary responsibility for every country and a main public health issue of the MOH. Leadership of MOH in the public arena includes drug regulation and access to quality drugs and as National Regulatory Authority must perform several functions to respond to an effective drug regulatory system. Moreover, an effective system for drug regulation can be cumbersome and difficult in terms of availability of human resources, and technology and extremely expensive. This is more evident in countries with smaller size of their national pharmaceutical market. The need to explore different modalities to address drug regulation that have been successful in other countries or regions cannot be avoided when analyzing the case of the Caribbean region.

Objectives of the meeting:

¹ ACP project: African American and Pacific Regions, Project financed by the European Community through WHO.

² Report of that meeting is available on request.

Presenting and discussing the basic functions of Drug Regulatory Authorities (agencies), as a basis for the Sub-regional assessment of National Regulatory system in the Caribbean countries.

Agenda

1. The meeting was opened by *Dr. Veta Brown, PWR CPC, Dr. Precious Matsoso, Director, Technical Cooperation for Essential Drugs & Traditional Medicines/WHO and Mrs Maryan Hinds, in liú of Antoinette Williams, Permanent Secretary, MOH.*

2. *Rosario D'Alessio from PAHO/WHO* coordinated the meeting and reviewed the background, the agenda and the methodology of the meeting.

3. As a base to better comprehend the responsibilities of an agency for drug regulation, *Dr. Precious Matsoso*, gave a presentation on the Basic Functions of National Regulatory Authorities, emphasizing their relevance and influence on public health policies³. She presented the dimensions of the regulation of drugs, the structural and administrative elements, technical aspects, functions and processes and levels. She pointed out that the countries need to have at least the key functions operating in order to protect and promote the public health.

Dr. Matsoso also talked about the WHO tools for the drug regulatory authority of medicines, vaccines, products for the health and traditional medicine. All these appraisal components are being integrated and a manual is being developed. Such processes are useful so that there is a monitoring of the formalization of the Good Regulatory Practices, the development of a graduation system, and the processes of accreditation. She indicated that in the period 2001-2006 more than 30 were visited, two of them in the Americas: Cuba and Bolivia. Among the main identified weakness of the 192 countries member of WHO, 20% have a well developed DRA, 50% have variable situation while 30% have a very limited or simple do not have DRA.

In regard to the Good Regulatory Practices she pointed out that is necessary to address the following aspects national and internationally: Sustainability and resources; Cooperation within and the agency and with other agencies; Transparency and accountability; Competency in evaluation of drug quality, safety and efficacy; Independency; Harmonization and mutual recognition; Transparency of the decision making process; and Resources and share of information, among other. She concluded the presentation pointing out the utilization of the WHO tools for assessment for the establishment of goals and the measurement of the performance with established objectives and standards. She pointed out the importance of requirements for the harmonization such as the reliability, joint action and the establishments of standards of sub-regional performance.

4. *Dr. Jose Pena, PAHO/WHO*, presented the WHO tool for drug regulatory assessment and the experience of its implementation in the area of vaccine in the

³ All pp presentations are in separate file as ANNEXES

Region of the Americas. In his presentation he pointed out that the Strengthening of the National Regulatory Authorities is a strategy for the improvement of the public health and that is a challenge for DRA. He explained the tool for assessment of the regulatory authority of vaccines, with functions, components, results, and cycle of application of the proposal. He presented the results obtained with the application of the tool in the Region of the Americas between 2002 and 2004, among them Brazil, Bolivia, Argentina, Peru, and Mexico. The aims of these assessments were to support NRA in the fulfillment of the six basic functions for vaccines and it responds rapidly to events attributed to vaccines in immunization. The approach is done in three areas: licensing, clinical trials, and surveillance. He commented on the expected results for the period 2005 to 2007 in Vaccine area and on the work plan developed including the participation of Vaccine in the Pan American Network for Drug Regulatory Harmonization initiative.

5. *Beverley Reynolds, representative of the Caribbean Community Secretariat* gave a presentation pointing out that CARICOM share the principle of WHO in drug access as a human right. She explained the rationale for establishing a harmonized regulatory system for the Caribbean countries, speaking about the regional context and the logic, the approach and the profits of regional harmonization, she considered that the drug regulation is a subject in the regional guideline and that aspects as the size of the countries in contrast to the task magnitude for the performance of the regulatory functions and associated costs and the reductions in human resources and financing and the institutional capacity should be considered. Among the profits of the harmonization there is also the possibility of standardization of the drugs available in the region, the maximization of resources and the personnel as well as economic benefits.

She presented the existing regional initiatives such as the regional national policy of drugs, the regional drug quality control laboratory, and the advisory committees of Pharmacy and Therapeutic Committee and TRIPS committee. She considers practical and feasible that regional strategies are developed, considering the political will and the already existing regional structure. She also pointed out as next steps: the realization of the assessment of the registration system in the Caribbean countries. The implementation of the study is a mandate from regional agreements and will include the dissemination of findings and a Plan of Work for improvement drug registration in the Caribbean countries based in the study results.

6. *Dr Peter Zinck, Chief Pharmacist of Fiji Pharmaceuticals*, presented the experience in addressing drug regulation in the Pacific Islands. Their experience was based on the framework of the regulatory functions and WHO graduation process and the challenges for the strengthening of the regulation of drugs. He pointed out that despite the difficulties, in order to guarantee drug access, quality, and drug safety, not to do anything is not an option; and it is important to have the knowledge on what has succeeded using the available information.

7. As an important part of the responsibilities of a national regulatory system, national regulatory authorities are expected to license establishments for

manufacturing, distributing and also for *dispensing* drugs. Those licenses are directed to the assurance of the quality, safe and efficacy of medicines but also to contribute to their rational use. Dispensing is, along with prescription, an important step in the process of using drugs. Ellen Grizzle, as representative of the Caribbean Community of Pharmacists, presented the subject of Drug Dispensing in the Caribbean countries. She said the Foundation was founded in 1976. She presented some existing controversies in the region related to the dispensing by prescribers and the prescription by pharmacists and the role of the technicians in pharmacy and inspectors. She spoke about the difficulty of harmonization of the education and post graduate continuous education opportunities for the 3,000 professionals in the Region.

8. Rational use of drugs is a responsible decision involving doctors, pharmacists and patients and National Regulatory decisions are to influence the use of drugs. *Jose Luis Castro, PAHO/WHO* addressed this subject. He presented a vision of the WHO Drug Strategy 2004-2007, the existing problems and the expected results. He pointed out the WHO components of RUD and the PAHO actions for the Americas and the planned activities to promote RUD in the Caribbean countries as part of the ACP project.

9. All participants representing each Caribbean country were asked to: give a brief presentation on the current situation of the regulatory system in their country, to draft an organizational structure of the MOH indicating the Regulatory Authority (or agency), and to indicate whenever possible the names of key officials and other persons of interest in the implementation of the assessment of DRA. It was not a pre-prepared presentation but a spontaneous view of that system in their countries. All presentations are annexed in this report. Facilitators of the two groups were:

Group 1: Adriana Ivama (Anvisa, Brasil) and José Pena (PAHO/WHO), and
Group 2: José Luis Castro (PAHO/WHO) and Silvia Boni (ANMAT, Argentina).

