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Regional Assessment of Drug Registration and Regulatory Systems in CARICOM Member States and the Dominican Republic

Final Report - Volume II

July 2009

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Regional Assessment of Drug Registration and Regulatory Systems of CARICOM Member States and the Dominican Republic

Final Report - Volume II:

Countries and Regional Quality Control Laboratory

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Antigua and Barbuda: Country Report

Country Background[1]

Antigua and Barbuda is located at the north eastern tip of the Caribbean islands chain and comprises the islands of Antigua, Barbuda and Redonda (uninhabited) with a total area of approximately 440 km². The population was approximately 82,000 in 2005, with 30% living in the urban area of the capital Saint John.

The country's Gross National Product was USD 11,050/capita in 2006 (current value). The economy is quite dependent on tourism and related services. Other important areas are agriculture, manufacturing for the local and export markets, and construction.

The Ministry of Health is responsible for regulation and strategy development, for public health and for service provision in the public sector. The main public sector institutions are the Holberton hospital in Saint John (in- and out-patient services) and an 8-bed health facility in Barbuda. In the districts, 26 health centers/clinics provide primary health care services.

The main causes of death are malignant neoplasms, heart disease, diabetes mellitus, hypertensive disease, and cerebrovascular disease. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 70.3 years 75.2 years	2008
Infant mortality rate (per 1000 life births)	21.8	2007
Maternal mortality ratio (per 100,000 live births)	not available	

Public health care is financed through tax contributions and levies for the Medical Benefit Scheme under which medicines for priority diseases are provided. In 2005, 11.1% of government expenditure was dedicated to health - approximately USD 339/capita.

Pharmaceutical sector context

Antigua and Barbuda does not have a National Medicines Policy. The CARICOM Model National Medicines Policy was not available. The OECS/PPS essential medicines list is used as a reference for the public sector. This list is supplemented with additional medicines that are being used. There are no national treatment guidelines. The use of generic medicines is neither actively promoted nor is it regulated (i.e. no provisions for generic prescribing or substitution).

There are 2 medical schools ('off-shore' US university campuses). One pharmacy school provides a 3-year diploma course.

1 Information in this section is sourced from 'Health in the Americas - Basic Indicators 2008' (PAHO 2008), 'Health in the Americas - Country Reports' (PAHO 2007), and World Health Statistics 2008 (WHO 2008)

The number of pharmacists registered with the Pharmacy Council is 70. A limited number of pharmacist assistants that were trained abroad are employed in the public sector and the Medical Benefic Scheme pharmacies. In 2007 there were 208 physicians and dentists.

Pharmaceutical manufacturing is not present in the country. Medicines are imported and distributed by approximately 10 wholesalers. For the public sector Central Medical Stores is procuring pharmaceuticals, mainly from OECS/PPS. In the public sector there are 2 pharmacies operating in the hospitals, and district health centers/clinics provide additional pharmaceutical services. The Medical Benefit Scheme operates 6 pharmacies. These pharmacies procure their supplies from the Central Medical Stores, but also from other sources. Respondents noted that in the Medical Benefit Scheme pharmacies a lot of originator (brand) products are used. The number of registered retail pharmacies was not available.

Legislative Provisions

Existing medicines legislation includes the Antibiotics and Therapeutic Substances Act, 1951 (ATSA); the Medical Act, 1938; the Pharmacy Act, 1995; the Public Health Act, 1957 (PHA) and the Caribbean Regional Drug Testing Laboratory Act, 1979.

Administration of the medicines laws in Antigua and Barbuda is vested onto a number of bodies. The Pharmacy Council is established under section 3 of the Pharmacy Act, 1995 to control and regulate the practice of pharmacy; the production, sale and dispensing of drugs and poisons and the examination and registration of pharmacists and premises for selling drug and poisons. The Antibiotics and Therapeutic Substances Act, 1951 provides for establishment of the **Licensing Authority** appointed by Governor General under section 3 of the Act. The function of the Licensing Authority is to control the manufacture, importation, storage, sale and use of antibiotics and therapeutic substances in Antigua and Barbuda.

Section 29 of the Pharmacy Act, 1995 repeals sections 40-57 of the Medical Act of 1938 as revised in 1961, which provided for regulation of the practice of pharmacy, registration of chemists and druggists and sale of drugs and poisons.

In as far as **delegation of regulatory functions** is concerned, the Minister under section 16 of the Pharmacy Act, 1995 may, after consultation with the Pharmacy Council, constitute a Board of Inspectors vested with powers to conduct inspection of premises, make enquiries and collect samples for the purpose of enforcing the Act. The Board of Inspectors is constituted by the Chief Pharmacist or his representative and two other members of the Board. District authority also is delegated some drug regulatory functions under the Public Health Act.

Table 2 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 2 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of		
Manufacturers	Yes	Licensing provisions more explicit in Antibiotics and Therapeutics Act than in Pharmacy Act
Importers	Yes	
Wholesaler/Distributor	Yes	Pharmacy Act
Retailers/dispensing outlets	Yes	
Other	N/A	

Key regulatory function/provision	Covered in legislation	Comments
Market Authorization	No	
Inspection of premises	Yes	
Establishment of Quality Control Laboratory	Yes	Caribbean Regional Drug Testing Laboratory Act establishes the regional quality control laboratory in Jamaica by 14 Caribbean countries
Control of clinical trials	No	
Control of counterfeit medicines	No	
Control of imports and exports	Yes	
Adverse drug reaction monitoring of products	No	
Control of product promotion and advertisement	No	
Provision for medicines distribution schedules/categories	Yes	
Control of narcotics and psychotropic substances	Yes	
Scope of regulated products	Yes	Human and veterinary drugs and poisons
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	Different sanctions provided under different laws
Power to make regulations	Yes	
Regulations made under the Act	Yes	Regulations under the Pharmacy Act not yet gazetted

Generally, the laws are not comprehensive enough to provide for all the key regulatory functions. Provisions for licensing manufacturers and importers are more explicit in the Antibiotics and Therapeutics Act than the Pharmacy Act. Missing provisions include market authorization, clinical trials, counterfeit medicines, product promotion and advertising and safety monitoring of products.

Licensing of manufacturers, importers, wholesalers, distributors, retail pharmacies: the Licensing Authority is responsible for issuance of licenses for the manufacture, importation, storage, sale and use of antibiotics and therapeutic substances. The Minister of Health is the authority responsible for issuance of licenses for wholesale and retail pharmacy upon advice of the Board of Inspectors and recommendation of the Pharmacy Council.

Inspection: For the purpose of enforcing the Pharmacy Act, the Board of Inspectors is responsible for inspection of premises, making enquiries and collecting samples for analysis. Inspection and collection of samples of any antibiotic and therapeutic substances under the Antibiotics and Therapeutics Act, is conducted by any person authorized in writing by the Licensing Authority under section 10 and 11 respectively.

Quality control of samples for analysis is done using the Caribbean Regional Drug Testing Laboratory which has been established under the Act ratified by 14 countries namely Barbados, Guyana, Jamaica, Trinidad and Tobago, Antigua and Barbuda, Belize, Bahamas, British Virgin Islands, Dominica, Grenada, Montserrat, St Christopher-Nevis-Anguilla, St Lucia and St Vincent.

Medicines distribution categories impliedly include prescription and non-prescription medicines although there are no clear provisions for medicines schedules in the Pharmacy Act. As for Antibiotics and Therapeutics Substance Act, there is a schedule that provides for medicines categorized as antibiotics and their salts.

The Misuse of Drugs Act 1974 provides for **control of narcotics and psychotropic substances.**

Scope of regulated products includes human and veterinary medicines and poisons.

Administrative and legal sanctions are provided in respective laws.

Power to make regulations: the Minister of Health is empowered by the Pharmacy Act of 1995 to make regulations. However, under the Antibiotics and Therapeutic Substances Act, 1951, the Cabinet is empowered to make regulations while the Central Board of Health is empowered to make regulations in relation to composition and labeling of drugs (and food) under the Public health Act.

Conclusion and recommendations: There is a clear fragmentation of medicines legislation which may affect efficiency and effectiveness of medicines regulation in Antigua and Barbuda[2]. The interpretation of the terms drugs and poison is also an issue that needs to be addressed with a view to clear meaning of the terms as used in the law, the scope of products regulated, and provision for distribution schedules/categories. There is need to harmonize the laws regulating medicines in order to provide for one comprehensive legislation for all medicines and related products. Considering the size of the country one National Regulatory Authority (e.g. the Pharmacy Council) could be responsible for regulation of the pharmacy profession and practice, as well as for regulation of products and other pharmaceutical businesses. Provisions for marketing authority could include a clause authorizing the Ministry of Health to delegate related assessment activities to a sub-regional body.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section are reflecting the outcome of interviews conducted with the Chief Pharmacist.

Organizational structure

There is no National Medicines Regulatory authority. The Pharmacy Council has been established under the Pharmacy Act, and a registrar has been appointed. The registrar functions as the Council's executive officer. Recommendations by the Council regarding the issuing of licenses to pharmacy premises and pharmacists are to be approved by the Minister of Health. The board of inspectors, consisting of the Chief Pharmacist and two more members of the Council has been appointed. The board of inspectors reports to the Minister of Health.

Licensing

Licensing of Premises

Licensing of pharmacy premises is done under the Pharmacy Council subject to satisfactory inspection results. Retail pharmacies and pharmaceutical wholesalers can only operate if a registered pharmacist is in place. Because regulations to the Pharmacy Act have not yet been gazetted valid licenses cannot be issued.

Internet pharmacies are not covered by the licensing system.

[2] Respondents noted that although still in force the Antibiotics Act is no longer being implemented.

Import Permits

Import of pharmaceuticals by the private sector is subject to a license for each shipment issued by the Ministry of Trade. Related invoices are first screened by the Chief Pharmacist who can recommend that an import license be rejected. Certificates of analysis for the pharmaceutical products to be imported are not available for screening by the Chief Pharmacist.

Import permits for narcotics need to be approved by the Chief Medical Officer.

Inspection and Surveillance

Inspections of the distribution channel are done by the Board of Inspectors. As per Pharmacy Act this Board consists of 3 inspectors (pharmacists) who perform this duty on a part time basis.

Pre-licensing inspections are guided by a checklist. During routine inspections expiry dates, labeling, and prescriptions are checked amongst others. Inspections are also conducted reacting on complaints by the public (e.g. reports of sale of antibiotics in markets).

No examples were given for counterfeit medicines and respondents did not think that there was currently a problem with counterfeit medicines.

Product Assessment and Registration

This function is not foreseen in the legislative system.

For the public sector, OECS/PPS is expected to employ adequate measures that ensure quality of medicines procured through that system.

The draft regulations to the Pharmacy Act foresee that conditions for sale of medicinal products will be according to three Schedules: pharmacy only, prescription only, and general sales.

Medicines quality control laboratory

Antigua and Barbuda is one of the 14 countries that established and are funding the Caribbean Regional Drug Testing Laboratory in Jamaica. From time to time medicines from the public sector are sent to this laboratory for testing. It was reported, however, that problems experienced rather relate to short shelf life of products than to suspected substandard quality.

Financing of drug regulation

The Pharmacy Council is financed through the Ministry of Health budget. Council members receive monthly stipends of EC$ 400 (USD 154).

Due to the fact that the regulations to the Pharmacy Act are not made official the Pharmacy Council cannot collect fees.

Human resources (including training)

Medicines regulation is done through the Pharmacy Council that has a membership of 7. The 3 official inspectors are appointed from amongst the Council members.

Public sector salaries for pharmaceutical professional staff are lower than in the private sector, and staff shortage is sometimes perceived as a problem.

Pharmacy Council members did not attend any specific training preparing them for performing the regulatory functions (including inspections).

Infrastructure

The Pharmacy Council does not have dedicated office space and related infrastructure. Meetings are either held in the office of the Chief Pharmacist or in the offices of the Medical Benefit Scheme.

Discussion

Antigua and Barbuda is one of the 10 CARICOM member states that do not have an operational registration system for medicines. As is the case for the other 6 CARICOM member states that are at the same time members of the Organization of Eastern Caribbean States (OECS) quality assurance for medicines provided through the public health sector has been largely delegated to the OECS/PPS that conducts pooled procurement of pharmaceuticals for OECS members.

The quality of medicines imported by the private sector is not controlled adequately, as it is largely based on screening of invoices. Although not mentioned by respondents the island nature of the country might facilitate illegal imports of pharmaceuticals, especially through Barbuda (movements of goods between Barbuda and Antigua are not subject to controls).

The work of the Pharmacy Council is commendable, considering that the draft regulations available since 2007 are not yet officially approved. This implies, amongst others, that the Pharmacy Council cannot issue valid licensing certificates.

Considering the relatively small market size and the human and financial resources requirements it might not be viable to develop and implement country specific legislation that requires in-country assessment of product dossiers for issuing of marketing authorizations. Antigua and Barbuda could therefore benefit from a regional registration system that would improve on the current quality assurance measures provided through OECS/PPS and also extend to the private pharmaceutical sector.

Recommendations

The brief assessment done in the context of this study does not provide the level of information required for developing detailed recommendations. However, for addressing some of the identified constraints in the short to medium term the following could be considered:

For the Government / Ministry of Health

- Ensure enactment of the Pharmacy Act Regulations
- Consider incorporation of relevant provisions of the Antibiotics Act into the Pharmacy Act and repeal the Antibiotics Act, which is not being implemented
- Provide office space and related infrastructure to the Pharmacy Council
- Support training of Pharmacy Council inspectors
- Develop a National Medicines Policy (can be based on the CARICOM Model Medicines Policy)

For the Pharmacy Council

- Identify suitable training courses for Council inspectors
- Identify possibilities for random inspection of private sector pharmaceutical imports

The Bahamas: Country Report

Country Background[3]

The Commonwealth of the Bahamas is located north-east of Cuba and north-west of the island of Hispaniola. The total surface area of 13,940 km² is made up of a group of around 700 islands. The majority of the population of 335,000 (2008) lives in the capital of Nassau on the island of New Providence (around 211,000), and in Freeport / Grand Bahama (around 50,000).

In 2007, the Gross National Product was USD 21,672.00/capita. The sectors most important for the country's economy are tourism and tourism related activities, and financial services. Inequity in the distribution of wealth was noted in the 2001 Bahamas Living Conditions Survey.

The Ministry of Health is responsible for all public health care related functions, i.e. financing, service provision and regulation through four structures, the Ministry of Health headquarters, the Departments of Environmental Health Services and Public Health, and the Public Hospitals Authority. Primary health care is provided through the Department of Public Health (New Providence and Family Islands), and the Public Hospitals Authority (Grand Bahama). The Public Hospitals Authority is further responsible for health services provided by the three government hospitals. The Department of Health operates health centers (level I and level II), and clinics, and in addition is responsible for implementation of the national health programs, including tuberculosis control, immunization, and Sexually Transmitted Infections. In 2003, there were 55 health centers - 41 on the Family Islands - and 59 satellite clinics.

The main causes of death are chronic non-communicable diseases, including hypertension, diabetes, coronary heart disease, stroke, chronic respiratory diseases, cancers, and injuries. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 71.0 years 76.7 year	2008
Infant mortality rate (per 1000 life births)	17.6	2007
Maternal mortality ratio (per 100,000 live births)	68.3	preliminary 2008

Public sector health care is financed through the government budget and user fees. Recurrent public health expenditure during 2002-2003 was estimated at USD 155,261,671 equaling 15% of total government recurrent expenditure.

Not-for-profit organizations, e.g. the AIDS Foundation or the Bahamas Heart Association also offer outpatient and community services.

In the private for profit sector the Doctors Hospital in Nassau and the Lyford Cay Hospital provide in- and outpatient services. In 2003, 286 private health clinics provided primary health care services.

[3] Information in this section is drawn from 'Health in the Americas 2007, Volume II - Countries' (PAHO 2007, 'Health in the Americas: Basic Indicators 2008' (PAHO 2008), and the completed assessment instrument.

These services are paid for out-of-pocket or through private health insurance. Expenditure by the latter was USD 102 million in 2001.

Pharmaceutical sector context

The Bahamas do not have a National Medicines Policy. There is a national formulary and an essential medicines list which is mandatory for the public sector. However, treatment guidelines for priority health conditions are not available. Generic prescribing is mandatory in the public sector, and there is a provision for generic substitution in the new Pharmacy Act of 2009.

The pharmaceutical delivery system is comprised of 4 government hospital pharmacies, 57 private pharmacies, and 99 government pharmacies and dispensing outlets (2009).

There were 141 pharmacists and 17 pharmacy technicians in 2005. In 2008 there were 460 physicians and 75 dentists. In addition, there were 11 Optometrists, 13 Chiropractors, and 3 Podiatrists. There is one program for training pharmacists, which is in its first year. The first intake was 23 students.

There are 11 pharmaceutical wholesalers/distributors. The Bahamas National Drug Agency has - amongst others - responsibility for procurement of pharmaceuticals for the public sector. Procurement is done through restricted annual tenders. Public sector pharmaceutical expenditure during 2007/2008 fiscal year was USD 14,507,880.

There is no pharmaceutical manufacturing industry in the country. The number of pharmaceutical products marketed was estimated to be approximately 1,500 with 25% being multi-source (generic) products.

Legislative Provisions[4]

Existing legislation include the Pharmacy Act 2009, the Health Professions Act 1998, and the Dangerous Drugs Act 1939 (last amended in 1994).