BAHAMAS: Vivienne Lockhart (Annex 1)

BARBADOS: Maryam Hinds (Annex 2)

BELIZE: Samira Gogora (Annex 3)

DOMINICAN REPUB: (Annex 4)

GUYANA: Fabiola Robertson (Annex 5)

JAMAICA: Cynthia Graham-Lewis (Annex 6)

SAINT LUCIA: Donna Daniel (Annex 7)

ST VINCENT: Tyrone Jack (Annex 8)

SURINAME: John Hasrat (Annex 9)

TRINIDAD & TOBAGO: Brenda Charles & Yvette Sylvester (Annex 10)

The groups address the difficulties in the region to fulfill the regulatory functions by each country, given the lack of human resources and all the existing limitations, presented on the previous day. During the discussion it was noted that there is a concern of the representatives to guarantee the autonomy of action of each country.

It was also discussed the importance that the proposed alternatives were feasible to implement. For that, it would be necessary to redistribute the functions in the national areas and regional. However, there was not consensus of which of them should be at each level, being the matter of the autonomy/sovereignty of the countries the biggest limitation to be address and solved.

9. *Working groups.* Based on the previous presentations and taking into account the weakness and strength of the current regulatory systems in the Caribbean, participants were divided in two groups to discuss which of the basic functions of a national regulatory agency could be centralized and which should be kept at country level. Annex 11 presents the result of the exercise of both groups. The following is a consolidated chart of the responses that reflects the opinion of the groups:

DRA Functions	Levels					
	1.National		2. Regional		3. Internat.	
Licensing— Manufacturer		O	X		X	
Licensing –Import	X	O	X			
Licensing – Retail	X	O	X			
Licensing – Dispensing	X	O				
Evaluation and Registration			X	O		
Inspection GMP/Manufacturers		O	X	O		O
Inspection New Drugs		O	X	O		
Inspection Clinical Trials	X		X	O	X	
Quality Control	X	O	X	O		
Drug Information and Promotion	X	O	X	O		O
Safety and Efficacy Surveillance- Pharmacovigilance	X	O	X	O	X	O

X = grupo 1 / O = grupo 2.

In regard to the **licensing** of manufacturers, one of the groups proposed that this activity should be carried out by a regional authority and that the existing international projects (such as WHO pre-qualification) should be recognized. Considering that the licensing requires a previous inspection, there was proposed the existence of a trained inspector body of the different countries of the region. The group considered that the licensing of importers and distributors should be a

responsibility shared among the authorities regional (in the sense to establish the directives and common requirements) and national (carry out the process) and that the licensing of establishments of dispensing is a national function, although with common directives and training of inspectors programs. The other group considered that all the processes of licensing should be national, but with directives for inspection and standards for the established products regionally, based on international directives. There was considered important the possibility of verification of traceability of the products, including the verification of the number of the lot.

Both groups considered that **drug evaluation and registration** can be a regional function, with a specific technical body trained for the appraisal of the files and the existence of a regional ethics committee. It was emphasized that it is indispensable that up-to-date information about the licensed companies or manufactures and the registered drugs should be available to all the countries, as well as any exiting problems related to them.

One of the groups considered that the **GMP inspection** should be a regional function, while the other group considered that it should be a responsibility shared among the regional and national authorities with common directives and possibility of mutual recognition. One of the groups considered that the inspections should be led by the national authority following the directives of GMP.

With regard to **quality control**, it was considered that the regional laboratory does not meet satisfactorily the needs of the countries, being necessary to seek alternatives and strategies to improve the utilization of this installed capacity.

There was considered the need for strengthening surveillance with regard to possible **counterfeited drugs** in the region with responsibility of the three levels. One of the groups considered that the use of kits for fast tests is a possibility as a first triage. Other related subjects are agents of terrorism and drugs that can be brought to the countries by tourists. It was identified that there exists little collaboration in the countries among the regulatory authorities and the customs.

With regard to the **drug promotion and drug information**, both groups considered that this is a responsibility that can be shared in the regional and national areas. One of the groups considered that there should be common directives and the exchange of information among the countries. Another group considered that the specification of label is one national function however it should have mutual recognition. Both considered that drug surveillance on information and promotion is a national function. The raising of a Regional Information Center on Drugs was proposal to support the regulatory activities.

With regard to the **monitoring of the safety and efficacy**, both groups considered to be an activity to be developed in the three levels, in which the reception of reports it can be a national function, the analysis in the regional area and afterwards the report to the international database (Uppsala Monitoring

Centre), as proposed during the regional course of Drug Surveillance, carried out previously this meeting.

10. A *panel* of invitees for this meeting was held as final session. The panel was composed by: Peter Zinck (Fiji), Brigitte Zirger (Canada), Justina Molzon (USA), Silvia Boni (Argentina), and Adriana Ivama (Brazil). Representatives from regulatory authorities participated in a fruitful Q&A session after the panel.

Peter Zinck (Fiji Pharmaceutical Services, Fiji) considered that many of the problems and limitations presented by the countries also exist in their region and it was noteworthy for the importance of the establishment of priorities by the countries. He pointed out the importance of the initiatives of regional collaborative networks and the processes of harmonization.

Justina Molzon (Food and Drug Administration, Estados Unidos) pointed out the importance of the establishment of regional and national responsibilities for the optimization of the utilization of the available resources, submitting a proposal for reflection with the acronym PIE, using the essential elements of the regulatory functions: Protect Public Health; Informed Decisions; and Effective Use of Resources.

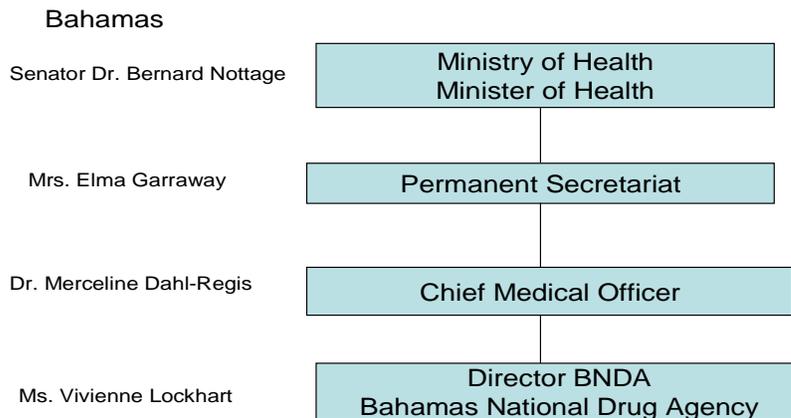
Brigitte Zirger (Health Canadá, Canadá) called again the attention for the need of establishment of a glossary as initial part of the process of harmonization. He pointed out that in Canada, as it is a Federation, the Health Canada also has functions shared with the provinces and other agencies and that the clear definition of functions and the collaboration among them are fundamental. She offered to the participants a CD containing all the information on the Health Canada and Canadian legislation.

Silvia Boni (Agência Nacional de Medicamentos, Alimentos e Tecnologias, Argentina) also pointed out the importance of the regional initiatives, citing the example of the participation Argentina in the MERCOSUR and the collaboration among the different authorities within the country.