Administration of the medicines laws in the Bahamas is vested in the Pharmacy Council and the Health Professions Council. The latter is responsible for the registration of pharmacists until the Pharmacy Act will be implemented.

Table 1 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 2 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of:		
Manufacturers	No	
Importers	Yes	foreseen under Pharmacy Act
Wholesaler/Distributors	Yes	foreseen under Pharmacy Act
Retailers/Dispensing outlets	Yes	foreseen under Pharmacy Act
Other		
Market Authorization	Yes	foreseen under Pharmacy Act

[4] The main medicines related legislation is the Pharmacy Act 2009, which is not yet publicly available. Information in this Section related to this Act is taken from responses on the assessment instrument.

Key regulatory function/provision	Covered in legislation	Comments
Inspection of premises	Yes	foreseen under Pharmacy Act
Establishment of Quality Control Laboratory	?	
Control of clinical trials	?	
Control of counterfeit medicines	Yes	foreseen under Pharmacy Act
Control of imports and exports	?	Import of narcotics under Dangerous Drug Act
Adverse drug reaction monitoring	?	
Control of product promotion and advertisement	?	
Provision for medicines distribution schedules/categories	?	
Control of narcotics and psychotropic substances	Yes	Dangerous Drugs Act
Scope of regulated products	?	
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	foreseen under Pharmacy Act
Power to make regulations	?	
Regulations made under the Act	No	are being developed

?: information not available (Pharmacy Act 2009 not available)

The Pharmacy Act 2009 could not be made available to us on time. The Act was passed in April 2009 and the official version is yet to be gazetted. We could therefore not perform a detailed analysis of the legislative provisions included in the Act.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

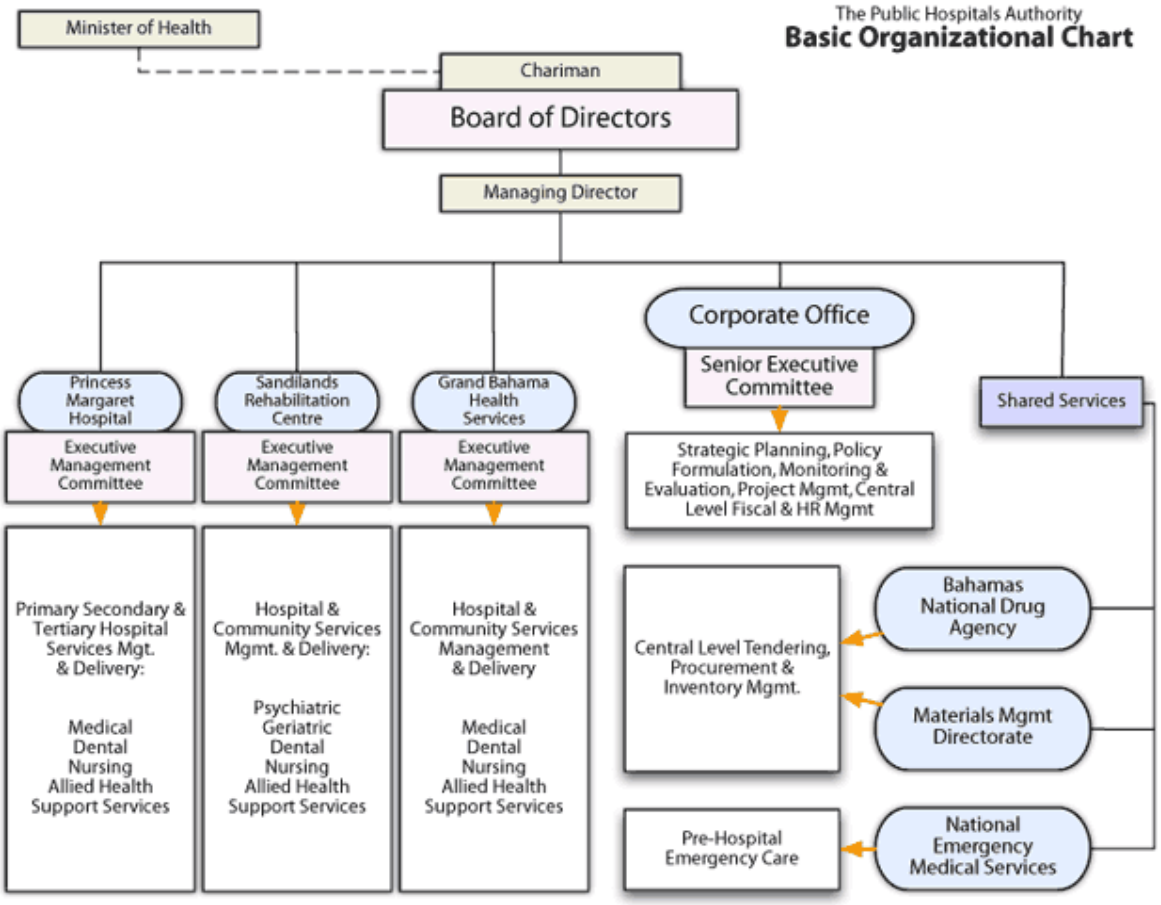
If not indicated otherwise, the findings reported in this section reflect responses from the assessment instrument. Most of the regulatory procedures have been provided for in the Pharmacy Act 2009 for the first time. As implementation is yet to begin there is no information on capacity, procedures, and processes for most assessment areas.

The Pharmacy Act of 1962 made provisions for the establishment of a Board and for licensing of premises and persons, and inspection. It also provided for 2 Schedules, i.e. prescription only and controlled drugs (Schedule 2), and products not falling under Schedule 2 (Schedule 1). It seems that this Act has not been enforced.

Organizational structure

The Pharmacy Council is supposed to be set up within the Ministry of Health. The Bahamas National Drug Agency responsible for public pharmaceutical services is set up under the umbrella of the Public Hospitals Authority (see Figure 1)

Figure 1 - Public Hospitals Authority Organogram



Source: Public Hospitals Authority website (www.phabahamas.org/about_org.php)

Licensing

Licensing of Premises

Currently premises handling pharmaceuticals (i.e. importers/wholesalers and pharmacies) only require business licenses. The Pharmacy Act 2009 makes provision for licensing of these establishments.

Import Permits

Import permits are issued for controlled substances by the Ministry of Health on recommendation of the Bahamas National Drug Agency.

Inspection and Surveillance

Distribution channel inspections are currently not carried out but are provided for under the Pharmacy Act 2009.

However, respondents noted that problems with counterfeit medicines were identified in terms of transshipment via the Bahamas to other countries. Local use of counterfeit medicines has not yet been documented.

Product Assessment and Registration

There is no operational product assessment and registration system in the Bahamas. Regulations being developed for the Pharmacy Act 2009 will provide for registration. It is anticipated that responsibility for this function will be given to the Ministry of Health.

For products to be offered on public sector tenders the Bahamas National Drug Agency requires proof of registration with the Medicines & Healthcare Products Regulatory Agency (UK), FDA (USA), or Medicines Regulatory Agencies in European Union countries. In addition, WHO pre-qualification is accepted as proof of quality, safety, and efficacy.

Medicines quality control laboratory

There is no regulatory quality control laboratory in the Bahamas. Currently samples of suspect products are sent to laboratories abroad. FDA laboratories in the USA and the Pharmaceutical Security Institute in Vienna have been used in the past. This is being coordinated through the Bahamas National Drug Agency.

Although being signatory to the Agreement establishing the Caribbean Regional Drug Testing Laboratory in Jamaica, the Bahamas do not make use of this laboratory. Respondents noted that the lead time is too long taking into account that usually test results need to be obtained fast.

Financing of drug regulation

There is no budget allocation for regulatory activities, which is not surprising as medicines regulatory structures have yet to be established.

The Pharmacy Act 2009 makes provision for fees payable to the Pharmacy Council for inspection and licensing activities. Fee rates will be established in the regulations.

Human resources (including training)

The Pharmacy Council will consist of 7 appointed members (part time) and 1 appointed registrar (full time). The Pharmacy Council will not have the power to hire or dismiss its own staff.

Information on training of staff in medicines regulatory areas was not provided.

Infrastructure

The Pharmacy Council has not yet been established and information on infrastructure could not yet be provided.

Discussion

Due to the current transition from a pharmaceutical market that was regulated at minimal level to a more comprehensive medicines regulatory system there was scarce information on regulatory capacity, processes and procedures. The commitment shown by government for scaling up medicines regulatory structures by passing the Pharmacy Act 2009 should be commended.

For the setting up of a medicines registration system the Bahamas could benefit from experiences of other countries in the region and cooperation with other Caribbean Medicines Regulatory Agencies is encouraged.

Recommendations

The brief assessment done in the context of this study does not provide the level of information required for developing detailed recommendations. However, we would like to make a few basic recommendations.

For the Government / Ministry of Health

- To ensure adequate financial and human resources support required for implementation of the Pharmacy Act 2009.
- To develop a National Medicines Policy that provides guidance on the envisaged development of the pharmaceutical sector, both private and public.
- To cooperate and consult with other Caribbean countries and members of the PANDRH when setting up structures and processes for a more comprehensive medicines regulatory system.

Barbados: Country Report

Country Background[5]

Barbados is the most easterly of the Caribbean islands. It has a land area of 431 km^2 (166 square miles) and had a total population of 281,968 in 2008. The country is divided into eleven parishes. The capital city, Bridgetown, is the most densely populated area with 37% of the total population.

In 2002, Barbados had a Gross National Product of USD 122 Million. For 2006 the Gross National Product per capita was estimated as USD 15,150 (PPP).[6] The country's economy is based mainly on tourism, financial and business services, construction, manufacturing and agriculture.

The Ministry of Health (MOH) is both a provider of health care services, and regulator of the sector. The health care delivery system includes the publicly funded Queen Elizabeth Hospital (QEH) that provides acute, secondary and tertiary care. A network of 5 district hospitals provides long term care for the elderly, a mental health hospital and a half-way house, a long term care facility and a rehabilitation centre for the physically and mentally challenged, and a hostel for homeless persons with AIDS. Services at 8 polyclinics are strategically located within easy access of catchment areas served. Health care services at government facilities are free of cost. The polyclinics are supplied with necessary equipment for the delivery of quality health care. There is a referral system between clinics, hospitals, the private sector and other support services. The Barbados Drug Service, a WHO Collaborating Centre, manages the provision of essential drugs in the country.

The private health care market, comprised of more than 100 general practitioners and consultants, is growing. There are also private sector radiological and diagnostic services. There is a private hospital that provides approximately 30 acute-care beds. Insurance companies market health insurance packages specifically to credit unions, trade unions and large organizations. In 2006, private households' out-of-pocket payments for health were 78.6% of private sector expenditure on health.

The main causes of death are ischemic heart disease, cerebrovascular disease, diabetes mellitus and HIV/AIDS, in that order. In 2008, the life expectancy of males was 71 years while that for females was 76.7 years. In 2005, Barbados had an infant mortality rate of 14 per 1000 live births[7] and a maternal mortality rate of 16 per 100,000 in 2005.

Health care services in Barbados are financed through government expenditure on publicly provided services, out-of-pocket payments and by private health insurance. In 2004, health expenditure per capita was USD 1,151 and the country was ranked 31 out of 177 countries on the UNDP Health Development Index ranking. In 2006, general government expenditure on health was 62.5% of total health expenditure. Total government pharmaceutical expenditure was BDS$ 10.4 Million (USD 5.2 Million) for the financial year 2007/8. PAHO, the Caribbean Regional Drug Testing Laboratory, the Caribbean Food and Nutrition Institute, the Caribbean Epidemiology Center, the Caribbean Environmental Health Institute, the Caribbean Health Research Council and the Inter American Development Bank provide technical and financial assistance mainly in the areas of environmental health, public health, human resources development, research methodology and health promotion.

[5] Information in this section is drawn from 'Health in the Americas 2007, Volume II - Countries' (PAHO 2007) and stakeholder interviews (assessment instrument)
[6] Health Situation in the Americas: Basic Indicators 2008 (PAHO 2008).
[7] Ibid.

This cooperation has mainly comprised training programs, technical assistance, development and use of information systems and the improvement of laboratory testing.

Pharmaceutical sector context

The Draft National Drug Policy for Barbados dated 2005 was reported to be undergoing amendment. There is, however, no Implementation Plan. The Committees deemed necessary for effective management and functioning of a National Drug Policy and an effective pharmaceutical sector are: a National Drug Policy Committee, a Drug Registration Committee, a Therapeutic or Hospital Drug Committee, a Drug Formulary Committee, a Drug Tender Committee, the Pharmacy Council, the Pharmaceutical Association, the Private Pharmacy Owners Association, a Drug Pricing Committee, Consumers Representatives, and Medical Representatives and Distributors.

Essential drugs are free to patients seen in government institutions. In 1981, the Special Benefit Service was established, and selected beneficiaries in both the public and private sectors obtain formulary drugs free of cost upon presentation of a prescription. Groups currently covered are persons 65 years and older; children under 16 years of age; and persons who receive prescribed formulary drugs for the treatment of hypertension, diabetes, cancer, epilepsy and asthma. Persons between 16 and 64 pay a reduced price free of duties and taxes at private participating pharmacies. The BDS pharmacy service consists of 14 pharmacies located across Barbados. Antenatal care for pregnant mothers before the twelfth week of gestation and health services for adolescents are provided at public polyclinics.

The drug regulation system is supported by expert committees – namely, the Drug Formulary Committee, Drugs and Therapeutic Committee, Drug Tender Committee, Narcotic Substance Abuse Committee and the Antidoping Commission. The Drug Formulary Committee assists with the development of the Barbados National Drug Formulary (BNDF). The formulary is updated on an annual basis and the latest version is the 27th edition and covers the period April 1, 2008 – March 31, 2009. Although the Terms of Reference for these expert committees are written in law there are no written procedures or written codes of conduct with regard to conflict of interest.

The pharmaceutical delivery system is comprised of 4 government hospital pharmacies, 1 private hospital pharmacy, 83 private for-profit retail pharmacies and 18 government health centre pharmacies. Only the private sector pharmacies are required to be licensed.

At the end of 2008, Barbados had approximately 300 registered pharmacists and no formally trained pharmacy auxiliary personnel. Local training of pharmacists takes place at the School of Pharmacy of the Barbados Community College and graduates are awarded a Pharmacy Diploma. There were 600 licensed physicians practicing in Barbados in 2008. Medical doctors are trained at the University of the West Indies campus at Mona, Jamaica. Data on the number of practicing dentists were unavailable.

There are 8 licensed pharmaceutical wholesalers/distributors that are all licensed as pharmaceutical importers. The Barbados Drug Service (BDS) has responsibility for procurement of pharmaceuticals. Importation, storage and distribution of pharmaceuticals on behalf of the public sector is outsourced to private sector wholesalers/distributors who are allowed a 32% trading mark-up on cost, insurance and freight.

Carlisle Laboratories Limited is the sole pharmaceutical manufacturer on the island and it also operates as a wholesaler/distributor. The company is privately owned and operated. Total domestic pharmaceutical production valued BDS$ 17.8 Million (USD 8.9 Million) and the total value of imports of pharmaceutical active ingredients valued BDS$ 14.8 Million (USD 7.4 Million) in 2008. Carlisle

Laboratories Limited exported BDS$ 3.1 Million (USD 1.6 Million) of finished pharmaceutical products in 2008. Implementation of an offshore research-based pharmaceutical company is nearing completion.

Legislative Provisions

Existing legislation include the Drug Service Act, 1983 as revised in 1991; The Food and Drug Adulteration Act, 1933; the Medical Registration Act, 1972 as revised in 1978; The Health Services Act, Chapter, 1969 as revised in 1997, The Pharmacy Act, 1986 as revised in 1993 and the Therapeutics Substances Act, 1950.

Administration of the medicines laws in Barbados is vested onto a number of bodies. The Pharmacy Council is established under section 10 of the Pharmacy Act, 1986 to control and regulate the practice of pharmacy, registration and control of persons admitted to practice, and registration of pharmacy premises for selling drugs and poisons. The Therapeutic Substances Act, 1950 empowers the Chief Medical Officer, under section 4 of the Act as **Licensing Authority** responsible for control of the manufacture for sale or supply of any drug or therapeutic substance to which the Act applies.

It is important to note some conflicting roles in administration of various laws. According the Pharmacy Act, the Director of Drug Services is a member of the Pharmacy Council while the Registrar is the Registrar of Corporate Affairs and Intellectual Property. On the other hand, section 3 and 4 of the Drug Services Act, 1983 establishes the Barbados Drug Services with the responsibility of (among others) overseeing the procurement, storage and distribution of drugs and related items and that adequate stocks is available at reasonable price. The mission of Barbados Drug Services is to provide quality pharmaceuticals to all residents of Barbados at an affordable price and to serve the beneficiaries in a courteous and efficient manner. In practice, the Barbados Drug Service is responsible not only for medicines policy implementation and monitoring but also for regulatory functions such as licensing of manufacturing, wholesale and retail pharmacy business.

In terms of autonomy of the national regulatory authorities, the Pharmacy Council and the Barbados Drug Service are both departments under the Ministry of Health.