Adriana Mitsue Ivama (Agência Nacional de Vigilância Sanitária, Brasil) considered that the opportunity for participation also was a learning opportunity. She cited the experience of Brazil of the establishment of the Agency and the strengthening of the regulatory agency was based on a serious problem of counterfeited drugs in the end of the 1990s, which lead to the change of the scenario in the country. Currently there is an effort in the sense of strengthening of the rational use of drugs, with the recent establishment of the National Committee of Rational Use of Drugs, coordinated by the Ministry of Health, Anvisa, and PAHO/WHO. She considered important that the regulatory authorities seek support and partnership together with the users, with professional associations, the public ministry (public defense), and legislative powers for the strengthening of the regulation.

11. *Closing and Next Step:* Dr D'Alessio thanked the participants pointing out the importance of this meeting for the establishment of priorities and directives for the preparation of a work plan for the steps to come. CARICOM Secretariat will implement the Assessment of regulatory system in the Caribbean region using the WHO assessment tool (#4 of this report). Expression of interest for that study is the CARICOM web page and it is expected the assessment will start in the next months. PAHO /WHO will contribute technically with CARICOM in the study. All participants of this meeting will receive along with the report of this meeting a copy of the WHO assessment tool, so they, based on the experience of this meeting, can be prepared and make the most of the evaluation. Results of the study will be disseminated among evaluated DRA and implementation for improvement will hopefully begin.

ANNEX 1: BAHAMAS

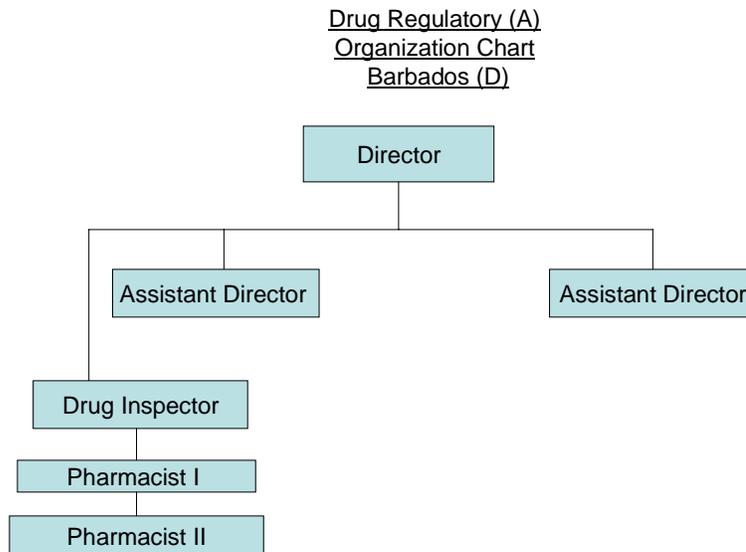


Drug Regulatory - Bahamas

- The Bahamas National Drug Agency (BNDA) acts as the regulatory agency for the Ministry of Health.
- The Agency has a staff compliment of 23 of which 5 professionals (pharmacist). The Agency is funded by government.
- Presently one manufacturing company in the Bahamas (Grand Bahamas). Inspection of facility undertaking by the department of environmental health, public laboratory, with assistance of quality control officer.
- Inspections of pharmacy facilities — retail and wholesalers (by Department of Environment Health) are presently done for the purpose of qualifications for licensing by the Licensing Board — Ministry of Finance.
- There are fees for licensing and inspection of these facilities.
- There is ad hoc inspection done by BNDA, upon request of the Ministry upon receiving knowledge of unusual activity at a facility (wholesaler/retail).
- There is no registration of products. In the public sector, there is a requirement for the registration of wholesalers and manufacturers who participates in the provision of drugs to the public sector (government).

- The product entering this system must meet the standards of the British Pharmacopeia, US Pharmacopeia, International Pharmacopeia or any other Pharmacopeia approved by the MOH on advice of the BNDA. The product must also be available for sale in the country from which it is manufacture/sold.
- The control of the importation/exportation and recordkeeping of narcotics and psychotropic substances are monitored by BNDA with the issuances of licenses and permits on behalf of the MOH.
- There is no local quality laboratory; however access to international labs is undertaken.
- No legal document to address control of promotion and advertising of drugs. However, to date promotion of products are done through the medical and pharmacy professions and their associations.
- Recall system based on documented communication to the appropriate level of distribution system.
- MOH is in the process of updating pharmacy legislation (premises, practice, person, products) which addresses fundamentals of drug safety.

ANNEX 2: BARBADOS



DRUG REGULATORY AUTHORITY

The Drug Regulatory Authority is under the *aegis* of the Barbados Drug Service. This Department is headed by a Director and the Organizational Chart appended shows the position of the Drug Inspector in the organization.

The Functions of the Regulatory Authority include the licensing of manufactures, importers, retailers and pharmacies.

The Pharmacy Council which is a *quasi* judicial body which has responsibility for the certification of premises and verification of the suitability of pharmacists.

Inspections

Inspections are carried out by the Regulatory Authority in order to determine the suitability of issuing licensing.

Quality Control

Quality Control is provided through the use of the Regional laboratory in Jamaica and other external laboratories in Canada and United Kingdom. Quality control is critical to the approval of sale of drugs which were manufactured in local commerce.

Drug Registration

The process of licensing manufacturers of drugs is undertaken by the Regulatory Authority. Currently Barbados does not register drugs.

Information and promotion is disseminated through the National Drug Formulary and public lectures at regular intervals during the year.

Surveillance

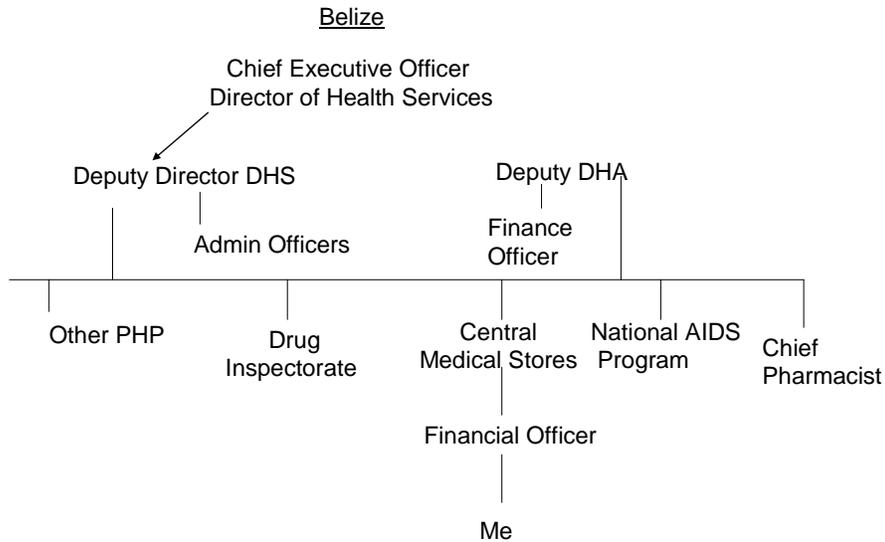
Drugs are taken from the market place by the Drug Regulatory Authority for purposes of testing and post marketing surveillance.

Pharmaceutical companies which seek to become suppliers of drugs to the Barbados Drug Service have their drugs tested for purposes of quality.

Drug Recall

The recall of pharmaceutical products is undertaken by the Regulatory Authority in collaboration with the Ministry of Commerce and the local distributor or manufacturer.

ANNEX 3: BELIZE



In Belize there is no established Drug Regulatory Authority but provisions for it is in the pharmacy Act which is at parliament to be passed into law.