Table 1 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 1 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of:		
Manufacturers	Yes	Barbados Drug Service (BDS)
Importers	Yes	BDS
Wholesaler/Distributors	Yes	BDS
Retailers/Dispensing outlets	Yes	Pharmacy Council (utilizes BDS inspection reports)
Other	N/A	
Market Authorization	No	
Inspection of premises	Yes	Inspectors appointed under sect 32 of the Pharmacy Act

Key regulatory function/provision	Covered in legislation	Comments
Establishment of Quality Control Laboratory	Yes	Not in the country's legislation, but Caribbean Regional Drug Testing Laboratory Agreement establishes a regional quality control laboratory in force in 14 countries including Barbados.
Control of clinical trials	No	
Control of counterfeit medicines	No	
Control of imports and exports	Yes	
Adverse drug reaction monitoring	No	
Control of product promotion and advertisement	No	
Provision for medicines distribution schedules/categories	Yes	
Control of narcotics and psychotropic substances	Yes	
Scope of regulated products	Yes	Human and veterinary drugs and poisons
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	Different sanctions provided under different laws
Power to make regulations	Yes	The Pharmacy Council and the Minister are empowered to make regulations under different laws for more or less similar matters.
Regulations made under the Act	Yes	Therapeutic Substances Act Regulations of 1950 Various regulations under the Pharmacy and Drug Service Act

Missing provisions in the respective laws include control of market authorization, clinical trials, counterfeit medicines, product promotion and advertising, and safety monitoring of products.

Licensing of manufacturers, importers, wholesalers, distributors, retail pharmacies:
Generally, there are conflicting roles in executing regulatory functions. Sections 3 and 4 of the Therapeutic Substances Act require that the Chief Medical Officer is the Licensing Authority to issue licenses for manufacture, sale or supply of drugs and therapeutic substances specified in the schedule to the Act. However, the BDS established for a different purpose under the Drug Services Act is actually performing these functions. On the other hand, licensing of wholesalers and retailers of drugs and poisons is the responsibility of the Pharmacy Council.

Inspection: Inspectors are appointed under sect 32 of the Pharmacy Act.

Quality control is done using the Caribbean Regional Drug Testing Laboratory (CRDTL) which has been established under the CRDTL Agreement and is in force in 14 countries namely Barbados, Guyana, Jamaica, Trinidad and Tobago, Antigua and Barbuda, Belize, Bahamas, British Virgin Islands, Dominica, Grenada, Montserrat, St Christopher-Nevis-Anguilla, St Lucia and St Vincent.

Medicines distribution categories include the Second Schedule to the Pharmacy Act providing for drugs that are to be compounded, dispensed or sold by a pharmacist or under the supervision of a

pharmacist. In addition, section 3 of the Therapeutic Substances Act provides for a schedule of antibiotics and therapeutic substances to be controlled under the Act.

Administrative and legal sanctions: different laws provide for different sanctions depending on the gravity of the offence.

Power to make regulations; The Pharmacy Council may, with the approval of the Minister make regulations as provided under Section 34 of the Pharmacy Act. The Minister may make regulations in respect of the Drug Services Act (Section 7). Under Section 18 of the Therapeutic Substances Act the Minister is empowered to make regulations for prescribing standards of strength, quality and purity of drug or therapeutic substances, the testing, and the form and conditions of licenses.

Regulations made under the Act include the Health Services (Control of Drugs) Regulations, 1970

Conclusion and Recommendation: There is a clear fragmentation of medicines legislation which may affect efficiency and effectiveness of medicines regulation in Barbados. There is need to harmonize the laws regulating medicines in order to establish one comprehensive legislation which provides for regulation of all medicines and related products. In this regard, the legislation should include a clear administrative structure to oversee implementation of the law and give a mandate to the national medicines regulatory authority to execute all the key medicine regulatory functions as recommended by the World Health Organization. The type of products to be regulated should also be clearly stipulated.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section reflect responses from interviews conducted with personnel of the Barbados Drug Service – including the Director, the two Assistant Directors, a Drug Inspector, the Senior Accountant, the Senior Pharmacist/Chief Dispenser and 3 Supply Inventory Officers. The Managing Director of Carlisle Laboratories Limited and the President of the Caribbean Association of Pharmacists (CAP) were also interviewed. Interviews were based on the approved assessment instrument.

Organizational structure

In Barbados, medicines regulation responsibilities are divided between the Barbados Drug Service (BDS) and the Pharmacy Council. The BDS is supported in its functions by two committees – the Formulary Committee and the Tender Committee. The organizational structure for drug regulation is illustrated in Figure 1.

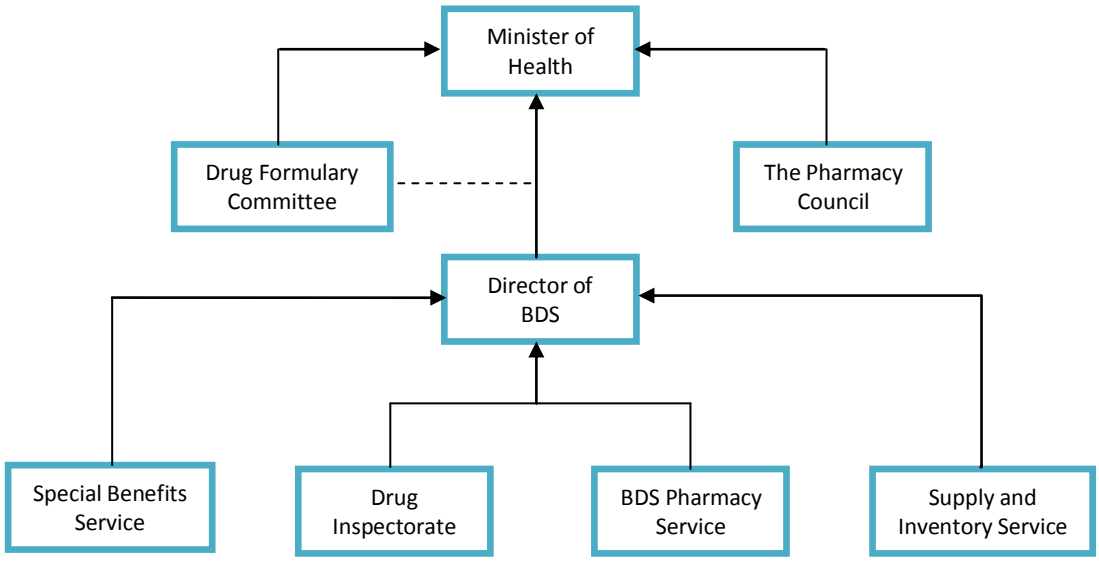
The BDS was established in 1980 under the Drug Service Act 1980-58 which, together with the Financial Administration and Audit (Drug Service) Rules 1980, governs its operations. Its areas of responsibility include:

- The Barbados National Drug Formulary (BNDF)
- The Supply and Inventory Service
- The Special Benefit Service (SBS)
- The Barbados Drug Service Pharmacy Service
- The Drug Inspectorate
- The Drug Information Centre (DIC); and
- PAHO/WHO Collaborating Centre in Drug Supply Management

The Drug Inspectorate functions include quality assurance, inspection of pharmacies, registration of manufacturers, and issuing of licenses to local pharmaceutical distributors for the importation of antibiotics, narcotic drugs, and psychotropic substances.

Under the Pharmacy Act 1986, the Pharmacy Council has responsibility for regulating the practice of pharmacy including the licensing of retail pharmacies, and the registration of pharmacists and authorized sellers of poisons.

Figure 1: Organizational Set-up of Medicines Regulation



Licensing

Licensing of Premises

The BDS issues licenses for pharmaceutical imports, manufacturers and wholesalers/distributors, while licensing of pharmacies, pharmacists and authorized sellers of poisons is done by the Pharmacy Council. An inspection report is one of the requirements for issuing a license to engage in a pharmaceutical business and for the renewal of licenses, this is done by the Drug Inspectorate unit of the BDS. Guidelines and criteria on pre-license requirements are published and are based on WHO documents. The requirements are defined in the laws and some result from specifications set by the BDS from time to time. Licenses are not issued for dispensing doctors.

Lists of licensed pharmaceutical establishments are not published.

The Pharmacy Act specifies that any establishment operating as a pharmaceutical establishment must be under the charge of a registered pharmacist.

Respondents advised that they were unaware of any unlicensed or illegal manufacturers or wholesalers of pharmaceutical products. It was felt to be possible that persons could be engaged in illegal importation of medicines or dispensing/selling of pharmaceutical products other than through a registered pharmacy. The extent of these illegal activities is not known.

There are no special legal provisions for licensing of internet pharmacies or internet retailers. It was reported that the Ministry of Trade is looking into this matter.

Import Permits

Import permits are issued by the BDS for the importation of antibiotics, narcotics and psychotropic drugs. All pharmaceuticals that do not fall in any of these three groups can be imported without an import permit and there is no monitoring or formal liaison between the BDS and the Customs Department. There is limited monitoring of packages coming through the Post Office and customs gives feedback to the BDS when there is suspicion of illegal activity.

Documentation relating to the import permit application process was not available. One of the requirements for the issue of an import permit is the submission of a Free Sale Certificate.

Inspection and Surveillance

There is neither a dedicated GMP inspectorate nor a dedicated distribution channel inspectorate. Inspection of the local manufacturer and the wholesalers/distributors is conducted by the 3 Drug Inspectors employed by the BDS. In addition, these inspectors also conduct inspections of retail pharmacy establishments to support licensing of these premises by the Pharmacy Council. All inspection activities are centralized and no fees are charged for the inspection services.

GMP Inspection

There are no written national GMP guidelines and there are no manuals or standard operating procedures (SOPs). GMP certification of the sole local pharmaceutical manufacturer is done on an annual basis for renewal of license and a GMP Certificate is issued. GMP certification is a prerequisite for the granting of export licenses. Enforcement measures were not needed to be taken over the past two years. Samples are not collected as part of the GMP inspection of the manufacturing plant. Training in GMP inspection has not yet taken place.

There have been no GMP inspections of manufacturing premises outside of Barbados.

Distribution Channel Inspection

There are written guidelines for Good Distribution Practices and there are inspection guidelines for inspectors. Planned 'preventive' inspections are not being done but efforts are made to inspect each of the 8 local pharmaceutical distributors at least once per year.

There were no violations recorded for the past 2 years. Inspectors do not collect samples as part of the inspection process.

There was no detection of counterfeit medicines. As there is no stringent monitoring of imports and inspections are conducted mainly for licensing purposes the chances of identifying counterfeit products are relatively low.

Product Assessment and Registration

There is no operational product assessment and registration system in Barbados. Pharmacists and Information Technology staff of the BDS have been trained in drug registration in accordance with the Electronic Common Technical document developed by International Conference on Harmonization (ICH) in preparation for the introduction of that system of drug registration in the near future. The implementation process has been delayed pending amendment to the legislation to allow BDS to collect fees for assessment and registration.

Measures taken by the BDS to ensure efficacy, safety and quality of pharmaceutical products marketed in the country include the pre-qualification of suppliers and random testing of samples. With regards to pre-qualification, suppliers must be WHO pre-qualified and submit an application to the BDS on a prescribed standard application form for inclusion on the list of approved suppliers of

drugs and related items under the provisions of the BDS program [Rule 41 of Financial (Drug Service) Rules, 1980]. The prescribed form captures both manufacturers (Part I) and local distributors (Part II). Manufacturers applying for registration are required to submit a certificate from the Regulatory Authority in the country in which the manufacturing plant is located and provide statements signed by an accredited Notary Public to substantiate that the manufacturer produces drugs for consumption in both the domestic and foreign markets. The applicant is also required to agree to the requirement to submit samples of products manufactured or represented as well as all relevant information of a product with respect to GMP to the Director, BDS on request. The applicant further agrees that any product supplied to the BDS shall have its labeling, package inserts and any other descriptive literature in the English language and comply with all the requirements of the Tender Documents for the Supply of Drugs and Related Items. In 2006/7, the BDS processed and approved 7 new applications made by manufacturers to be listed as approved suppliers of drugs and related items.

The BDS invited tenders for 2,239 pharmaceuticals and related items in 2006/7, which represented a 15.5% decrease when compared with the previous financial year. There was no available data on the total number of pharmaceutical products for human use being marketed in the country or the proportion of marketed pharmaceutical products in the country that are generic products.

The access to market information was limited given the available time for the country visit. Hence, the award of products to suppliers for 2008/9 as listed in the BNDF for the 29 different medicines included in the survey basket was used as a proxy and is summarized in Table 2.

Table 2 - Availability of basket medicines (formulary products)

Total number of drugs in basket	**29**
Number with 4 alternative products	1
Number with 3 alternative products	4
Number with 2 alternative products	7
Number with 1 product	5
Number where only the originator brand is on the formulary	3
Number with no listed supplier**	9
Number not on the formulary	2

** Persons were directed to contact the BDS to access supplies of ARVs

Two of the 29 products in the survey basket of medicines were not listed in the formulary – valganciclovir and didanosine 400mg (strength not listed).

Medicines quality control laboratory

The existing law does not provide for the establishment of a regulatory quality control laboratory. There is no local testing of pharmaceutical products. Samples collected by the BDS Drug Inspectorate are sent to either the Caribbean Regional Drug Testing Laboratory (CRDTL) in Jamaica or Eurofins, England for testing. The latter testing laboratory is used in a very limited way due to the high cost for testing. In 2006/7, 34 samples were sent to the CRDTL for testing.

In Cabinet Note 2008 entitled *The Restructuring of the Barbados Drug Service* the BDS emphasizes the absolute need for a drug registration system to complete its drug regulatory function. The BDS was, however, silent on the matter of an effective registration system requiring access to a reliable and affordable quality control laboratory, and the strategies it intends to implement to achieve this.

Financing of drug regulation

There is a specific budget allocation for drug regulation. Budgetary data for the past three years are outlined in Table 3.

Table 3: Budget for Drug Regulation (Barbados $)

Budget section	Year: 2006/7	Year: 2007/8	Year: 2008/9
Capital budget	58,935	14,000	20,000
Salaries	3,821,348	4,361,321	4,380,567
Supplies & Materials**	43,445,790	46,779,543	51,396,209
Miscellaneous	408,258	570,007	680,619
TOTAL	**47,734,331**	**51,724,871**	**56,477,395**

**Mainly drugs for public pharmacies and reimbursement to private pharmacies for the Special Benefits Service

The schedule of fees levied by the BDS for drug regulation services are outlined in Table 4. Fees are published. Total fees collected for each of the last three years are detailed in Table 5. The fees are not made available for the BDS' use in defraying operational expenses. The BDS reported that there is a problem with financial sustainability.

Table 4: Schedule of Fees

Type of service provided	Fee charged	Currency
Initial Registration of Premises	$500	Barbados $
Initial Certification of Premises	$100	Barbados $
Re-certification of Premises	$100 annually	Barbados $

Table 5: Fees Collected for Drug Regulation (Barbados $)

Year: 2006/7	Year: 2007/8	Year: 2008/9
124,343	163,664	189,994

In its 2006/7 Annual Report, the BDS reported that its expenditure stood at 13% of the total health budget (current and capital) for the 2005-06 fiscal year and at 12% in the 2006-07 fiscal year. It stated that this figure was too high for a developing country and that it would be implementing some technological and human resource strategies and tactics to achieve an acceptable level of expenditure, while still maintaining optimum patient care.

Human resources (including training)

The two main entities involved in drug regulation – the BDS and the Pharmacy Council - are currently staffed as documented in Table 6. The table includes only one technical staff for the Pharmacy Council -the Registrar – as all other Council members sit as a Board appointed by the Minister of Health. Being under the Ministry of Health, the BDS does not have the power to hire or fire personnel. This is the responsibility of the Ministry of the Civil Service.

Table 6: Staff complement of regulatory entities

Staff category	Barbados Drug Service	Pharmacy Council
Technical full time	5 (pharmacists)	1 (Registrar)
Technical part time	0	0
Administrative full time	3	0
Administrative part time	0	0

The BDS reported a shortage of both technical and administrative staff. The main reason given for the shortage is bureaucratic delays in approving a restructuring proposal submitted as part of Cabinet Note MP 2014 Vol. 3 dated April 2008. The staff shortage was reported to be resulting in activities either taking much longer to be completed, having to be rushed or being totally neglected. In addition, it was difficult to release staff for training.

The average net monthly salary of personnel in drug regulation was perceived to be much lower than counterparts in the private sector. However, the salary comparisons in Table 7 reveal this not to be the case in reality. There is reported to be a low turnover of staff at the BDS.

Table 7: Comparative Salaries – Public vs. Private Sector (Barbados $)

Categories	Average Net Monthly Salary
Public Sector Drug Regulatory Inspector	$3,627
Pharmacist in Private Retail Pharmacy	$2,114 – 3,554
Pharmacist in a Private Hospital Pharmacy	$2,114 – 3,554
Pharmacist in an import/wholesale distribution channel	$2,848
Head of production in private pharmaceutical plant	$4,004
Person releasing batches of finished products in a pharmaceutical plant	$2,425

Each staff member working in drug regulation has a job description but it was recognized that these would need to be reviewed in accordance with the restructuring proposal. In addition to being appointed based on defined levels of education and experience, staff are appointed based on years of service and seniority.

Staff development planning takes place at the central level, namely the Ministry of the Civil Service. The BDS has no training budget of its own; hence, it makes annual submissions for inclusion of its training needs in the Ministry of Health's training budget. Over the past three years, drug regulatory staff members have received training in Drug Regulatory Agency administration and management (2 every 2 years), product assessment and registration (7) and pharmacovigilance (7). Sources of financing for training were the government's budget and PAHO.