We have presently seven hospitals, 40 health centers, 4 polyclinics and 170 private pharmacies.

All do not have a registered pharmacist attending at the site so the enforcement of the current laws we have are weak which are Chemist and Druggist Act, Antibiotics Act and Dangerous Drug Ordinance.

Currently the country has the Maximum Price (MPC) contract on stream in the Ministry of Health where in the contracts to our suppliers we specify the manufacturer of the products we want. So, there is no manufacturer in Belize; therefore, all is imported.

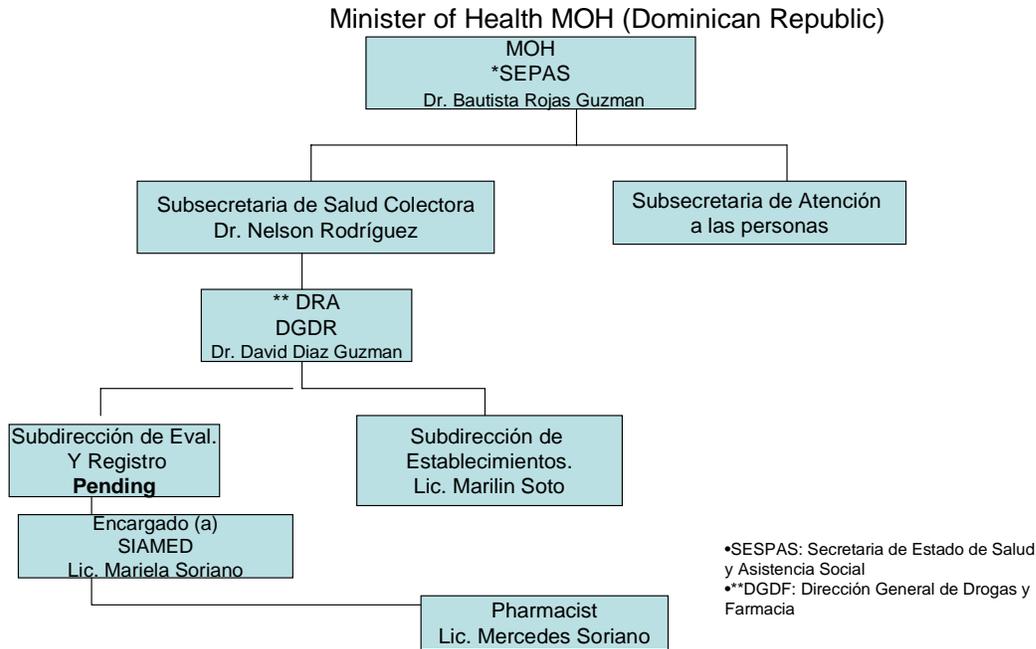
We have one drug inspector who inspects the MPC products at importation and for other drugs being imported; a custom entry is submitted to the Ministry for necessary clearances; also narcotics and Psychotropics under the regulation of the INCB.

Inspections are done on a negative reporting basis and not really randomly. Also only if products are reported as problematic, then they are sent opt CDTRL lab in Jamaica for testing.

ANNEX 4: DOMINICAN REPUBLIC

República Dominicana

SEPTEMBER 19TH 2006



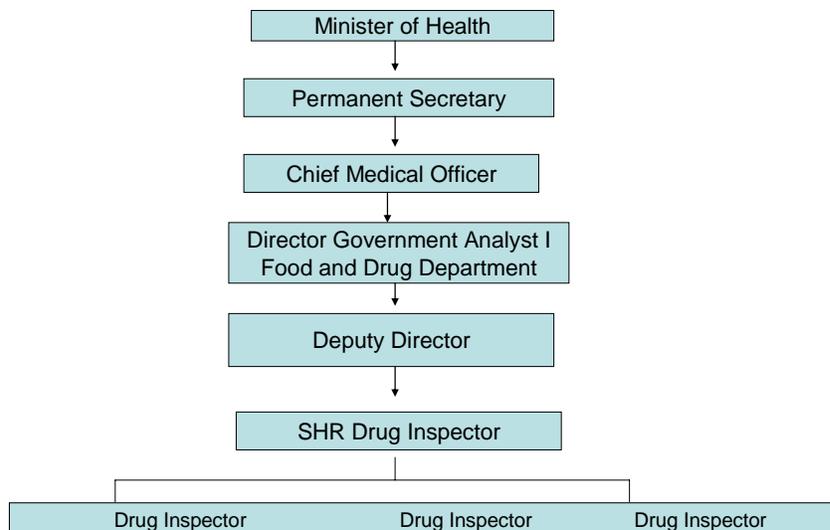
Actions of the DRA of Dominican Republic:

- It is a country localized between Haiti and Puerto Rico.
- The population is around 9,000,000 of people. The DRA (Dirección General de Drogas y Farmacia) it's a dependence of the Minister of Health (SESPAS), and it's subdivided in two subdirecciones:
 - Evaluation and registration of Pharmaceutical products
 - Pharmaceutical establishment (this includes community pharmacy manufacture and also distributions of drugs.
- Our legal framework is based in the law 42-0 and its regulation 246-06, the last one, define pretty well all the requirements need it to obtain a product license, manufacturing license and also to obtain a distributor license
- We use a data-base (SIAMED) to hold all the information that we manage. Our staff is composed of around 30 pharmacists; the financing is made by MOH. The cost for Registration of a product is as follows:
 - Pharmaceutical Products around 200.00 US dollars
 - Medical devices around 100.00 US dollars
 - Natural products around 100.00 US dollars

- Cosmetics products around 100.00 US dollars
- The time to wait until obtain a registration is well defined in our lane 42.01(90 days), products that have priority as Anti retroviral, products for the cancer could obtain the license.
- Dominican Pharmaceutical market is compound with around 2000 pharmacies, 1200 distributors, 500 importers and around 100 manufactures.
- Evaluation and Registration of Products: We have 2 committees:
 - A technical committee in charge of the evaluation of generic products, repetitive molecules; the most important points at the evaluation process is the presence of CPP (Imported Products), pharmacological information, manufacturing process and product analysis certificate.
 - Consultant's Committee in charge of the evaluation of ___ molecules, the most important point are the presence of Pre-Clinical and Clinical studies, the technical information is evaluated by the other committees
- Quality Control: We have a well equipped laboratory: *Laboratorio Nacional Dr. Degaldo*, which is also a dependence of MOH, all the products before obtain a license must be approved chemical and microbiological analyses (when it's required), that's not include Biological products (at the moment we don't have capacity to do this kind of test)
- Public Sector: We have an entity in charge of the supplier of medication product, medical devices into the publics hospitals and public pharmacies this organism works partially with DRA (all products for the public supplier should be has a license)
- Inspection Activity: We do inspections, routine inspection (once a year) to certificate the accomplishment of the GMP and special inspection when a manufacturer or distributor has presented deficiencies report.
- Mayor weakness
 - Problems in the national use of modification (people get medicines without prescription in all national geography, that's include the antibiotic abuse.
 - We don't have a National Policy of prices control
 - Pharmacist aren't always as presents at the communities pharmacy
 - We don't have a Pharmacovigilance program
 - We don't have a unit in charge of the information-promotion of the pharmaceutical products.

ANNEX 5: GUYANA

Guyana



The Drug Inspectorate Division conducts the following activities

- Inspection of drug and cosmetic manufactures they are two (2) drug manufactures and five (5) cosmetic manufacturers. Each manufacturer is expected to have qualified and experienced personnel involved all levels of production. Inspections are conducted by the 31st of March to facilitate licensing for the current year and routine inspection thereafter. Application fee \$1500.00 (guy)
- Inspection of drug, cosmetic, medical device import and wholesalers/distributors bands. Drugs importers must employ a pharmacist who would be in control of all pharmaceuticals and records. They are inspected by 21st March to facilitate licensing for the current year and routine inspection thereafter. Application fee \$1500.00 (guy)
- Inspection of retail outlets- pharmacies, patent shops, hospital dispensaries, cosmetics counters and supermarkets. Pharmacies and patent shops are licensed by the Pharmacy and Poisons Board, while the pharmacist license is issued by the Pharmacist Council.
- Examination of import licenses and custom entries (if they are sent by the Guyana revenue Authority)
- Collecting samples of drugs, cosmetics and medical devices submitting it for analysis and or examination. Analysis for drugs are done by Drug Chemistry Laboratory within the Food and Drug Dept and by the Caribbean regional Drug Testing Laboratory (CRDTL) in Jamaica. Samples are taken from the public and private sector.

- Investigation of consumer complaints
- Examination of labels and label draft for compliance
- Preparing and solving consumer advisory and press releases.
- Preparing import authorizations and reports for submission to INCB concerning narcotics and psychotropic substances. They are six (6) importers the pharmacist is in control at all times of the buy and records held- the narcotic cupboard. They are inspected every quarter to facilitate reporting to INCB. Application fee \$5000 (guy) their five thousand dollars \$5000 (guy) for each consignment imported thereafter.
- Reviewing of legislation – this is an going science the laws and regulations used are outdated
- Enforcement decisions for non-compliance
- Monitoring of precursor chemicals. There is not a formal system.
- Registration of pharmaceuticals: There is no registration committee. There is a list of requirements that importers must adhere to. The documents submitted are reviewed by the inspectors, samples collected are sent for analyses either to the local laboratory on the regional Laboratory. Registration fee/dosage form \$2000.00 (guy).
- Ad finance comes from the Ministry of health and fees go into the Ministry's Account.

Contact Persons:

Minister of Health: Hon Dr. Leslie Ramsammy
 c/o Ministry of Health
 Brickdam, Georgetown, Guyana

Chief Medical Officer: Dr. Rudolph Cummings
 c/o Ministry of Health
 Brickdam, Georgetown, Guyana

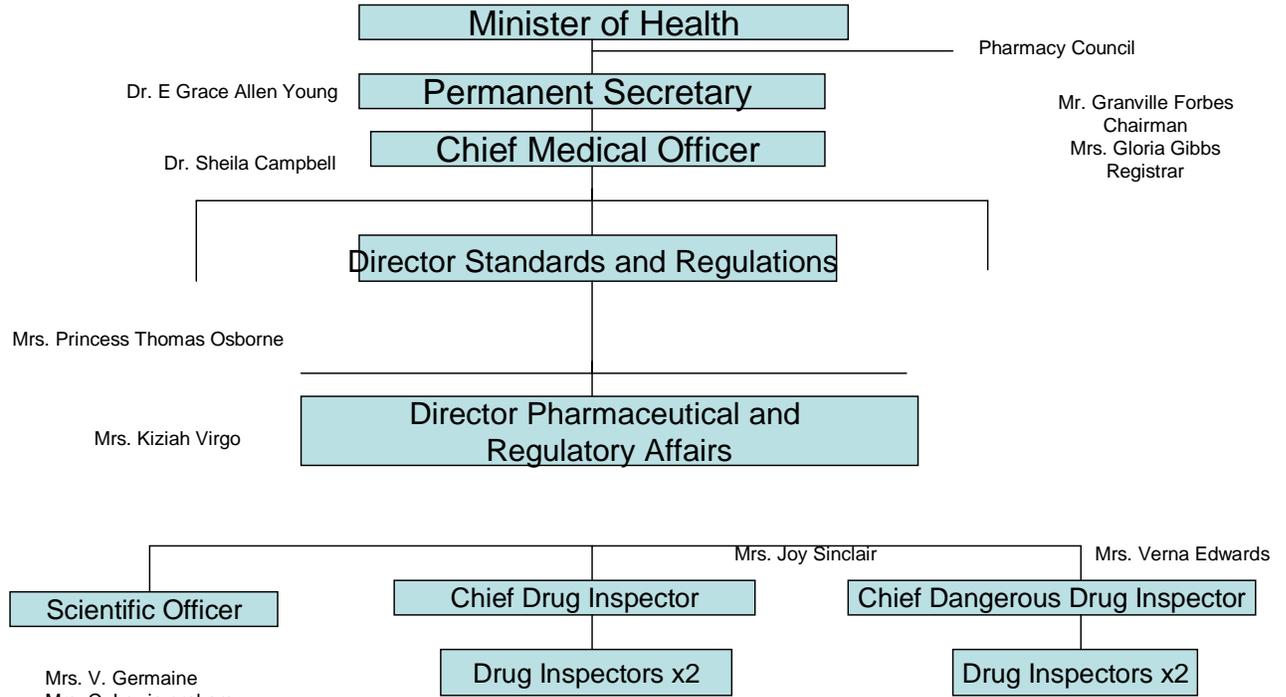
Director Food and Drug Dept: Mrs. Marlin Collins
 c/o Food and Drug Dept
 Mudlot, Kingstown, Georgetown, Guyana

Snr Drug Inspector (ag): Mrs. Fabiola Robertson
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Guyana Pharmacists Association
 Guyana Medical Association

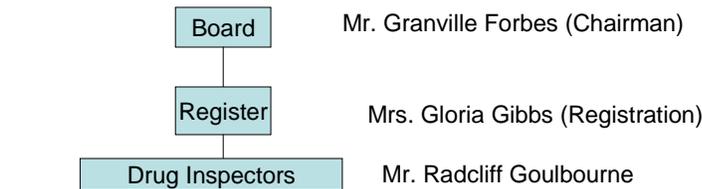
ANNEX 6: JAMAICA

**Jamaica
Organizational Charts**



P.T.O.

Pharmacy Council



Other Contacts:

Mrs. Ellen Grizzle	President CAP Member of Pharmacy Council
Mr. Norman Dunn	President, Pharmaceutical Society of Jamaica
Dr. Eugene Brown	Director, School of Health Sciences, University of Technology
Dr. M. Gossell-Williams	Pharmacologist UWI, Jamaica Pharmacology Dept
Mrs. E. Gayne-Shilleto	Chamber of Commerce Jamaica

Prepared by Cynthia Lewis-Graham

SUMMARY OF FUNCTIONS OF NATIONAL DRUG REGULATORY AUTHORITY OF JAMAICA

The functions are carried out by two agencies:

1. Pharmaceutical & Regulatory Affairs Department (PRAD)

- Located in the offices of the Ministry of Health
- Financed by the Ministry of Health
- Technical staff - 8 pharmacist
- Three Units — Registration; Dangerous Drug; Inspection and Permits
- Legislations — Food and Drug Act and Regulations, Dangerous Drug Act and Regulations, Precursor Chemical Act among others
- Regulates products, premises, practice
- Reports to the CMO and Permanent Secretary
- Committees — Product Registration, Central Drug & Therapeutics, Ethics