Infrastructure

The BDS has dedicated office space, computers, printers, internet and e-mail access, and adequate transport facilities. There is an outstanding matter of the relocation of the BDS to a more suitable location. As a result of the deterioration in the building where the BDS is currently housed, the trade union representing the BDS staff made written submission to the Permanent Secretary on June 21, 2007 advising that due to attendant safety and health risks unionized staff would be working until 12 noon each day until such time as the relocation to a safer location is completed. The relocation is still to be implemented. Carton boxes have been packed for months, based on promises that the

relocation is about to take place. This has resulted in a backlog of work and inefficiency in daily regulatory operations.

Discussion

The BDS and, by extension, the drug regulatory system in Barbados is operating under severe constraints, such as:

- no drug assessment and registration system together with inadequate import controls;
- lack of local drug quality control laboratory or speedy turnaround of testing by CRDTL;
- inadequate staffing, delay in approval of restructuring proposal;
- poor working environment;
- bureaucratic delays in critical decision making;
- system not financially sustainable;
- no training budget; and
- outdated legislation.

These constraints have contributed to reported weaknesses in the drug regulatory system as follows:

- no approved National Drug Policy or Implementation Plan;
- poor importation controls;
- slow implementation of drug registration and pharmacovigilance systems;
- fragmentation of licensing and inspection activities due to multitasking of staff;
- lack of GMP guidelines and manuals for GMP inspection;
- no planned, preventative distribution channel inspections;
- lack of written procedures and codes of conduct for expert committees;
- inadequate training of staff;
- inadequate quality assurance of imported and locally manufactured drugs;
- inadequate performance monitoring and evaluation;
- no regulation of herbal medicines or internet pharmacies;
- inspectorate lacks authority to exact compliance when violations are detected;
- inability of BDS to retain fees collected.

BDS strengths include the high level of commitment of its staff, the high level of experienced technical staff, a transparent and competitive procurement system, and an up-to-date National Drug Formulary that is generally accepted and utilized by field staff.

The fact that BDS is performing both, procurement and regulatory functions, is a matter of concern as conflict of interest might arise.

Based on the foregoing constraints and consequent weaknesses, it can be concluded that Barbados is at risk for exposure to counterfeit and unsafe drugs due specifically to the inadequacies identified in its importation controls, the lack of a medicines registration system, no pharmacovigilance system and poor quality assurance systems.

Recommendations

There is no doubt that there are a number of strengths to be found in Barbados' medicines regulatory system but there is also significant room for improvement to ensure that patients are receiving quality medicines. To address some of the identified constraints in the short to medium term we recommend the following:

For the Ministry of Health:

- Approval and implementation of the National Medicines Policy;
- Development of an Implementation Plan;
- Review and approve the BDS restructuring proposal;
- Finalize any outstanding issues relating to the relocation of the BDS;
- Enact the necessary legislation to allow BDS to collect registration fees;
- If it is decided that BDS continues providing regulatory services ensure that safeguards preventing conflict of interest arising from the BDS procurement function are implemented
- Provide the required budgetary funding and allow BDS to retain collected fees;
- Enact legislation for the regulation of internet pharmacies and herbal medicines.

For the Barbados Drug Service:

- Document, in writing, codes of conduct and written procedures for expert committees;
- Expand the issue of import permits to include all medicines for human use;
- Prepare written guidelines, manuals and SOPs for GMP inspection;
- Develop a system of planned, preventative inspections;
- Implement a minilab and have a system of sample testing to enhance quality assurance;
- Prepare a staff development plan in keeping with the restructuring proposal.

Belize: Country Report

Country Background[8]

Belize is located in Central America, sharing borders with Mexico to the north and with Guatemala to the south and west. The total surface area is 22,700 km². For 2008 the estimated population was 301,022. Approximately half of the population is living in urban areas.

The country's Gross National Product was USD 3,740/capita in 2006 (current value). The economy is based on agriculture, forestry, fishing and mining. Economic growth has been influenced by exports and tourism.

The Ministry of Health is responsible for policy and planning, public health, regulation and standard setting, international cooperation and monitoring and evaluation. The Ministry of Health also operates health services. Within the context of health sector reform responsibilities are being decentralized to the 4 health regions. A National Health Insurance Fund has been established under the Social Security Board, which will be purchasing basic health services of defined standards from private and public sectors. This was piloted in Belize district and subsequently extended to the Southern Health Region in 2005.

The Ministry of Health operates 8 hospitals (including the national referral hospital) and rural health centers that also provide outreach services (40 health centers and 60 health posts in 2006). Through the private sector health care was provided in 54 clinics and 5 small hospitals.

In 2006 the main causes of death were diabetes, hypertensive disease, cerebrovascular diseases, other forms of heart disease, and HIV/AIDS[9]. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 66.39 years 70.08 years	2008
Infant mortality rate (per 1000 life births)	23.65	2008
Maternal mortality ratio (per 100,000 live births)	140	2006

Public health care is government financed through the Ministry of Health budget and the Social Security Board (National Health Insurance). Co-payments are charged for selected services. In 2006 the total Ministry of Health budget translated to BZD 228.82/capita (USD 119/capita) and represented 8.7% of the government budget.

Pharmaceutical sector context

Belize does not have a National Medicines Policy to guide development of the pharmaceutical sector. There is a National Formulary and official treatment guidelines for priority health conditions. The National Formulary lists those medicines that are being provided in the public sector. Medicines

[8] Information in this section is sourced from 'Health in the Americas - Basic Indicators 2008' (PAHO 2008), 'Health in the Americas - Country Reports' (PAHO 2007), and the survey questionnaire

[9] Health Statistics of Belize 2002 to 2006 (The Epidemiology Unit Ministry of Health, 2007)

are listed by their generic names, and generic prescribing is mandatory in the public sector. There are no legal provisions addressing generic substitution.

Apart from anti-retrovirals, where one generic product each was available, the medicines in the survey basket were available in at least 2 different generic versions. Valganciclovir and Imatinib mesilate were not available at all.

There is a medical school (off-shore US university campus). At the University of Belize studies for pharmacy (associate degree) and various nursing degrees are offered.

The number of registered pharmacists was 60 in 2008. There were 250 physicians, and 36 dentists.

Industrial pharmaceutical manufacturing is not present in the country. Medicines are imported and distributed by approximately 30 importers. For the public sector Central Medical Stores is procuring pharmaceuticals. There are 75 private retail pharmacies, and in the public sector 15 pharmacies operate in the hospitals and health centers. Limited pharmacy services are provided by nurses in the remaining health centers and clinics.

In 2008 Ministry of Health pharmaceutical expenditure stood at BZD 10.2 Million (USD 5.3 Million or USD 17.6/capita). In 2006, medical supplies accounted for 12.6% of the Ministry of Health recurrent budget.

Legislative Provisions

Existing medicines legislation include

- The Chemists and Druggists Act, Chapter 311, 1 January 1940, Amendments in force as at 31st December 2000,
- The Antibiotics Act, Chapter 33, 1 May 1948, Amendments in force as at 31st December 2000,
- The Food and Drugs Act, Chapter 291, 9 May 1953, Amendments in force as at 31st December 2000,
- The Misuse of Drugs Act, Chapter 103, 12 November 1990, Amendments in force as at 31st December 2000, and Subsidiary Laws

Administration of the medicines laws in Belize is vested to a number of bodies. Authority to administer the Antibiotics Act is vested upon the **Antibiotics Control Committee** established under section 3 of the Antibiotics Act as revised in 2000. The function of the Antibiotics Control Committee is to control the manufacture, importation, storage, sale and use of antibiotics in Belize. **The Board of Examiners** chaired by the Director of Health Services is established under section 5 of the Chemists and Druggists Act of 1940 for the purpose of examining persons wanting to be registered as chemists and druggists and for regulation of sale of drugs and poisons as provided under section 22-41 of the Act.

In as far as **delegation of regulatory functions** is concerned, some regulatory functions such as inspection and taking food and drug samples for analysis are delegated to authorized officers as provided under the Food and Drugs Act. According to sections 32 and 33 of the Food and Drugs Act, 1953, the duty to enforce the Act is vested upon both the **Local Authority** and the **authorized officers** assigned by the Minister responsible for health and appointed by the Public Service Commission.

Table 2 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 2 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of:		
Manufacturers	Yes	Antibiotics Act
Importers	Yes	Antibiotics Act
Wholesalers/Distributors	Yes	Licensing provisions more explicit in Antibiotics Act than in Chemists and Druggist Act
Retailers/Dispensing outlets	Yes	Chemists and Druggists Act
Others	Yes	Section 41 of Chemists and Druggists Act, empowers Minister to issue authority to any person to sell drugs and poisons under prescribed conditions
Market Authorization	No	
Inspection of premises and manufacturing sites	Yes	
Establishment of Quality Control Laboratory	Yes	Caribbean Regional Drug Testing Laboratory Act establishes the regional quality control laboratory in Jamaica by 14 Caribbean countries
Control of clinical trials	No	
Control of counterfeit medicines	No	
Control of imports and exports	Yes	Antibiotics Act
Adverse drug reaction monitoring	No	
Control of product promotion and advertisement	No	
Provision for medicines distribution schedules/categories	Yes	
Control of narcotics and psychotropic substances	Yes	
Scope of regulated products	Yes	Food, drugs and poisons
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	Different sanctions provided under different laws
Power to make regulations	Yes	
Regulations made under the Act	Yes	e.g. for Misuse of Drugs Act

Generally, the laws are not comprehensive enough to provide for all the key regulatory functions. Provisions for licensing of manufacturers, importers, wholesalers/distributors are more explicit in the Antibiotics Act than the Chemists and Druggists Act. Missing provisions include control of market authorization, clinical trials, counterfeit medicines, product promotion and advertising and safety monitoring of products.

Licensing of manufacturers, importers, wholesalers, distributors, retail pharmacies: the authority to license manufacturers, importers and distributors of antibiotics is vested upon the Antibiotics Committee under the Antibiotics Act. For drugs and poisons, section 22 of the Chemists and Druggists Act empowers the Examiners Board chaired by the Director of Medical Service to regulate the sale, retail, dispensing or compounding of drugs, poisons or patent or proprietary medicines in a shop under the direct charge and supervision of a duly registered chemist and druggist.

Inspection: According to section 3 of the Food and Drugs act, 1953, the Minister responsible for Health may designate in writing any person who is a veterinary officer, meat inspector, medical officer or public health inspector as an authorized officer. In addition, a local authority may appoint suitably qualified persons to be authorized officers for purposes of exercising powers conferred under the Act.

Quality control of samples for analysis is done using the Caribbean Regional Drug Testing Laboratory which has been established under the Act and is in force in 14 countries namely Barbados, Guyana, Jamaica, Trinidad and Tobago, Antigua and Barbuda, Belize, Bahamas, British Virgin Islands, Dominica, Grenada, Montserrat, St Christopher-Nevis-Anguilla, St Lucia and St Vincent.

Medicines distribution categories include antibiotics and other therapeutic substances, drugs and poisons. The Chemists and Druggists Act provides for poisons list and exemptions under the first, sixth and seventh schedules. The Misuse of Drug Act provides for Part I (class A), Pat II (class B) and Part III (class C) drugs, which compares with schedule 1,2,3,4 of the UN Conventions.

Control of narcotic and psychotropic substances; is under the National Drug Abuse Control Council in the Prime Minister's Office. The Council is established under the Misuse of Drugs Act, 1990 as revised in 2000, to oversee the control of narcotic drugs and psychotropic substances, classification of controlled drugs, restrictions on production, importation and exportation, cultivation, sale and use of such drugs as required under International Conventions for controlled drugs.

Scope of products regulated includes drugs and poisons; However, the definition for drug and poison is not clearly stipulated in the Chemists and Druggists Act. A drug is defined as to include medicine, compound medicine and medicinal preparation while a poison means the articles named and described in the first schedule and so declared by the Minister. This makes it difficult to determine the scope of regulated drugs and whether or not it includes both human and veterinary medicines.

Administrative and legal sanctions include penalties under the Antibiotics Act, on summary conviction to a fine not exceeding BZD 500 or imprisonment for a term not exceeding six months, or both fine and imprisonment.

Power to make regulations is vested on the Minister of Health under the Antibiotics Act, upon recommendations of the Antibiotics Control Committee.

Available regulations include the Misuse of Drugs Act (Commencement) Order and Misuse of Drugs Regulations.

Conclusion and Recommendation: There is a clear fragmentation of medicines legislation which may affect efficiency and effectiveness of medicines regulation in Belize. There is need to harmonize the laws regulating medicines in order to have one comprehensive legislation which provides for regulation of all medicines and related products. Regulation of pharmacy profession and practice can be done by a separate organization such as a Pharmacy Council.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section are reflecting the responses provided on the self-administered assessment questionnaire.

Organizational structure

There is no National Medicines Regulatory authority. Medicines regulatory activities are coordinated at the Ministry of Health under the Drug Inspectorate Unit. This unit reports to the Director of Health Services.

Licensing

Licensing of Premises
Licensing of pharmacy premises has been done since 2007 by the Ministry of Health. Pharmacies can only legally operate if a registered pharmacist is present. Pharmaceutical importers, wholesalers, and internet pharmacies are not being licensed.

Import Permits
Import permits are issued by the Ministry of Health for products administered under the Misuse of Drugs Act, and import of antibiotics needs to be authorized by the Ministry of Health.

Inspection and Surveillance

Inspections of the distribution channel are conducted by the Drug Inspectorate Unit. Due to shortage of human resources and transport inspections are mainly done as reaction on complaints.

No examples were given for counterfeit medicines and respondents did not think that there was currently a problem with counterfeit or substandard medicines. Suitcase traders are suspected to import medicines into Belize, but the extent of the problem is unknown.

Product Assessment and Registration

This function is not foreseen in the legislative system.

For the public sector, the central medical stores tender system and visual inspection of goods before distribution are used as quality assurance measures. Controls for private sector pharmaceutical imports are restricted to antibiotics and controlled drugs.

Medicines quality control laboratory

Belize is one of the 14 countries that established and are funding the Caribbean Regional Drug Testing Laboratory in Jamaica. The laboratory is being used for testing of samples collected from the distribution chain and during public tender evaluation.

Financing of drug regulation

There is no specific budget allocated to medicines regulatory activities. The Drug Inspectorate Unit is financed under the Ministry of Health budget. Respondents noted that the available budget is not adequate and negatively affects regulatory activities.

Human resources (including training)

Medicines regulation is done through the Drug Inspectorate Unit by two technical staff members. Respondents noted that the shortage of technical and administrative staff results in a weak

regulatory unit with no knowledge of the pharmaceutical products entering the country (apart from antibiotics and controlled drugs).

Public sector salaries for pharmaceutical professional are comparable to those in the private sector.

None of the Ministry of Health officials in charge of medicines regulation did receive special training related to regulatory functions and activities during the last 3 years.

Infrastructure

The Drug Inspectorate Unit does have dedicated office space and related infrastructure. Access to transport required for inspection activities is, however, inadequate.

Discussion

Belize is one of the 10 CARICOM member states that do not have an operational registration system for medicines. The quality of medicines imported by the private sector is not adequately controlled, and the fact that pharmaceutical importers and wholesalers are not licensed can have additional negative impacts on safety, efficacy and quality of medicines on the market.

Inadequate legislation and shortage of financial and human resources available for medicines regulation are the main causes for problems identified by the respondent, i.e.

- indiscriminate sale of prescription drugs
- operation of pharmacies without a registered pharmacist
- significant increase in the number of pharmaceutical establishments without the required approval
- questionable quality of pharmaceuticals imported by the private sector

We were informed that a Draft Pharmacy Act is available that provides for registration of medicines. This was already mentioned in 2006 - the process of passing the Pharmacy Act appears to be slow.

Considering the small population it might not be viable to implement legislation that requires products assessment and registration for pharmaceutical products by a Belize regulatory authority. The country could benefit from a regional registration system and an adequately staffed, trained, and financed in-country pharmaceutical inspectorate.

Recommendations

The brief assessment done in the context of this study does not provide the level of information required for developing detailed recommendations. However, for addressing some of the identified constraints in the short to medium term the following could be considered:

For the Government / Ministry of Health

- Lobby for passing of the Pharmacy Act
- Recognizing the public health relevance put effective medicines regulation (ensuring efficacy, safety, and quality of medicines) high on the agenda
- Ensure adequate financial and human resources for the Drug Inspectorate Unit
- Support training of medicine regulators
- Develop a National Medicines Policy (can be based on the CARICOM Model Medicines Policy)

For the group drafting the Pharmacy Act:

Unfortunately we did not have the opportunity to read the Draft Pharmacy Act. We would like, however, to recommend that the Pharmacy Act will make provision for regional harmonization and collaboration with any regional medicines regulatory structure that might be established in the medium term.

Dominica: Country Report

Country Background[10]

Dominica is located between the islands of Guadeloupe to the north and Martinique to the south, covering an area of 790 km². The official population was 71,008 in 2006, 74% living in urban areas.

The country's Gross National Product was USD 7,879 USD/capita in 2006 (ppp value). Apart from government services the economy is based on tourism, construction, manufacturing, and agriculture.

The Ministry of Health is responsible for regulation, policy development and planning, and provision of primary and secondary health care. Primary health care is provided free of charge and delivered through 7 districts in 2 district hospitals, 7 health centers, and 44 health clinics. Secondary health care is provided in the Princess Margareth Hospital in Roseau, and a fee for service system applies.