2. The Pharmacy Council (PC)

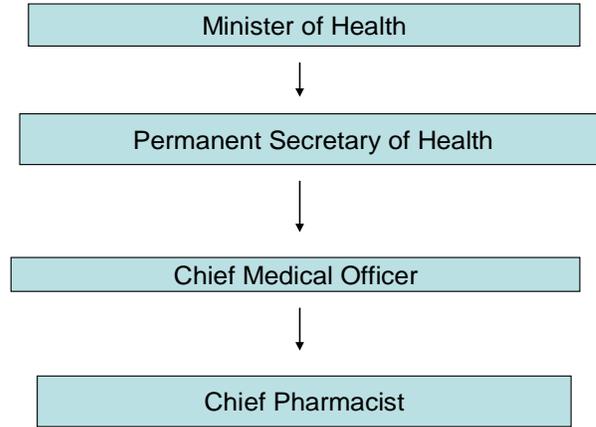
- A statutory body
- Decision making body is a board of 10 members, 6 of which are nominated by the pharmacy association the other four by the Minister of Health
- Technical staff — 5 pharmacists
- Legal Framework — Pharmacy Act and Regulations among others

- Regulates persons, premises and practice
 - Report to the Minister of Health
 - Various Committees
- * Approximate number of pharmacists = 600
 - * Approximate number of pharmacies = 300
 - * Approximate number of major manufacturers = 7
 - * Licensing of manufacturers, retailers, wholesalers, importers and dispensers is done by PC while the product is done by PRAD. Permit to import drugs is done by PRAD.
 - * Drug evaluation and registration is the responsibility of PRAD done through sound application of medical, scientific, and technical knowledge.
 - * The Government Chemist Lab. is mandated to do quality analysis of all products submitted for registration. Registration "Lead Times" vary from 60 working days in the case of "emergency drugs" to 120 days in the case of new drugs.
 - * The cost for registration of a product is Ja\$ 5,000 (US\$80).
 - * Inspection of facilities is done jointly by PC and PRAD. The inspector has the power to enter and inspect any facility that manufacture, store, sell or dispense drugs at any time and has the power to seize products and records where a breach of the law has been found.
 - * The Government Chemist Laboratory supported by the CRDTL is mandated to do quality analysis of all drugs. This is done for all products for registration, scheduled targeted products and random sampling of products.
 - * The PRAD is responsible for promotion and control of advertising of drugs. Ads are reviewed and approved before release. PRAD and PC are responsible for information and promotion of drugs done through a series of publications, seminars and public education programmes.
 - * Copies of adverse drug reporting forms are published in the VEN List of Drugs and the National Formulary and the PharmWatch Newsletter for reporting events. Reports of these events are reviewed by the CDTC. Post marketing surveillance of drugs through random sampling and testing is done periodically. DUR and audits are done periodically.
 - * The DRA interacts and collaborates with various stakeholders in the carrying out of its responsibilities.

ANNEX 7: St. LUCIA

September 19th 2006

Saint Lucia



Other Important Persons

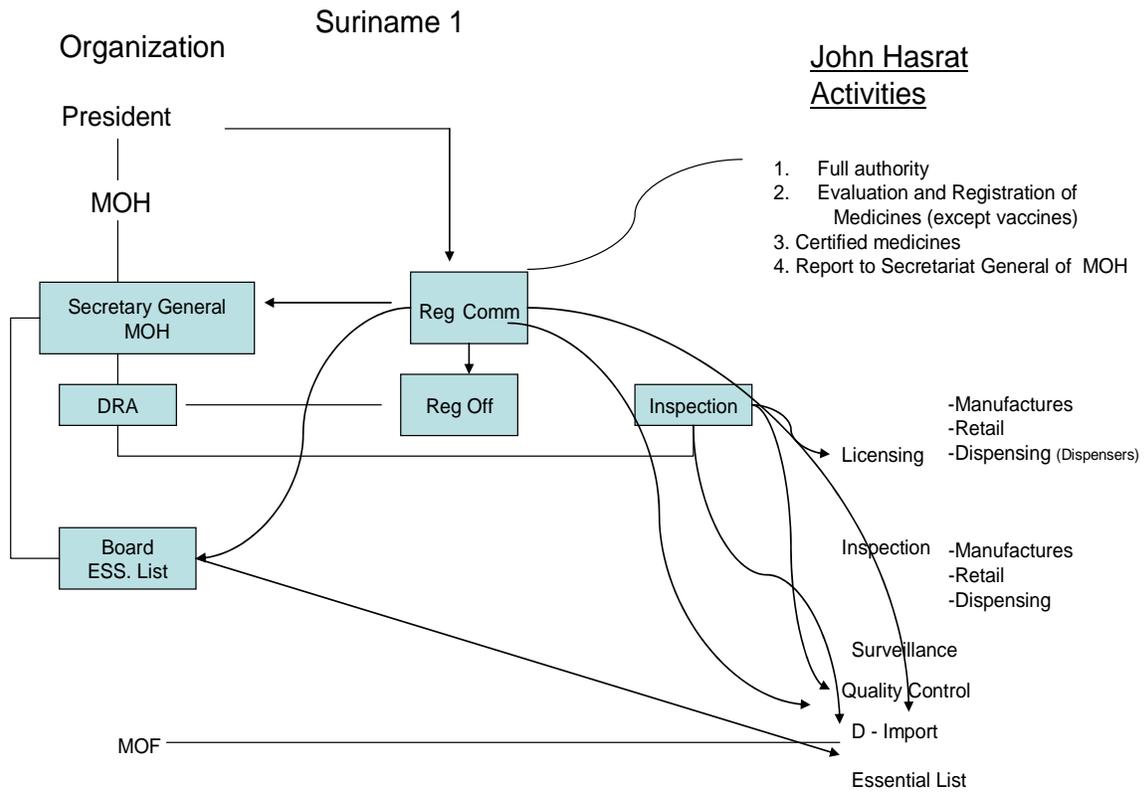
Mr. Francis Burnette
Managing Director
OBLS/PPS
Morne Fortune

Drug Regulatory Harmonization

- St. Lucia does not have a Drug Regulatory Authority (DRA) and thus does not register drugs, pharmaceuticals or medical supplies.
- There are no drug manufacturing companies in St. Lucia.
- St. Lucia does have a Pharmacy Council established by the Pharmacy Ad: No. 8 of 2003 and thus has the authority to register pharmacists, pharmacies and authorized sellers of poisons.
- Only the regulations pertaining to registration have been passed, the rest of the regulations are with the Attorney Generals Office (Drafting Legislation Department)
- There are:
 - Thirty three (33) Community pharmacies (Health Centre's)
 - Three (3) Hospital pharmacies
 - One (1) Polyclinic
 - Twenty Seven (27) Private pharmacies
 - Seventy (70) registered pharmacists

- There is not a drug inspector on staff at the Ministry of Health, but the Pharmacy Act does allow the Pharmacy Council to appoint a pharmacist to perform the functions of a drug inspector.
- Procurement of Drugs
Over six hundred (600) drugs and medical supplies are procured for the OECS (Organization of Eastern Caribbean States) by OECS/PPS (Pharmaceutical Procurement Service) for the public sector. This office performs the quality control and surveillance functions for the public sector.
- The private sector is virtually unregulated in the OECS (OECS = St. Lucia, St. Vincent and the Grenadines, Grenada, Dominica, Grenada, St. Kitts and Nevis).