In 2003, the main causes of death were malignant neoplasms, hypertensive illnesses, heart disease, diabetes mellitus, and cerebrovascular disease. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 75 years 78 years	2006
Infant mortality rate (per 1000 life births)	13.6	2006
Maternal mortality ratio (per 100,000 live births)	no death recorded	2006

Public health care is financed through the government budget and user fees at secondary care level.

Pharmaceutical sector context

Dominica has a draft National Medicines Policy dated 1999. The two main objectives are availability of safe, effective, and affordable quality essential medicines, and rational medicines use. The draft policy prescribes that medicines marketed in Dominica must be registered, and foresees the establishment of a drug inspectorate at the Ministry of Health. .

The OECS/PPS essential medicines list is used as a reference for the public sector. National treatment guidelines exist for some priority health conditions (e.g. hypertension, diabetes). The use of generic medicines is neither actively promoted nor is it regulated (i.e. no provisions for generic prescribing or substitution). In practice generic substitution is done in all sectors unless this is expressly prohibited by the prescriber.

There are 2 medical schools and a nursing school. A 2-year certificate pharmacy course had been taught until the requirements changed to BSc in the context of CARICOM. Since 1978, 428 medical

[10] Information in this section is sourced from 'Health in the Americas - Basic Indicators 2008' (PAHO 2008), 'Health in the Americas - Country Reports' (PAHO 2007), stakeholder interviews, and the Health Information Unit at the Princess Margareth Hospital.

doctors have been registered with the medical board, and 66 dentists and 11 nurse practitioners are registered with their respective boards. Pharmacists are not being registered, and their total number is not known.

Pharmaceutical manufacturing is not present in the country. The number of private sector medicines importers is unknown. For the public sector Central Medical Stores is procuring pharmaceuticals mainly from OECS/PPS. For additional procurement Central Medical Stores only uses known suppliers.

There are 12 private retail pharmacies. In the public sector pharmaceutical services are provided in 8 health center / hospital pharmacies operated by pharmacists. The total number of pharmacists employed in the public sector is 16.

Legislative Provisions

Existing medicines legislation includes the Medical Act of 1938 and the Dangerous Drugs Act of 1938. The Medical Act has some provisions related to pharmacy. A copy could not be made available.

A Pharmacist Profession Bill has been available since 2004. The Bill provides for the establishment of the Pharmacy Council charged with registration and licensing of pharmacists and pharmacies, and related activities.

Apart from the Dangerous Drugs Act, there are no legal provisions available that regulate the marketing and distribution & sale of medicines or the pharmacy profession. The only pharmaceutical regulatory activity performed by the Ministry of Health pharmacy division is submission of samples of suspect quality to the Caribbean Regional Drug Testing Laboratory in Jamaica (through OECS/PPS).

Conclusion and recommendations: There is a clear lack of medicines legislation which may affect quality, efficacy, and safety of medicines - particularly those circulating in the private sector. The government should make it a priority to pass the Pharmacist Professions Bill and to draft additional legislation as envisaged in the draft National Medicines Policy.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section are reflecting the outcome of interviews conducted with the Chief Pharmacist.

Organizational structure

The Ministry of Health has a pharmacy division, headed by the Chief Pharmacist. The Chief Pharmacist is physically stationed at Central Medical Stores in the Princess Margareth Hospital compound. There is no National Medicines Regulatory authority and no drug inspectorate.

Licensing

Licensing of Premises
Premises that deal with pharmaceuticals are only being licensed as businesses.

Import Permits
Import permits are issued for narcotics and controlled drugs only. These permits are issued by the Chief Medical Officer.

Inspection and Surveillance

There are no provisions for pharmaceutical inspections, and they are not being conducted.

No examples were given for counterfeit medicines and respondents did not think that this was currently a problem although there are no controls on medicines imports or distribution channels.

Product Assessment and Registration

This function is not foreseen in the legislative system.

For the public sector, OECS/PPS is expected to employ adequate measures that ensure quality of medicines procured through that system.

Medicines quality control laboratory

Dominica is one of the 14 countries that established and are funding the Caribbean Regional Drug Testing Laboratory in Jamaica. From time to time medicines from the public sector are sent to this laboratory for testing. There was one case where test results of samples of a private sector donation were negative (sub-standard).

Financing of drug regulation

The pharmacy division operates under the Ministry of Health budget. There are no special funds for financing of drug regulation.

Human resources (including training)

There is no public sector staff assigned to drug regulatory activities. Quality assurance activities are being conducted within the context of central medical stores operations.

Public sector salaries for pharmaceutical professional staff are similar to the private sector.

Ministry of Health pharmacy staff did not attend any specific training preparing related to regulatory functions.

Discussion

Dominica is one of the 10 CARICOM member states that do not have an operational registration system for medicines. As is the case for the other 6 CARICOM member states that are at the same time members of the Organization of Eastern Caribbean States (OECS) quality assurance for medicines provided through the public health sector has been largely delegated to the OECS/PPS that conducts pooled procurement of pharmaceuticals for OECS members.

The quality of medicines imported by the private sector is not controlled at all. Except for controlled medicines there are no formal schedules that establish which products are prescription-only, pharmacy- only or for general sale. Discussions with the retail sector revealed that some pharmacies create their own guidelines based on ethical and professional considerations and international practices.

Considering the small market size and the human and financial resources requirements it might not be viable for Dominica to develop and implement legislation that requires in-country assessment of product dossiers for issuing of marketing authorizations. The approach taken in the draft National

Medicines Policy is pragmatic: registration of medicines in Dominica would be obligatory, but would be based on the registration status in exporting countries and in other countries in the region.

Dominica could thus benefit from a regional assessment/registration system that would improve on the current quality assurance measures provided through OECS/PPS and also extend to the private pharmaceutical sector.

Recommendations

The brief assessment done in the context of this study does not provide the level of information required for developing detailed recommendations. However, for addressing some of the identified constraints in the short to medium term the following could be considered:

For the Government / Ministry of Health

- Update and adopt the draft National Medicines Policy of 1999
- Develop a policy implementation plan
- Ensure processing of the Pharmacist Professions Bill
- Draft a Medicines Bill that provides for marketing authorization, scheduling of medicines, and a drug inspectorate
- Support training of drug inspectors

For the Pharmaceutical Society

- develop/adopt common guidelines for pharmacy practice, including lists for prescription-only and pharmacy-only pharmaceutical products

Dominican Republic: Country Report

Country Background[11]

The Dominican Republic is located on the western part of the island Hispaniola, which it shares with Haiti. The land area covers 48,442 km² and the population was estimated at 9.9 million (2008). Sixty-nine % of the population lives in urban areas. The country is divided into 31 provinces and the National District.

The country's Gross National Product was USD 5,500/capita (PPP) in 2006. Income distribution is highly inequitable. The economy is based on services, industry, and agriculture. The main industries are tourism, sugar processing, mining, textiles, cement, and tobacco.

Public and private health services operate under direction of the Ministry of Health (Secretario de Salud Publica y Asistencia Social/SESPAS). Nine regional health services provide public primary, secondary and tertiary care as autonomous entities with legal status. The Ministry of Health implements priority health programs and preventive activities through de-concentrated health districts. In 2002, public sector health facilities consisted of 1,037 facilities, amongst them 6 specialist hospitals, 8 regional hospitals, 107 municipal hospitals, 22 provincial hospitals, 615 rural clinics, 90 health posts, 30 health centers, and 159 physicians' offices. The Social Security Institute operated another 210 primary, secondary, and tertiary level health facilities.

The main documented causes of death in 2002 were circulatory diseases, malignant neoplasms, communicable diseases (including AIDS and TB), external causes, and conditions originating in the perinatal period. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 69.5 75.7	2008
Infant mortality rate (per 1000 life births)	30.7	2007
Maternal mortality ratio (per 100,000 live births)	72.8	2007

Public sector health care is financed from the government budget and the social security system (government, employer and employee contributions). The social security system including the family health insurance is still to be fully implemented, and the objectives of universal coverage and access have not yet been attained. In 2002, national per capita spending on health was USD 191, with the Ministry of Health spending USD 40 and households USD 93. At the same time 74% of the population did not have any type of health insurance. A great proportion of the poor is thus still missing access to subsidized services and need to pay out-of-pocket. Medicines accounted for 54 - 60% of household spending on health care[12].

[11] If not indicated otherwise information in this section is based on 'Health in the Americas - Country reports' (PAHO 2007), 'Health in the Americas - Basic Indicators 2008' (PAHO 2008), Plan de Desarrollo Estratégico Institucional 2008 - 2012 (Dirección General de Drogas y Farmacias 2008), and stakeholder interviews.

[12] Plan Decenal de Salud 2006 - 2015 (SESPAS 2006)

Pharmaceutical sector context

The Dominican Republic has an officially approved National Medicines Policy (Politica Farmaceutica National) dated 2005. An implementation plan for the public sector is available, and a national workshop for development of the implementation plan for the private sectors is planned for this year. The National Medicines Policy includes a comprehensive situational analysis of the pharmaceutical sector. The 3 main objectives are:

- to ensure access to essential medicines to the population, focusing on those of interest for public health and the Dominican Social Security System
- to guarantee quality, safety and efficacy of medicines circulating in the country, and
- to promote and develop strategies to facilitate development of a culture of rational use of medicines.

It is noteworthy that the policy includes implementation of flexibilities allowed under TRIPS (as documented in the DOHA Declaration) amongst the strategies chosen to ensure access to essential medicines.

There are national treatment guidelines for the primary level (edition 2008), and an essential medicines list, classifying the medicines by level of care (edition 2006).

In 2009 there were 5 to 6 medical schools and 3 pharmacy schools. The number of pharmacists is approximately 2,000 (these figures refer to 'ever registered', i.e. do not present the number of practicing professionals).

There are 160 licensed (pharmaceutical) manufacturers, 9 of which belonging to foreign companies. There is no research based pharmaceutical industry, and local manufacturers procure generic medicines only.

Medicines are imported and distributed by 490 private (pharmaceutical) importers/distributors. In addition, 364 (pharmaceutical) distributing-only businesses are registered[13]. PROMESE/CAL procures and distributes essential generic medicines for the public sector. The organization has been established under the Presidency of the Republic by official decree in the year 2000. Under the direction of PROMESE/CAL 424 'Farmacias del Pueblo' operate, where generic essential medicines are sold at prices considerably lower than in the for-profit retail sector. PROMESE/CAL does not yet have the capacity to provide all medicines included in the essential medicines list.

In the private for profit retail sector 2,812 pharmacies are registered with the Ministry of Health Direccion General de Drogas y Farmacia (DGDF). In addition, there are 54 public hospital pharmacies. According to the law all pharmacies need to be under full time supervision of a pharmacist. Medicines are also being dispensed/sold in over 1,000 lower level health facilities operating under the Ministry of Health.

Legislative Provisions

Existing medicines legislation include

- Ley General de Salud (Ley 42-01) [General Health Act] of 08.03.2001, amended by Act 22-06 of 15.02.2006

[13] N.B: Pharmaceutical establishments to be registered include manufacturers of medicines, cosmetics, products for personal & domestic hygiene, and medical chirurgic material; drug stores, distributors and pharmacies. Figures for pharmaceutical establishments in the strict sense were not available.

- Reglamento 246-06, sobre Medicamentos (Medicines Regulations), of 09.06.2006, amended by Decree 625-06 of 22.12.2006
- Ley 50-88 sobre drogas y sustancias controladas (Drugs and Controlled Substances Act) of 30.05.1988
- Ley 87-01 de la Seguridad Social (Social Security Act) of 09.05.2001

Administration of the medicines laws in the Dominican Republic is vested to a number of bodies. The Ministry of Health in coordination with the National Health Council is the authority to administer the General Health Act. Articles 103 to 107 provide for the regulation of pharmaceutical establishments, and articles 114 to 119 establish the competencies of the Ministry of Health related to medicines, as well as the general requirements for the issuing of a marketing authorization.

The Medicines Regulations established under the General Health Act assign the DGDF within the Ministry of Health as responsible for implementation of the regulations.

Table 2 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 2 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of:		
Manufacturers	Yes	
Importers	Yes	
Wholesalers/Distributors	Yes	
Retailers/Dispensing outlets	Yes	
Others	No	
Market Authorization	Yes	
Inspection of premises and manufacturing sites	Yes	
Establishment of Quality Control Laboratory	Yes	National Public Health Laboratory Dr Defillo - Department for Medicines Analysis
Control of clinical trials	No	Is addressed indirectly under offences / no procedures for authorization included
Control of counterfeit medicines	Yes	Manufacturing, import, export, distribution, storage and/or marketing of counterfeit medicines are criminal offences by law
Control of imports and exports	Yes	import control as per Medicines Regulations
Adverse drug reaction monitoring	Yes	
Control of product promotion and advertisement	Yes	Classifications provided for promotion to general public, promotion to professionals, and no promotion allowed
Provision for medicines distribution schedules/categories	Yes	Free sale, prescription only, special prescription for narcotics & controlled drugs
Control of narcotics and psychotropic substances	Yes	

Key regulatory function/provision	Covered in legislation	Comments
Scope of regulated products	Yes	Medicines for human use, cosmetics, personal hygiene products and domestic hygiene products with health risk as well as all materials used for manufacture (Medicines Regulations)
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	
Power to make regulations	Yes	
Regulations made under the Act	Yes	Medicines Regulations

Licensing of manufacturers, importers, wholesalers, distributors, retail pharmacies: the authority to license manufacturers, importers and distributors of pharmaceutical products is vested upon the DGDF. Operation of manufacturing premises, distributors and pharmacies require full-time technical supervision by a licensed pharmacist. For public sector hospitals that do not have their own pharmacy, medicines management can be supervised by the pharmacist of the closest public health facility.

Inspection: Articles 150 and 151 of the General Health Act provide for inspections and inspectors, including defining the power of inspectors. The Medicines Regulations prescribe that the DGDF assigns adequately qualified staff as pharmaceutical inspectors, who are provided with official accreditation. Conducting of inspections and the power of inspectors is further addressed in Part Five of the Medicines Regulations.

Quality control of samples for analysis is done by the National Laboratory for Public Health Dr. Defillo. The Medicines Regulations provide for the option to use other accredited quality control laboratories.

Medicines distribution categories include free sale, ordinary prescription, and special prescription (under the Drugs and Controlled Substances Act). For imported products the 'free sale' category will only be approved if the specific product is also authorized to be marketed without prescription in the country of origin.

Control of narcotic and psychotropic substances is regulated under the Drugs and Controlled Substances Act, which provides for 5 different Schedules. The National Directorate for the Control of Drugs is charged with enforcement of the Act. Within this context the Ministry of Health is responsible for issuing licenses for importation and marketing of controlled drugs.

Scope of products regulated includes pharmaceutical products that are defined as follows: any simple or combined substance, either natural or synthetic or a mixture of them, dispensed to human beings with the purpose of prevention, diagnosis, cure, treatment and minimization of sicknesses or symptoms associated to them.

Administrative and legal sanctions are provided for in the General Health Act and the Medicines Regulations. These range from temporary suspension of licenses to operate a pharmaceutical business to several years of imprisonment for defined criminal offences.

Power to make regulations under the General Health Act is vested to the Ministry of Health in cooperation with the National Health Council.

Available regulations include the Medicines Regulations (Decree 246-06) and its amendments.

Conclusion and Recommendation: Generally, the laws and regulations are comprehensive and up-to-date. Control of clinical trials could be addressed more specifically. The definitions for medicines in the General Health Act and in the Medicines Regulations differ slightly. In addition, it appears that the terms 'medicine' and 'pharmaceutical product' is used interchangeably in the Medicines Regulations, while their definitions differ. For clarity these definitions could be revised.

An independent body for regulation of the pharmacy profession does not exist. In 2008, a Pharmacy Association Bill was drafted to address this shortcoming, but follow up is slow.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

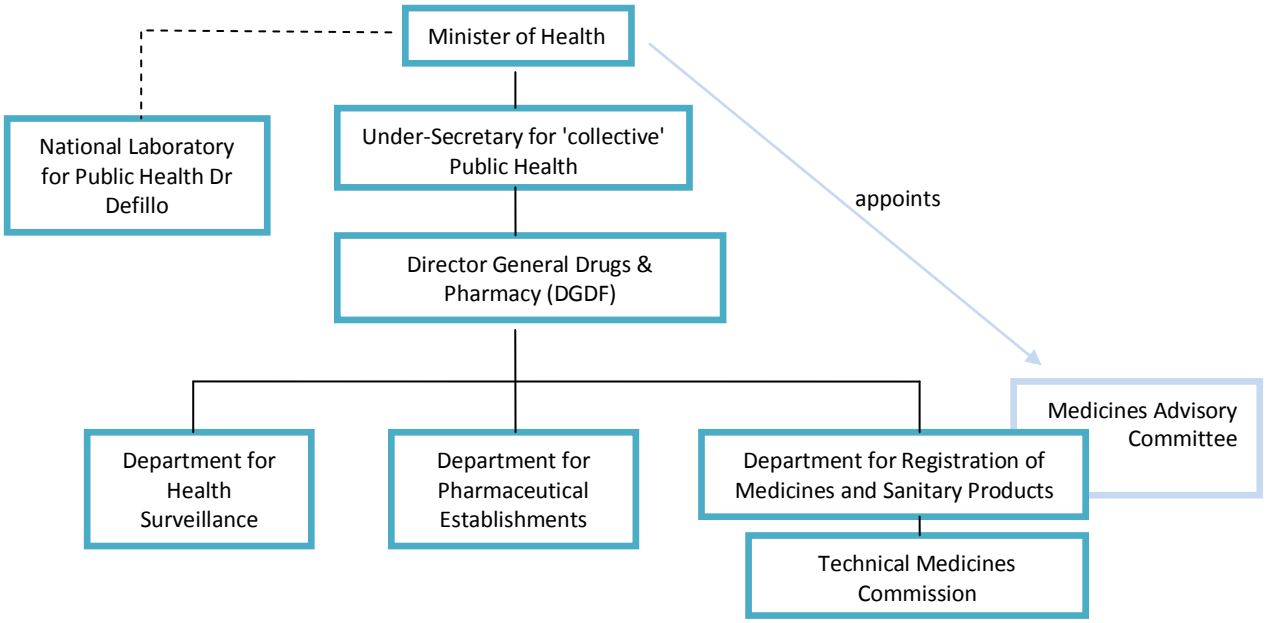
If not indicated otherwise, the findings reported in this section are reflecting the outcome of interviews conducted with the stakeholders of the DGDF of the Ministry of Health. Interviews were based on the approved assessment instrument.

Organizational structure

The DGDF in the Ministry of Health is functioning as regulatory agency. Three departments are charged with product registration, registration of pharmaceutical establishments, and surveillance respectively. The Medicines Regulations provide for the establishment of various external advisory committees. These include the Medicines Advisory Committee, Committee for GMP, Pharmaco-vigilance Committee, Essential Medicines Committee, and the Pharmacy Board.

Within the DGDF the Technical Medicines Committee is charged with assessment of applications for registration of known products. Figure 1 provides a summary diagram of the organizational set-up of the medicines regulatory agency within the Ministry of Health.

Figure 1: Organizational Set-up of Medicines Regulation



The 3 departments are headed by directors and are further organized in units.

Licensing

Licensing of Premises

Within the DGDF the department for pharmaceutical establishments is responsible for registration and authorization of pharmaceutical establishments. Conditions are established in the Medicines Regulations and partially available on the Ministry of Health webpage (www.sespas.gov.do). The system is deconcentrated to the provincial Ministry of Health directorates. These directorates are supervised monthly.

Inspections are conducted before licenses are issued, and for renewal of licenses. The Pharmacy Board, an external advisory committee[14], advises on issues related to authorization of pharmacies. Farmacias del Pueblo operated under PROMESE/CAL are authorized automatically. Approximately 70% of these pharmacies operate under the direction of a pharmacist.

During the period September 2007 to September 2008, 301 new licenses were issued (opening of pharmacies), and 321 were renewed. There were no suspensions or cancellations of existing licenses. Table 3 provides examples for licensing fees charged. These moneys are not retained by DGDF or the Ministry of Health.

Table 3 - Licensing Fees

Type of license issued	Fee in Dominican Pesos	Fee in USD
Opening of pharmacy	6,000	168
Renewal of pharmacy license	2,000	56
Moving of pharmacy	2,000	56
Opening of manufacturing business	7,000	197
Renewal of manufacturing license	6,000	168

An undated list of licensed pharmaceutical establishments is available at the Ministry of Health website.

Internet pharmacies are not covered by the current regulations.

Import Permits

Import permits are required for the import of pharmaceutical products. These are issued subject to presentation of

- the written acknowledgement by DGDF that the importing agency is registered as a pharmaceutical establishment, and that the product to be imported is included in the medicines register ("Reconocimiento Sanitario para los Fines Aduanales"), and
- a GMP certificate for the manufacturing plant and a Certificate of Free Sale provided by the importer

As per Medicines Regulations the DGDF also authorizes imports of unregistered medicines for use for a specific patient, for investigational use, for donations, and in cases of emergencies.

[14] Member comprise Association of Pharmacy Owners, Pharmacy Union, MOH Juristic Dept., DGDF, and the Dominican Association of Pharmacists

For the import of drugs administered under the Drugs and Controlled Substances Act special provisions apply.

Inspection and Surveillance

Inspection and surveillance is done by DGDF through the department for health surveillance and the department for pharmaceutical establishments. Standard Operating Procedures for these departments are under development. In addition, the Ministry of Health conducts surveillance activities under the Directorate 'Authorization and Accreditation' (Habilitacion y Accreditacion).

Under the DGDF department for health surveillance the unit for good pharmaceutical practices is in charge of planned, follow-up, and GMP inspections. In addition, inspections reacting to complaints are done. In practice, planned routine/preventive inspections are not yet carried out.

Related to **GMP inspections,** GMP guidelines for the Dominican Republic are available, and GMP certificates are issued for premises (not products). Export of medicines is done on a very low scale (only 2 or 3 manufacturers). Either GMP certificates or Free Sale certificates are issued for export purposes. For issuing of GMP certificates a fee of DOP 500 (USD 14) is being charged.

Respondents noted that there might be manufacturers operating without being GMP certified. This is partially due to the fact that implementation of the Medicines Regulations has only started recently with the appointment of the new Director General. The different technological level at which local manufacturers are operating has been mentioned as a problem (DGDF Strategic Plan 2008-2012/DGDF 2008).

Standard for **inspections of the distribution channel** (Good Distribution Practices, Good Pharmacy Practices) have still to be developed. Distribution channel inspectors do have guidelines on how to conduct inspections. Inspections outside Santo Domingo are deconcentrated to the Ministry of Health provincial directorates. Related to issuing of licenses for pharmaceutical establishments 663 inspections were carried out during the previous year.

During inspections the following has been detected: no license or expired licenses of pharmaceutical establishments; pharmacist not present; illegally imported, unregistered, expired and counterfeit products; products not authorized for sale in a particular establishment.

At the time of our visit a big case of counterfeit anti-tetanus gamma globulin - supposedly manufactured by Ranbaxy and one (inexistent) Cuban company - emerged, in which various pharmaceutical distributors and pharmacies were involved. In recent months, considerable quantities of illegally sold medicines were confiscated and several businesses, including distributors, pharmacies, and a manufacturing establishment, were closed (see news section at www.sespas.gov.do).

In order to address these problems a 'national inter-institutional plan against the illicit medicines market' is being developed.

Product Assessment and Registration

All medicines marketed in the Dominican Republic need to be either registered or authorized by the DGDF. Authorization applies to medicines imported for specific patients or investigational use, may apply to donations, and in emergency situations.

All classes of medicines for human use are being assessed for registration by DGDF.

As per the computerized database SIAMED, 10,635 products received marketing licenses during the period 2003 to 2008: 10,125 pharmaceutical specialties, 429 natural products (herbal medicines), and 81 medico-chirurgical products. At the time of our visit 10,410 pharmaceutical specialties were registered according to information provided by the SIAMED system[15].

The Technical Medicines Commission within the department for registration of medicines & sanitary products is responsible for assessing applications for 'known' (generic) products. A flow chart for the assessment process and Standard Operating Procedures are available. The Commission presents its recommendations to the Director of the department, who is the authority to decide on whether or not registration is granted.

New pharmaceutical products are being assessed by the external Medicines Advisory Committee. New pharmaceutical product is defined as a product that does not contain a chemical entity which has previously been approved in the territory of the Dominican Republic. Chemical entity does not mean an inactive ingredient which might be contained in the new pharmaceutical product (Decreto 625-06).

The Medicines Advisory Committee is appointed by the Minister of Health. Article 7 of the Medicines Regulations specifies the personal and economic interests that are incompatible with a membership in advisory committees.

A registration certificate is being issued, and the corresponding registration number has to be printed on the product package (can be in addition to registration numbers of other countries).

Conditions of sale are 'Free Sale', 'Prescription', and 'Controlled'. Factors determining whether a medicine can be classified as 'Free Sale' are defined in Article 212 of the Medicines Regulations.

Applications for registration have to be submitted on standard application forms (available on the Ministry of Health website). Applications have to be accompanied by samples of the finished product.

The following technical information/documentation is currently required to accompany the application for 'known' products:

- GMP Certificate (plus Free Sale Certificate for imported products)
- INN and certificate of trade mark (if applicable)
- Complete qualitative and quantitative composition
- Pharmacological classification (ATC)
- Dosage form, method of administration, and package
- Indication, contraindications, warnings, and precautions
- For each active ingredient: INN, chemical formula, molecular weight and information regarding the manufacturer(s)
- Chemical, pharmaceutical and biological information
    - Complete composition including active ingredients, excipients, coating material etc.
    - Monograph
    - Method of manufacturing
    - Quality control methods (including starting materials, in-process, and final product)
    - Packaging material specifications
    - Shelf-life and storage conditions (including stability studies)

[15] The SIAMED data base is not yet up-to-date. There is still a backlog of approximately 1 year for updating relevant information.

- Original quality control certificate of finished product
- Documentation on how to dispose of unused product
- Conditions for use and dispensing

For new products the following additional information is required:

- Clinical studies and trials (published and non-published) including study protocols (including studies for efficacy an safety)
- Clinical pharmacology establishing pharmacodynamic and pharmacokinetic properties (active ingredient and metabolites), interactions, and clinical efficacy and safety
- Summary of mode of action
- Toxicity data, studies establishing carcinogen and mutagen potential, and effects on the reproductive system

Specific additional requirements are documented for biological products.

Except for biological products samples are analyzed at the National Public Health Laboratory Dr Defillo. Registration will only be granted if a positive test result is obtained. Registration is subject to renovation every 5 years.

Regarding **linkages with intellectual property laws**, data exclusivity and early working provisions are regulated in Article 32 of the Act 424-06 - Implementation of the Dominican Republic-Central America Free Trade Agreement (DR-CAFTA). A data exclusivity period of 5 years for non-disclosed information is provided for pharmaceutical products (subject to solicitation by the applicant), and early working is allowed. In that case the regulatory authority is obliged not to issue the final marketing authorization before patent expiry of the originator product. The patent holder has to inform the regulatory authority about any existing patent when submitting the application for a new drug. In turn the regulatory authority is required to inform the patent holder about any application for marketing authorization by a third party during the validity period or the patent.

In practice, notification of a known patent holder is the only provision currently being implemented by the Ministry of Health. Any further action is seen as the responsibility of the patent holder. The regulatory authority continues to process the application and grants marketing approval if warranted.

Fees are charged for registration related services. Examples are provided in Table 4.

Table 4 - Registration Fees

Type of license	Fee in Dominican Pesos	Fee in USD
New Product	7,000	197
Natural Product	3,000	168
Variations	3,000	168
Renewal (every 5 years)	7,000	197

There is no independent appellate body. Applicants can submit an official complaint to the Director General DGDF. If the conflict is not being resolved further complaints will proceed using the established administrative procedures.

The Medicines Regulations establish the **time limit** for deciding on applications for registration at 90 days. In practice, this time limit is often exceeded. Respondents estimate that currently it takes 4 to 5 months from submission of the application to notification of the decision.

Due to the different documentary requirements and assessment processes for known (generic) and new products, the time to process applications for known products is usually shorter. Applications for registration of anti-retrovirals, anti-tuberculosis, and anti-cancer drugs as well as vaccines are given priority.

Table 5 provides an overview of activities related to registration of medicines during 2008.

Table 5 - Processing of Applications during 2008 (Source: SIAMED)

Type of product	No of applications received	No of applications approved	No of applications rejected	No of applications with decisions pending
Pharmaceutical Product	2,166	499	32	1,666
Natural Product	156	22	0	134
Medico-chirurgical product	32	20	0	12
TOTAL	**2,354**	**541**	**32**	**1,812**

One reason given for the high number of pending applications was the fact that the department is working in parallel on reviewing 'old' applications for the purpose of updating the SIAMED database. Another contributing factor noted by respondents was delays in receiving test results from the quality control laboratory.

Availability of registered products for the basket medicines was checked using the database available at the Ministry of Health website. Table 6 summarizes the results.

Table 6 - Availability of basket medicines (registered products)

Total number of drugs in basket	**29**
Number with 3 alternative products registered	16
Number with 2 alternative products registered	0
Number with 1 product registered	6
Number where only the originator brand is registered	0
Number with no registered product	6

Products where only one alternative was registered included 5 of the 10 HIV/AIDS medications. In all cases multi-source (generic) versions were registered. Products without registered alternative included 5 of the anti-retrovirals and Valganciclovir. Some of these anti-retrovirals are included in the 2006 essential medicines list. They might be procured with special authorization of the DGDF.

Medicines quality control laboratory

The department for medicines analysis of the National Public Health Laboratory Dr Defillo is in charge of analyzing samples for the purposes of registration, and samples taken from the distribution chain.

Due to time constraints we could not visit the laboratory, and no assessment of capacity and procedures was done.

Respondents at DGDF indicated that the laboratory is working under human and structural constraints. Not all means required for testing are available, and not all required tests can be performed.

Financing of drug regulation

The DGDF as well as the national laboratory operate under and are financed through the Ministry of Health. Fees collected can not be retained.

Respondents noted that available budgets are not sufficient to effectively carry out regulatory functions.

Human resources (including training)

The complete and exact staffing situation at DGDF could not be established. Table 7 summarizes the number of technical staff that was communicated by respondents.

Table 7: Technical staff of DGDF departments

Dept. for pharmaceutical establishments	Dept. for health surveillance	Dept for registration & evaluation of medicines
6	8	app. 30

In addition, there are 9 technical staff (mainly for inspections) at provincial health directorate level, who are 'shared' amongst the central level departments. Administrative staff is under the office of the Director General.

Shortage of staff was noted to affect performance of all three departments, with a particularly negative effect on inspection activities.

One respondent noted that a staff establishment that would respond to the responsibilities given to the DGDF under the Medicines Regulations has not yet been defined. Efforts were being made to recruit an additional number of 50 pharmacists to support DGDF at national and decentralized levels.

Being under the Ministry of Health the regulatory authority does not have power to hire or fire personnel. Salaries for technical pharmaceutical staff in the Ministry of Health were said to be acceptable, although lower than those paid in the private sector. Salaries were also said not to reflect the different responsibilities of the existing posts.

The DGDF does not have a dedicated training budget and no formal training plan. Within the Ministry of Health training (including related budgets) is under the responsibility of the Directorate General of Planning. While training courses are attended, these are either not specific for drug regulation or not at the appropriate level.

Respondents of all three DGDF departments noted that technical staff does not yet have the specific technical expertise required to optimally perform in their respective posts.

Infrastructure

Office space available for the DGDF appeared to be limited, but well organized and equipped. However, the official e-mail addresses provided as links on the Ministry of Health DGDF website were not working when tried by us before the visit.

Respondents noted that there was a lack of transport with a negative impact especially on inspection activity.

Discussion

The Dominican Republic belongs to the 6 study countries that have an operational medicines registration system, and it is the country with the most up-to-date legal medicines regulatory framework. On the other hand, the Dominican Republic is the country most affected by availability of substandard and counterfeit medicines.

Constraints that impact performance of the medicines regulatory system include

- Shortage of human resources, especially inspectors
- Inadequate technical capacity of some technical staff
- Shortage of financial resources
- Inadequate capacity of the quality control laboratory

These constraints contribute to some of the reported problems, e.g. the assumed high number of pharmaceutical establishments operating without license; licensed establishments not complying with legal requirements (absence of pharmacist, sale of prescription medicines without prescriptions, etc.); or availability of unregistered, substandard, and counterfeit medicines on the market.

The DGDF and partners are commended for development of the Strategic Development Plan for the Directorate, where the above mentioned constraints are being addressed. Implementation of the plan foresees amongst others capacity building of staff, development of guidelines and standard operating procedures, provision of adequate number of staff and operational needs (e.g. transport), and formalization of inter-institutional collaboration. Some of the activities are planned to be done by technical advisors.

Two issues appeared not yet to be resolved: Firstly, for registration of 'known medicines' submission bio-equivalence studies is not required. While this is supporting the local industry that is said to be lacking the capacity for conducting bio-equivalence studies, this might negatively impact inter-changeability and acceptability of generic medicines. Secondly, the provisions for patent protection and data exclusivity established in the DR-CAFTA Act 424-06 are not yet being fully implemented.

Recommendations

It is beyond the scope of this assessment to provide a comprehensive set of recommendations for the improvement of the medicines regulatory system in the Dominican Republic. In addition, much preparatory work has already been done in the country.

We therefore limit our recommendations to a few key issues for the short to medium term:

For the Government / Ministry of Health

- Ensure as far as possible that adequate budgets for the implementation of the DGDF strategic plan will be made available;

- Take up the Pharmacist Association Bill to ensure adequate regulation of the pharmacy profession

For the DGDF:

- In collaboration with the local manufacturing sector develop strategies for phased implementation of bio-equivalence studies as requirement for registration of known medicines (risk based approach);
- Consider more extensive collaboration with other medicines regulatory agencies in the region, especially regarding assessment of applications for registration of new products, and combating the illicit medicines markets;

For cooperating partners:

- Consider provision of financial and technical support to implementation of the DGDF strategic plan a priority.

Grenada: Country Report

Country Background[16]

Grenada consists of the islands Grenada, Carriacou, and Petit Martinique situated about 100miles north of Venezuela and 90 miles southwest of Barbados. The total surface area is 344 km² and the population was approximately 106,000 in 2008.

The country's Gross National Product was USD 8,770/capita (PPP) in 2006. Important economic sectors are construction, mining and quarrying, and tourism.