ANNEX 8: SURINAME

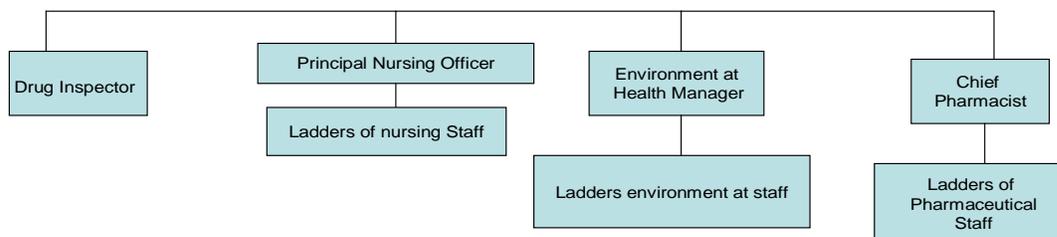


1. All coordinators are known in each unit of the organization
2. Strength: Human Resources
3. Weakness:
 - a) no quality control lab
 - b) no good communication with international organizations, esp. experts

ANNEX 9: St VINCENT AND THE GRENADINES (SVG)

Saint Vincent and Grenadines

The Chief Administrative Officer. – (P.S) Chief Technical Officer -CMO



Description:

- SVG Drug regulatory Authority can be considered an embryonic work in progress. In 1996 SVG appointed a Drug Inspector. He was autonomously located in the medical administration in the Ministry of Health. His immediate supervisor was the ministry's chief technical advisor (the Chief Medical Officer). However he found his functions largely limited by the lack of proper pharmacy legislation.
- In SVG there was an overhaul of the Dangerous Drug Act in 1988 and this was renamed the Drug (prevention of Misuse) Act. This act provided for the control of imports, exports storage and handling of Narcotic and Psychotropic in keeping with the INCB. All trading activities take place under license process by the Drug Inspector and issued under the signature of the Chief Medical. This Act provide for inspection by Inspectors.
- SVG first pharmacy Act became effective in December of 2004. It makes provision for a five member pharmacy Council consisting of The Chief Pharmacist, The Chief Medical A layer and two pharmacist nominated by the Pharmacy Association.

- The Council responsibility includes:
 - The licensing of Pharmacies, Pharmacist, pharmacy owners and sellers of poisons.
 - Making of regulation under the Pharmacy ACT including regulations for the control of Imports, exports, manufacturing, storage and disposal of pharmaceuticals
 - Make regulation for the control of the sale of Poisons.
 - The registration of Drugs

- The act makes provision for the Drug Inspector(s) to act as monitors and enforcers of the regulations. They have Authority to enter any premises where they suspect drugs are being sold and they may confiscate or quarantine any products of suspicious quality.

- Svg also pass a chemical Act in 2003 which seek to control dangerous Chemicals and Precursor substances. This act also falls under the Authority of Minister of Health whose inspectors are responsible for the monitoring.

- The deficiencies include:
 1. The body of regulation under the Pharmacy Act is still under discussion by stakeholders (should be submitted to the Ministry of Legal Affairs before the end of the year (2006)
 2. Regulation under the Drug (prevention of misuse) ACT were not revised with the core ACT and need to be urgently updated.
 3. There is not national drug policy in place. (The Drug Inspector has recently (2week ago) been asked to look into this matter by the Chief Medical Officer. Matters to be at will include Drug registration (not now practice), the Handling of denoted and expired goods, the establishment of a function formulary and therapeutic Committee
 4. Drug registration (not now practice), and would present a real challenge given a lack of competence in the area, a regional approach has been advanced by the rug Inspector to the Ministry.
 5. Quality Control also present real challenge given the absent of an analytical laboratory in the country. Samples are collected and sent either directly or "more so through the OECS Procurement Unit to the Caribbean regional Laboratory in Jamaica. Biological Quality Control remains a questionable.
 6. Surveillance is limited There is no Pharmacovigilance system in place and no effective ARD drug reporting system. There is annual on site pharmacy inspection by sole Drug Inspector, and responding to serious reports of poor Pharmacy practice.
 7. A need exist for tighter cooperation between the custom department and the DRA with regard to arrival of Pharmaceutical at the ports of entries

ANNEX 10: TRINIDAD & TOBAGO

Yvette Sylvester
Drug Inspectorate Division
Ministry of Health



Pharmaceutical Regulation Trinidad and Tobago

- Population of Trinidad and Tobago — 1.3 M
- Area— 1,869 Sq. Miles
- Importers/Distributors — 38
- Manufacturers - 6
- Public Sector Units (Hospitals, Health Centers) — 121
- Private Sector Units (Hospitals, Pharmacies)- 321

- Trinidad and Tobago is guided by a **National Drug Policy** which outlines broad policies for the several areas related to drugs, drug use, drug supply and its management.

- The goal of the National Drug Policy is to ensure accessibility of drugs which are safe and effective for the population of the country.

- The National Drug Regulatory System
The National Drug Regulatory System is operated mainly by two (2) divisions of the MOH. These divisions are therefore funded by the MOH and are staffed by Public Servants. They are the Drug Inspectorate Division and the Chemistry/Food and Drugs Division. The other unit in the

system is the Council of the Pharmacy Board constituted under the Pharmacy Board Act. This is a Statutory Authority accountable to the Minister of Health. The council obtains funding from fees obtained from registration, licenses, inspections, education and training etc.

- **The Drug Inspectorate Division** monitors the Importation, manufacture, distribution, sale and disposal of unserviceable antibiotics and narcotics. The Drug inspectorate Division acts as the secretariat to the Antibiotics Control Committee which is constituted under the Antibiotics Act. The Drug Inspectorate Division has a staff of ten (10) pharmacists including the Principal Pharmacist. Staff selection is based on seniority in the service
- **The Chemistry/Food and Drugs Division** monitors the importation, manufacture, sale, distribution and disposal of all other drugs including herbal medicinal products which have become unserviceable. The Chemistry/Food and Drugs Division is the secretariat for the Drug Advisory Committee which is constituted under the Food and Drugs Act. The Food and Drugs Division has a staff of fourteen (14) including the Chief Chemist, Director Food and Drugs Division.
- **Training** by both divisions is mainly in house. In some instances training modules are also used (I)Drug Lab.). Procedure Manuals and Guidelines are available.

REQUIREMENTS FOR REGISTRATION

- Requirements for registration are documented and available for prospective applicants.
- Applicants are given appointments for submission of applications. Applications not meeting requirements are rejected.
- Dossiers must include a completed application form, and a Certificate of a Pharmaceutical Product (CPP) in the WHO format.
- Dossiers must have all Pharmaceutical, Pharmacological and Clinical /Equivalence documentation. Three product samples, at least 1G raw material and two samples each of packaging including literature insert must be submitted with the application.
- Dossiers are submitted to the experts for assessment.
- Product samples are submitted for testing.
- Applications are then submitted to the respective Committees for consideration.
- Narcotic applications go directly from the Drug Inspectorate to the of the Minister of Health for approval.
- Antibiotics — The Manufacturing firm must be approved for gazetting by the Minister of Health as a manufacturing firm from which antibiotics may be

imported.