The Ministry of Health is responsible for the provision of public sector health services, and for regulation, policy and planning in the context of the National Medium Term Economic Strategic Plan. The public health sector is organized in 7 health districts, 6 of which have a health center providing primary preventive and curative care. Thirty health stations distributed across the country provide first level services, and secondary care in the public sector is being provided in 4 hospitals (1 psychiatric). Hospitals operate under a grant provided by the Ministry of Health.

In 2002, the main causes of death were diseases of the circulatory system, malignant neoplasms, diseases of the respiratory system, and parasitic diseases. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 66 years 70 years	2006
Infant mortality rate (per 1000 life births)	18	2007
Maternal mortality ratio (per 100,000 live births)	not available	

Public health care is financed through tax contributions and support by cooperating partners. Services are provided free to the patients. Hospitals provide special services to private patients that are charged for at nominal fees.

Pharmaceutical sector context

Grenada does not have a National Medicines Policy. The OECS/PPS essential medicines list is used as a reference for the public sector. This list is supplemented with additional medicines that are being used. There are no national treatment guidelines. Generic prescribing is mandatory in the public sector, and the law provides for generic substitution.

There is 1 medical school and 1 pharmacy school, the TA Marryshow Community College, where an Associate of Science degree is being obtained. There are 109 physicians, and 75 pharmacists (associate degree). Pharmacy technician training is not provided, but pharmacy attendants are being trained on the job.

[16] Information in this section is sourced from 'Health in the Americas - Basic Indicators 2008' (PAHO 2008), 'Health in the Americas - Country Reports' (PAHO 2007), and the assessment instrument.

Pharmaceutical manufacturing is not present in the country. Medicines are imported, distributed and sold by 16 importers, 8 wholesalers, and 40 retail pharmacies. For the public sector the Ministry of Health Procurement Unit is procuring pharmaceuticals, mainly from OECS/PPS (90%). In the public sector there are 4 pharmacies operating in the hospitals, and district health centers/clinics provide additional pharmaceutical services.

Legislative Provisions

Existing medicines legislation include; Pharmacy Act (Cap 241) of 1987, Medical Products (Regulations) Act, 1995, Drug Abuse (Prevention and Control) Act, 1992, Food and Drugs Law, 1986 and Antibiotics Act. Unfortunately neither the principal Pharmacy Act nor the Antibiotics Act was available on time for assessment. The information provided in this section is therefore based on the Pharmacy (Amendment) Act, 1992; the Medical Products (Regulations) Act, 1995; Drug Abuse (Prevention and Control) Act, 1992 and the Food and Drugs Law, 1986.

Administration of medicine legislation is done by the Pharmacy Council headed by the Chief Pharmacist who serves as a Registrar to the Council.

Medicine regulatory functions are delegated to Authorized Officers appointed by the Public Service Commission who are empowered to assist the Registrar to perform duties and to exercise powers under the Pharmacy and Medical Products Acts.

Table 2 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 2 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of:		
Manufacturers	Yes	
Importers	Yes	
Wholesalers/Distributors	Yes	
Retailers/dispensing outlets	Yes	
Other	N/A	
Market Authorization	Yes	
Inspection of premises and manufacturing sites	Yes	
Establishment of Quality Control Laboratory	Yes	
Control of clinical trials	No	
Control of counterfeit medicines	Yes	indirectly in Medical Products Act, Article 17 e)
Control of imports and exports	Yes	
Adverse drug reaction monitoring	No	
Control of product promotion and advertisement	No	
Provision for medicines distribution schedules/categories	Yes	
Control of narcotics and psychotropic substances	Yes	Drug Abuse (Prevention and Control) Act, 1992
Scope of regulated products	Yes	Human and veterinary medicines and poisons

Key regulatory function/provision	Covered in legislation	Comments
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	Provided in different laws depending on gravity of offence
Power to make regulations	Yes	The Minister under the Pharmacy and the Medical Product Acts
Regulations made under the Act	Yes	Medical Products (Regulations) Act, 1995; Pharmacy (Fees) Regulations, 1982

Generally, the Pharmacy Act provides requirements for manufacturers, importers, wholesalers/distributors and retailers to be licensed. In addition, the Medical Products (Regulations) Act, 1995 provides requirement for licensing of medicinal products. Missing provisions include control of clinical trials, product promotion and advertising and safety monitoring of products. From the original Acts available to us it is unclear whether the Registrar under the Medical Products (Regulations) Act is reporting to the Pharmacy Council.

Licensing of manufacturers, importers, wholesalers, distributors, retail pharmacies:
Grenada Pharmacy Council is vested with the responsibility to license manufacturers, importing agencies, wholesalers, distributors, hospital dispensaries, pharmacies and retail outlets. It also responsible for import and export control. The Registrar is responsible for the issuing of product licenses for medicinal products, which is a legal requirement for a particular medicine to circulate in the market.

Quality control can be done using the Caribbean Regional Drug Testing Laboratory which has been established under the Agreement establishing the Caribbean Regional Drug Testing Laboratory Act and is in force in 14 countries namely Barbados, Guyana, Jamaica, Trinidad and Tobago, Antigua and Barbuda, Belize, Bahamas, British Virgin Islands, Dominica, Grenada, Montserrat, St Christopher-Nevis-Anguilla, St Lucia and St Vincent.

Medicines distribution schedule/categories; It was not possible to establish the distribution schedule for medicines the principle Pharmacy Act was not made available.

Control of narcotics and psychotropic substances is done under the Drug Abuse (Prevention and Control) Act, 1992.

Scope of products regulated includes human and veterinary medicines.

Administrative and legal sanctions are provided in different laws depending on the gravity of the offence.

Power to make regulations is vested on the Minister who is empowered to make regulations under the Pharmacy and Medical (Regulations) Act.

Available Regulations include the Pharmacy (Fees) Regulations, 1982.

Conclusion and Recommendation: There is need to harmonize the laws regulating medicines in order to have one comprehensive legislation which provides for regulation of all medicines and related products including antibiotics which are administered under the Antibiotics Act. Considering the size of the country, regulation of pharmaceutical products and the pharmacy profession could be done under on National Regulatory Authority.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section are reflecting the responses provided on the self-administered assessment instrument.

Organizational structure

The Pharmacy Council has been established under the Pharmacy Act, and the registrar (being the Chief Pharmacist) has been appointed. The Pharmacy Council reports to the Minister of Health.

Licensing

Licensing of Premises
Licensing of importers, wholesalers, and retail pharmacy premises is done under the Pharmacy Council. Respondents noted the absence of adequate regulations and guidelines for this process.

Internet pharmacies are not covered by the licensing system.

Import Permits
Only medicines administered under the Drug Abuse (Prevention and Control) Act require an import permit. Licensed importers are not required to obtain import permits for other pharmaceutical products.

Inspection and Surveillance

Inspections of the distribution channel are done by the Pharmacy Council.

No examples were given for counterfeit medicines. However, respondents think that the possibility it high that counterfeit and sub-standard medicines are circulating in the country.

No contraventions against the existing pharmacy and medicines laws were registered by the Pharmacy Council during the past 3 years.

Product Assessment and Registration

Although this function is foreseen in the legislative system, it is not currently performed. One reason provided was that technical expertise for assessment of product dossiers was difficult to find.

For the public sector, OECS/PPS is expected to employ adequate measures that ensure quality of medicines procured through that system. For the private sector no specific quality control measures are being employed.

Medicines quality control laboratory

Grenada is one of the 14 countries that established and are funding the Caribbean Regional Drug Testing Laboratory in Jamaica. From time to time medicines from the public sector are sent to this laboratory for testing. Respondents noted the lack of an adequate quality control laboratory as a constraint.

Financing of drug regulation

The Pharmacy Council is financed through the Ministry of Health budget. The Pharmacy Act Regulations stipulate the fees that can be charged for issuing of licenses to pharmacists and pharmacies. Respondents, however, stated that this provision is not being implemented.

Human resources (including training)

In the current system 2 technical Ministry of Health staff are assigned full-time to medicines regulatory issues.

Public sector salaries for pharmaceutical professional staff are lower than in the private sector, and staff shortage is perceived as a problem, and felt to be one reason for the fact that the regulatory system is very weak.

Medicines regulatory staff did not attend any specific training preparing them for performing the regulatory functions (including inspections).

Infrastructure

Office space and related infrastructure available for the regulatory unit are said to be inadequate.

Discussion

Grenada is one of the 10 CARICOM member states that do not have an operational registration system for medicines. The difference is that Grenada does have a law that provides for such a system. As is the case for the other 6 CARICOM member states that are at the same time members of the Organization of Eastern Caribbean States (OECS) quality assurance for medicines provided through the public health sector has been largely delegated to the OECS/PPS that conducts pooled procurement of pharmaceuticals for OECS members.

The quality of medicines imported by the private sector is not controlled adequately. The system relies on registration of importers and wholesalers.

Respondents noted that human and financial resources constraints negatively affect the regulatory system. In addition, weak regulations and the lack of policies and guidelines for performing regulatory functions (e.g. inspections) hamper operations. On the positive side, it was said that existing staff is very dedicated.

Considering the relatively small market size and the human and financial resources requirements it might not be viable to implement country specific legislation that requires in-country assessment of product dossiers for issuing of marketing authorizations. Grenada could benefit from a regional assessment/registration system that would improve on the current quality assurance measures provided through OECS/PPS and also extend to the private pharmaceutical sector.

Recommendations

The brief assessment done in the context of this study does not provide the level of information required for developing detailed recommendations. However, for addressing some of the identified constraints in the short to medium term the following could be considered:

For the Government / Ministry of Health

- Review Pharmacy and Medical Products Acts to include missing provisions
- Consider incorporation of relevant provisions of the Antibiotics Act into the Pharmacy Act and Medical Products Acts and repeal the Antibiotics Act
- Provide office space and related infrastructure to the Pharmacy Council
- Support training of Pharmacy Council inspectors
- Develop a National Medicines Policy (can be based on the CARICOM Model Medicines Policy)

For the Pharmacy Council

- Identify suitable training courses for Council inspectors
- Contact PAHO/WHO office for assistance with sourcing of standard guidelines for inspections

Guyana: Country Report

Country Background

Guyana is located on the northeastern shoulder of South America. It is bordered by Venezuela in the west and northwest, by the Amazon Basin of Brazil to the south and southwest, by Suriname on the east and by the Atlantic Ocean in the North. It is the only English speaking country in South America. The country covers an area of 214,970 km^2 and had a total population of 770,794 in 2008.

In 2005, Guyana had a Gross National Product of USD 760 Million, which translated into USD 1,011 per capita. In 2006, GNP/capita was estimated at USD 3,410 (PPP).[17] The country's economy is based mainly on the agricultural, forestry, fishing, mining and service sectors.

The Ministry of Health is the leading agency in the health sector. It carries out service delivery functions as well as policy formulation, standard setting, monitoring and evaluation. To carry out its mission of improving the spiritual, physical and mental health status of the Guyanese people, the Ministry of Health (MOH) is organized into seven programs – Administration, Disease Control, Primary Health Care, Regional Health Services, Health Sciences Education, Standards and Technical Services and Rehabilitation Services. Regulation of the sector is accomplished mainly through the establishment of policies, the enforcement of standards and the use of health legislation. The delivery of health services is the responsibility of Regional Democratic Councils (RDCS) who receive funding from the Ministry of Local Government. The Ministry of Health retains responsibility for the vertical health programs in the entire country.

The private companies own and operate 10 hospitals as well as diagnostic facilities, clinics and dispensaries. The private health services have been expanding rapidly and provide about half of all curative services. Most of these services are provided in the capital and other urban centers.

The main causes of death are ischemic heart disease, HIV/AIDS, cerebrovascular disease and diabetes. In 2008, the life expectancy of males was 63.8 years while that for females was 69.2 years. In 2005, Guyana had an infant mortality rate of 47 per 1000 live births, and a maternal mortality rate of 120 per 100,000 in 2006.[18]

In Guyana, the main source of health sector financing is government taxation. Funds are directed to the health sector through the Ministry of Health, Regions, other Ministries and agencies. The public health sector generates only insignificant revenues. Medical care, including medicines in the public sector, is free. According to information contained in *Assessment of the Pharmaceutical Sector in Guyana* (September 2007) the 2007/8 government budget for drugs and medical supplies was GYD 1.4 billion (USD 7 million or USD 10 per capita) of which approximately 48% was for the Georgetown Public Hospital Corporation (GPHC). The total budgeted Government of Guyana (GOG) pharmaceutical expenditure for the financial year 2008/9 was also USD 7 million.

There is no comprehensive social security system in Guyana. The National Insurance Scheme (NIS) operates a social insurance program for employees of the public and private sectors. The Scheme provides benefits for sickness (not employment related), maternity, medical care and job-related injury. The coverage given by NIS is low and covers approximately 18% of the population. In the private sector, the health insurance provided is minimal and there are no data available on the percentage of the population covered. The principal sources of financing in the private sector are

[17] Health Situation in the Americas: Basic Indicators 2008 (PAHO 2008).
[18] Ibid.

through fees from individual patients. Several non-governmental organizations, including religious organizations, provide services on a not for profit basis.

Pharmaceutical sector context

Guyana has a Draft National Medicines Policy (NMP) dated January 2008 together with a draft Implementation Plan. The Directorate of Technical and Professional Standards of the MOH is the Policy Unit responsible for the development and implementation of the NMP. The Lead Technical Officer is the Head of the Drug Control Authority, and the implementing agencies include the Food and Drug Department (FDD), the Materials & Management Unit (MMU), the Regional Health Authorities (RHAs), the RDCs, the Georgetown Public Hospital Corporation (GPHC) and the non government (including private) sector. These together make up the National Medicines Policy Committee (NMPC).

The drug regulation system is supported by both expert committees and groups. The National Formulary Committee assists with the development of the National Formulary. The latest version of the Essential Drugs List, the 3rd edition, covers the period 2007-2008. It should be noted that there are no written Terms of Reference, procedures or codes of conduct to guide the activities of these expert committees as the committees were reported to have only been recently established.

In addition to the expert committees, a consultant from SCMS has been assisting with strengthening the country's pharmaceutical supply chain management system through capacity building of the Pharmacy Bond including quality assurance procedures. SCMS has also been providing technical support for the automation of the drug assessment and registration system. PAHO also provides technical and training assistance on an ongoing basis.

The pharmaceutical delivery system is comprised of 26 government hospital pharmacies, 6 private hospital pharmacies, 100 private for-profit retail pharmacies, 104 government health centre pharmacies, and 3000 patent shops (authorized to sell a limited number of medicines). Of these, the private sector pharmacies and the patent shops are required to be licensed.

At the end of 2008, Guyana had 183 registered pharmacists and 32 formally trained pharmacy assistants. Local training of pharmacists takes place at the University of Guyana and graduates are awarded an Associate of Science Degree. The Department of Health Education of the Ministry of Health conducts the training program for Pharmacy Assistants. There were 367 licensed physicians and 42 medical extension workers (MEDEX) practicing in Guyana in 2008. Data on the number of practicing dentists were unavailable.

There are 29 licensed pharmaceutical wholesalers/distributors, of which 27 are involved in the importation of finished products. The Materials Management Unit (MMU) has responsibility for the procurement, storage and distribution of pharmaceuticals and other medical supplies for the public sector health facilities and general supplies for the MOH. The MMU falls under the Administration section of the Ministry of Health. The MMU does not employ international competitive bidding for determining procurement sources. Pharmaceuticals are procured by either sole supplier or direct purchasing methodologies through the locally based pharmaceutical manufacturer and wholesaler, New Guyana Pharmaceutical Corporation (GPC).

There are two pharmaceutical manufacturers in Guyana - New Guyana Pharmaceutical Corporation (New GPC) and Twins. The GOG has a 10% stake in New GPC. There is no information on the total pharmaceutical market in Guyana. Although New GPC promised to provide information on its value of domestic pharmaceutical production, value of imports of pharmaceutical active ingredients, and value of exports of finished pharmaceutical products, they were apparently unable to obtain

approval from its minority shareholder to release these figures. New GPC estimates that its activities accounts for 95% of the total pharmaceutical production in the country, with the other pharmaceutical manufacturer, Twins, accounting for the remaining 5%. Data for the total value of imports of finished pharmaceutical products were unavailable. There is no research-based pharmaceutical industry in Guyana.

Legislative Provisions

Existing medicines legislation includes the Antibiotics Act, 1952; as revised in 1998; the Pharmacy and Poisons Ordinance Act of 1956, the Food and Drugs Act, 1971 as revised in 1998, the Narcotics Drugs and Psychotropic Substances (Control) Act and the Pharmacy Practitioners Act of 2003.

Administration of medicine legislation is foreseen to be done by the Pharmacy & Poisons Board established under the Pharmacy & Poisons Ordinance Act, the Pharmacy Council established under the Pharmacy Practitioners Act, and the Drug Advisory Committee foreseen to be established under section 26 of the Food and Drugs Act to assist and advise the Minister with respect to drug standards, conditions of sale of drugs and any other matters connected therewith in the interest of, and for the protection of, the public health. The Chief Medical Officer is vested with powers to control the manufacture, importation, export and use of antibiotics and controlled drugs under the Antibiotics Act, 1953 and the Narcotics Drugs and Psychotropic Substances (Control) Act respectively. There is also established a Pharmacy and Poisons Board under section 3 of the Pharmacy and Poisons Ordinance which is responsible for control of manufacturing, importation and storage of antibiotics in Guyana.