- Other Drugs including herbal medicinal products must be approved for gazetting by the Minister of Health.
- Recommendation for approval is made by the respective Committees.
- Applicants are issued letters of approval or rejection with the reasons for rejection.
- Registers are computerized and information is available to the public but not through any web page.

IMPORTATION OF DRUGS

- Only drugs registered for use in the country may be imported for use by the population.
- Antibiotics and narcotics require import and withdrawal permits issued by the drug Inspectorate.
- Import permits for controlled drugs are issued by the Chemistry/Food and Drugs Division. For other drugs import permits are only required when one is submitting an application for registration.
- Food and Drug Inspectors are assigned to ports of entry. Illegal importations are seized by customs.
- Importers, public and private sector pharmacists and nurses on wards etc. have to account for all antibiotics, narcotics and controlled drugs under their charge. Doctors in the private sector must account for all narcotic preparations purchased and administered.

Pharmacovigilance

There is no Pharmacovigilance System. Some aspects of it exist. There is a reporting form for adverse events. A condition for registration is that the regulatory body be informed by the manufacturer of any adverse events of the registered product which may occur. In addition, any product banned by stronger regulatory authorities is brought to the attention of the relevant committees.

Recalls by the manufacturer are dealt with promptly by the MOH

Quality Surveillance - Done but probably not enough

Disposal Of Unserviceable Items

- Firms are expected to submit a request for destruction of unserviceable items.
- Public sector units submit applications for destruction. The quantity of each item to be disposed of is verified by a Board of Survey for destruction of unserviceable items.
- Destructions are done mainly by incineration or by burial after crushing.
- A report on the destruction is done and a Certificate of Destruction is issued.

- During General inspections of retail pharmacies unserviceable items are destroyed by wetting with water and discarded down the drain or in the garbage bin.

Licensing

Licenses are to be renewed annually. There are different licenses issued:

Pharmacy License — Wholesalers and Retailers (Pharmacy Board Act)

Antibiotics — Wholesalers and Retailers (Antibiotics Act)

Controlled Drugs — Wholesalers and retailers (Food and Drugs Act)

Manufacturer License — Food and Drugs Act

Pharmacy License — Wholesalers and Retailers (Pharmacy Board Act)

Antibiotics — Wholesalers and Retailers (Antibiotics Act)

Controlled Drugs — Wholesalers and retailers (Food and Drugs Act)

Manufacturer License — Food and Drugs Act

Practicing Certificate — Issued to Pharmacists (Pharmacy Board Act.)

Regulatory Inspections

- New Pharmacies and Firms - Inspections done to verify that certain requirements under Pharmacy Board Act, Antibiotics Act and Dangerous Drugs Act are met before licenses to operate are granted.
- General Inspections of records and stock balances are expected to be done at least every two years. Reports are written. Warning letters issued if necessary. Legal action taken if necessary. There are penalties for contravention of all legislation relating to pharmaceuticals.
- New Pharmacies and Firms - Inspections done to verify that certain requirements are met before licenses to operate are granted.
- General Inspections of records and stock balances are expected to be done at least every two years.
- Reports are written. Warning letters issued if necessary.
- When there is no incoming pharmacist. An inspection is done to verify the stock left and the cupboards are closed.
- Manufacturing Firms - Inspected annually against a check list to ensure GMP in keeping with WHO standards.
- A file which is kept up to date is maintained by each regulatory administration for each unit private and public dealing in pharmaceuticals.

Advertisement And Promotion

- Under The Food and Drugs regulations it is an offence to advertise to the general public for human use a third Schedule drug (Prescription Only Drugs) or a controlled drug.
- Under The Food and Drugs Act it is an offence to label, package, treat, process, sell or advertise a drug in a manner that is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

ANNEX 11: Results from Working Groups

DRA Functions	Levels			Comments
	1.National	2. Regional	3. Internat.	
Licensing— Manufacturer		X Regional body representative of all countries Fees collected could support Travel and logistics.	X	Costs of making change vs. keeping the way things are. Implications for law as most countries require domestic licensing. Currently being done but resource intensive. Could move towards registration list of companies to meet domestic responsibility. Licensing of a manufacturer is a thorough inspection. Use a pool of inspectors from the different countries. Legal and financial ramifications. If done at regional level who will issue the license? A representative regional body. Regional inspectors less bias and chance for corruption. Possible to have greater inter-regional trading if regional approach. Context of single market economy. Free flow of goods.
Licensing –Import	X	X		Large importers in region. Should be left at national level. Policy and guidelines could be regional.
Licensing – Retail	X	X		
Licensing – Dispensing	X			With regional guidelines and common training but issued nationally and inspected nationally.
Evaluation and Registration		X		Regional body would review and register products. Would require common application. All countries need to have access to updated information about licensed companies and registered products.
Inspection GMP		X		Inspection of a manufacturer is a thorough inspection. Regional inspection teams with common inspection guide and training. Harmonize requirements.
Inspection Clinical Trials	X	X	X	National Inspection to regional and international GCP guidelines.
Quality Control	X	X		Regional Labs not meeting country needs so looking at other options. If source everything out would lose technical capacity. Consult looking at issues and assessment of the institution, turnover time, equipment and funding. Recommended changes being implemented Felt better to have one central lab meet the needs of the region and maintain reference standards. Develop priority list of drug categories to be tested. Sample collection of targeted products. Should be aware of increasing possibility of counterfeits being

				introduced into the system. Field kit rapid testing for triage of possible counterfeits. Terrorism agents and tourists' drugs present unique analytical issues. Need of cooperation of MOU with DRA and customs
Drug Information and Promotion	X	X		General requirements at national level. Monitoring of promotion at national level. Sharing of information between countries. Regional Drug Information Center proposed to support regulatory activities.
Safety and Efficacy Surveillance- Pharmacovigilance	X	X	X	Collect reports at national level, analyze at regional level and report to international data bases.

GROUP 2:

	Country	Regional	International	
DRA Functions	LEVEL 1	LEVEL 2	LEVEL 3	Justific/comments
Licensing M	x			National for establishment and facilities: The entity, the company and the facilities should register at the National level. The product should be registered at the National level. The review of the dossier should be Regional for product registration. There should be a main regional center for dossier review. Inspection, quality control activities should be performed by the country but standards on products can be established for the region. Information on manufacturer details should be shared at the regional level. The guidelines are international.
Licensing I	x			National: The importer, the facilities, to verify the storage of what is imported. Also each product and lot should be licensed at the national level.
Licensing R	x			National
Licensing D	x			
Registat Gen		x		The review and evaluation of the dossier and registration: regional. It can be registered regionally then each country manages licensing.
Regist New D		x		II
Regist C Trial		x		They should also be registered at the Regional level with the functioning of a regional ethics committee. A pharmacist should be involved
Inspection Man	x	x	x	Local plants inspected at the National level to be recognized in the Region. It are not clear if it should be done by a Regional center or by each country or both. Regional with international collaboration for plants outside the region.
Inspection New	x			Facilities:
Inspection clin trial		x		
QC	x	x		
QC counterf	x	x	x	Counterfeit should be agreed in the three levels
Inform	x	x		Labeling should be established with national and regional recognition.
Promotion	x			The promotion would be very difficult to regulate at the regional level.
Surveillance	x	x	x	National reporting system with a Regional and International (Uppsala) collecting of reports.