In as far as the autonomy of the drug regulatory body is concerned, all bodies responsible for medicines regulation are under the Ministry of Health. According to the Ministry of Health structure, Food and Drug Department and Office of the Chief Pharmacist both report to the Chief Medical Officer.

Medicines regulatory functions are delegated to authorized officers appointed under the Food and Drugs Act. They have powers to conduct inspection and take food and drug samples for analysis.

Table 1 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 1 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of:		
Manufacturers	Yes	
Importers	Yes	
Wholesalers/Distributors	Yes	
Retailers/Dispensing outlets	Yes	Pharmacy & Poisons Board
Other (Patent Shops)	N/A	Pharmacy & Poisons Board
Market Authorization	No	Not expressly provided for, but assessment & registration done under the Food & Drugs Department
Inspection of premises	Yes	Appointed under sect 20 of the Food and Drugs Act

Key regulatory function/provision	Covered in legislation	Comments
Establishment of Quality Control Laboratory	Yes	(1) Laboratory at Food & Drug Department; (2) Materials Management Unit (MMU) Minilab (40 items)
Control of clinical trials	No	
Control of counterfeit medicines	Yes	implied
Adverse drug reaction monitoring	No	
Control of product promotion and advertisement	Yes	
Provision for medicines distribution schedules/categories	Yes	
Control of narcotics and psychotropic substances	Yes	The Narcotics Drugs and Psychotropic Substances (Control) Act
Scope of regulated products	Yes	Food, Drugs and poisons, cosmetics and therapeutic devices
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	Provided in different laws depending on gravity of offence
Power to make regulations	Yes	Minister empowered under sect 25 of the Food and Drugs Act, sect 21 of the Antibiotics Act & and sect 98 of the Narcotic Drugs and Psychotropic Substances (Control) Act
Regulations made under the Act	Yes	e.g. Food & Drugs Regulations 1977

Generally, the Food and Drugs Act, the Antibiotics Act and the Narcotic Drugs and Psychotropic Substances (Control) Act all provide restrictions for manufacturers, importers, wholesalers/distributors and pharmacy retailers. The Food and Drugs Act, also provides for issuance of market authorization of drugs. Missing provisions include control of clinical trials, counterfeit medicines and safety monitoring of products.

Licensing of manufacturers, importers, wholesalers, distributors, retail pharmacies:
The Food and Drug Department is vested with the responsibility to license manufacturers, importers and wholesalers/distributors. The Department is also responsible for issuance of Market Authorization of drugs.

Pharmacies and patent shops are licensed by the Pharmacy & Poisons board and need a license from the Food & Drug Department for dealing in OTC and controlled drugs and medical devices.

Quality control is can be done using the Caribbean Regional Drug Testing Laboratory which has been established by 14 countries namely Barbados, Guyana, Jamaica, Trinidad and Tobago, Antigua and Barbuda, Belize, Bahamas, British Virgin Islands, Dominica, Grenada, Montserrat, St Christopher-Nevis-Anguilla, St Lucia and St Vincent. Practically, analysis is done by the Food and Drug Department Laboratory and Materials Management Unit (MMU) Minilabs.

Medicines distribution categories are provided in third schedule of the Food and Drugs Act, as Part I and part II drugs.

Control of narcotics and psychotropic substances The Narcotic Drugs and Psychotropic Substances (Control) Act, 1988 provides for control of the possession of, and trafficking in, narcotic drugs and

psychotropic substances and cultivation of certain plants and for matters connected therewith. The Police officers and Comptroller of Customs have been vested powers to inspect any premise dealing with controlled drugs and to seize consignments.

Scope of regulated products includes food, drugs (human and veterinary), poisons, cosmetics and medical devices, narcotic drugs and psychotropic substances.

Administrative and legal sanctions are provided for in different laws and depend on gravity of offences.

Power to make regulations is vested on the Minister of Health empowered under section 25 of the Food and Drugs Act, section 21 of the Antibiotics Act and section 98 of the Narcotic Drugs and Psychotropic Substances (Control) Act.

Conclusion and Recommendation: The existing legislation and regulations regarding medicines control are partly outdated and there is confusion due to fragmentation and overlap in the different legislative documents and regulations. For example, legislation on inspection can be found in the Pharmacy and Poisons Ordinance 1956, Food & Drugs Act 1971 as well as in the Food & Drugs Regulations 1977. Important legislation is lacking, such as for the registration and marketing authorization for medicines, storage of narcotics and donation of medicines.

There is need to harmonize the laws regulating medicines in order to have one comprehensive legislation providing for regulation of all medicines and related products including antibiotics which are administered under the Antibiotics Act. Since there is already a system for regulation of food and drugs, it is recommended that one regulatory body be established to regulate quality, safety and/or efficacy of medicines, food, cosmetics and therapeutic devices. Alternatively, separate food from other products and establish two independent bodies.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section reflect responses from interviews conducted with the Chief Medical Officer, Director Standards and Technical Services, Director Food and Drug Department, the Chief Pharmacist, Chairman of the Pharmacy Council of Guyana, Registrar of the Pharmacy & Poisons Board, Procurement Manager of the Materials and Management Unit and the Chairman/Managing Director of New GPC Inc. Interviews were based on the approved assessment instrument.

Organizational structure

There was reported to be no organizational chart for the Guyana's medicines regulation system. There is no single agency in the country with responsibility for drug regulatory matters. The Food and Drug Department (FDD) - a department of the MOH - and the Office of the Chief Pharmacist, which both report to the Chief Medical Officer, were identified as having chief joint responsibility for coordinating drug regulation centrally at the national level. Other agencies assigned with aspects of drug regulation include the Pharmacy Council of Guyana, the Pharmacy and Poisons Board, and the Directorate of the Standard and Technical Services (STS) Branch. All drug regulatory functions are carried out at the central level with the exception of quality assurance that also takes place at the regional level.

The FDD operates under the Food and Drug Act 1971 and the Food and Drug Regulations 1977 and has responsibility for:

- Licensing of pharmaceutical manufacturers, distributors/wholesalers and pharmaceutical imports.
- Inspection of pharmaceutical manufacturers (GMP) and distribution channels.
- Performing drug quality tests through its quality control laboratory.
- Regulating advertising and promotion of pharmaceuticals.

Although not covered under the legislation, the FDD does assessment and registration of pharmaceutical products since 1995. In addition to drug regulation, the FDD also has regulatory oversight for food, cosmetics, and medical devices.

The Pharmacy and Poisons Board (PPB), operating under the Pharmacy and Poisons Ordinance Act 1956 and the Counter Prescribing Act is chaired by the Chief Medical Officer and has responsibility for the inspection and licensing of pharmaceutical retail establishments, pharmaceutical wholesalers, authorized sellers of poisons, and patent shops (shops approved to sell over-the-counter drugs). The PPB is appointed by the Minister of Health.

The Standards and Technical Services (STS) section of the MOH inspects health facilities to ensure compliance with established standards, as stipulated under the Health Facilities Licensing Act 2007. Should a hospital pharmacy not meet the required standards, the STS has the power to order the closure of such pharmacy.

With the institution of the Pharmacy Practitioners Act of 2003, Part 111, Sections 6 to 9 (inclusive) of the Pharmacy and Poisons Ordinance 1956 were repealed. This paved the way for the establishment of the Pharmacy Council of Guyana (PCG) that has operated since 2004 and has responsibility for the setting and maintaining of standards for pharmacists and practice of pharmacy, setting the standards for pharmacy related training and for the admission of pharmacists to pharmacy practice. The PCG is appointed by the Minister of Health.

The Office of the Chief Pharmacist coordinates pharmaceutical service delivery within the public sector and has responsibility for the training program for pharmacy assistants.

Licensing

Licensing of Premises

The FDD issues licenses for pharmaceutical importers, manufacturers and wholesalers/distributors, while licensing of pharmacies and patent shops is done by the Pharmacy and Poisons Board (PPB). In addition, the FDD issues OTC, narcotics, and medical device licenses to registered pharmacies. An inspection report is one of the requirements for issuing a license to engage in a pharmaceutical business and for the renewal of licenses. In addition, except for patent shops, a license is only recommended if a registered pharmacist is in place. Licenses are not issued for dispensing doctors. There are no special legal provisions for licensing of internet pharmacies or internet retailers.

The conditions for issuing the different licenses are published and known by the applicants. Guidelines for licensing are available and are based on those of the WHO.

Lists of licensed premises and establishments are not published but are made available upon request. Lists of revoked licenses or applications for licenses not granted are not published or distributed to interested parties.

Public hospital pharmacies are not required to be licensed, however, the MOH's Standards and Technical Services issues licenses to public health facilities under the Health Facilities Act. If a

hospital fails to comply with stipulated standards, or if the pharmacy department in particular fails to meet required standards, the STS has the power to order the closure of the pharmacy.

Respondents confirmed that there are unlicensed establishments engaged in the manufacture of herbal medicines, while they surmised that it is highly probable that there are unlicensed or illegal establishments engaged in the importation and distribution of drugs as well as the dispensing or selling of pharmaceutical products. The numbers of these unlicensed or illegal establishments was unknown, although it was felt that there could be significant numbers of the latter. In addition, it was felt that there are an unknown number of persons engaged in dispensing or selling pharmaceutical products outside licensed premises. When illegal selling of drugs is identified the drugs are seized and destroyed.

Licensing of Pharmacy Professionals

Under the Pharmacy Practitioners Act 2003, the Pharmacy Council of Guyana (PCG) registers and issues licenses to eligible persons to become practicing pharmacists. Eligibility requirements include successful completion of a course of study in pharmacy at an approved institution and completion of a minimum six months internship. The PCG also maintains a register of pharmacy assistants.

Import Permits

Import permits are issued by the FDD for the importation of registered medicines and unregistered medicines for emergency use by individual patients. The importation of all other unregistered products is subject to approval of an emergency waiver by the Chief Medical Officer. Despite the issuing of import permits, due to Guyana's size and its largely unprotected borders, there is deemed to be a significant amount of smuggling of pharmaceuticals into the country. In addition, the FDD cites lack of cooperation and feedback from the Customs Department as another challenge contributing to poor control of pharmaceutical imports. There also appears to be a flourishing suitcase trade in pharmaceuticals.

Inspection and Surveillance

There is neither a dedicated GMP inspectorate nor a dedicated distribution channel inspectorate. Inspection of manufacturers and distribution channels is conducted by 4 of the technical persons (all pharmacists) assigned to the FDD. These 4 persons are not dedicated inspectors but also carry out functions related to licensing and drug assessment and registration. The Pharmacy and Poisons Board has one full-time inspector with responsibility for the inspection of retail pharmacies, patent shops and all premises where pharmaceutical items are retailed or wholesaled. All inspection activities are centralized.

GMP Inspection

The FDD inspectors utilize the WHO GMP guidelines for inspection of manufacturers. There are no additional manuals or standard operating procedures (SOPs). GMP certification of the two local pharmaceutical manufacturers is done on an annual basis, usually within the first three months of the year to facilitate relicensing requirements. GMP certification is a prerequisite for the granting of export licenses. Post licensing inspection takes place in response to complaints and there was one such inspection in 2008.

Samples may be collected as part of the GMP inspection of manufacturing plants. If these samples fail laboratory tests the FDD may issue a product recall, hold samples for further investigation, or require that the product be destroyed. There have been no GMP violations recorded for the past two years.

There have been no GMP inspections of manufacturing premises outside of Guyana.

Distribution Channel Inspection

The FDD inspectors operate without written guidelines for distribution channel inspection. There are no manuals or standard operating procedures (SOPs). The 27 local pharmaceutical distributors are inspected at least once per year.

There were 3 violations recorded in 2007 and 1 in 2008. These included finding substandard products and products stored under improper conditions. These violations resulted in the seizure of products. If and when violations do occur the FDD issues violation notices and withholds the license until the required recommendations are implemented.

In general, there are usually no administrative measures or judiciary sanctions applied. Warnings are usually issued and the regulatory agency tries to work with persons to get compliance. It was felt that, even if applied, the fines are too small to have any significant punitive impact.

There are no separate fees levied by the FDD for inspections as it is deemed that these are covered under the relevant license fees.

Respondents felt that there are too many agencies conducting inspections of wholesalers/ distributors and pharmacies. The Pharmacy Council, the Pharmacy and Poisons Board and the FDD conduct inspections of these premises, resulting in duplication of effort and inconvenience to the entities being subjected to inspection. The view was also expressed that there is insufficient sharing of information among the relevant agencies.

Product Assessment and Registration

It was reported that drug assessment and registration is a requirement under the Food and Drug Act 1971. Review of the Act, however, revealed no such explicit requirement.

The FDD has an operational product assessment and registration system that commenced in 1991. The system is partially automated through the assistance of SCMS. Software suitable for full automation of the registration system is yet to be identified. All pharmaceuticals for human use are required to be registered by the FDD for use in Guyana whether manufactured locally or imported by the private sector or by the government purchasing agency from overseas pharmaceutical manufacturers. There is no periodic renewal of registration and no system of product re-evaluation. Donated pharmaceuticals are not subject to registration and there is no system in place to ensure their quality, efficacy and safety. In addition, herbal medicines and veterinary drug products are not subject to registration, although the latter is subject to market authorization from the FDD.

The FDD was unable to provide data on the total number of pharmaceutical products for human use registered in the country, the total number of these pharmaceutical products being marketed in the country or the proportion of registered pharmaceutical products in the country that are generic products.

Availability of registered products for the 29 different medicines included in the survey basket is summarized in Table 2.

Table 2 - Availability of basket medicines (registered products)

Total number of drugs in basket	29
Number with 3 alternative products registered	4
Number with 2 alternative products registered	5
Number with 1 product registered	15
Number where only the originator brand is registered	5
Number with no information provided	5

Four of the 5 products, for which there was no information, were on the 2007-2008 Essential Medicines List (EML) – amitryptiline, glibenclamide, didanosine and zidovudine. Levofloxin is not on the 2007-2008 EML. The reason for the lack of information on these items was not clear. It could be that the respondent only listed those items that were currently in stock. As a consequence, the table may not be a true reflection of the registration status of the basket of medicines.

There are no committees that support the FDD in its assessment and registration activities and none of the functions are outsourced. The Director of the FDD is the final decision maker with regards to the registration of a drug.

Applications for registration of a new drug or a known drug are submitted using the same standard application form. Guidelines for the submission of dossiers for the registration of drug products are published. The following information needs to be included in the submitted dossiers:

- Product monograph;
- A draft of every label, package insert and product brochure proposed to be used in connection with the drug;
- A certified copy of a Certificate of Pharmaceutical Product (WHO Certification Scheme);
- A batch certificate of a pharmaceutical product (WHO Certification Scheme);
- A notice of compliance or a certificate from the Regulatory Authority of Canada, USA, UK, or Australia certifying that the drug is approved for use in either of the said countries;
- Samples of dosage forms;
- Reference standards of the active ingredients.
- Product Dossier containing the following information:
    - Description of the drug including dosage forms;
    - Description of the plant and equipment used in the manufacturing, processing and packaging the new drug;
    - Drug substance – name, source, method of manufacture, physicochemical properties, impurities, specifications and test methods, stability, packaging and batch analyses;
    - Excipients – names, source, appearance, properties, specification and test methods;
    - Dosage forms – names, source, formulation, method of manufacture and controls, specifications, test methods, batch analyses, packaging and stability;
    - Therapeutic classification;
    - Route of administration;
    - Indications, contra-indications and side effects;
    - Dosage and administration;
    - Description of the important positive and negative features of the drug;
    - Investigational studies including Pharmacology, Toxicology and Microbiology, and Evaluation of Investigational Studies;
    - Clinical studies including Clinical Pharmacology, Clinical Trials, evaluation of Clinical Trials and conclusion of clinical studies; and
    - Published and unpublished Pharmacological, Toxicological, Bacteriological or clinical reports.

Renewal of registration is required if there is a change in product formulation or a change in the site of manufacture.

The FDD has no written SOPs to guide the staff in drug assessment and registration activities and there is no flow chart outlining the process. There are no written criteria for approving or rejecting applications for registration. The criteria for granting marketing authorization include safety, efficacy and cost-benefit analysis.

There are no criteria to determine to which Schedule a registered drug is assigned; the FDD is guided by the US FDA.

There was uncertainty regarding whether the FDD takes intellectual property rights into account when registering medicines but it was felt that international patents are recognized. The FDD indicated that it has no input in the evaluation of patent applications. The FDD grants the first pharmaceutical company to register a medicine a temporary exclusive right to the submitted information and therefore does not rely on such information when approving the products of other companies thereby making an abbreviated registration procedure of generic products impossible for a certain period.

Following approval for registration, a Certificate of Marketing Authorization is issued to the successful applicant and a unique registration number is issued. There is no requirement that this number be printed on product packaging or labeling.

A GYD 2000 (USD 10) fee is levied for each registration application. Applicants submit this payment directly to the MOH.

There is no formal independent appellate body. Appeals can be submitted to the Minister of Health. There have been no such appeals for the past two years.

The average turnaround time for assessment and registration is 120 days for both innovator and generic products. There is no formal fast track system for assessment and registration; however, temporary registrations are granted to facilitate emergency use of drugs and this takes an average turnaround time of 7 days. The maximum time limit allowed for assessment and registration is 180 days for normal applications and 7 days for temporary registration. There are no sanctions or recourse to applicants if the FDD exceeds the 180-day maximum time limit.

Data on the number of applications received and processed in the past two years were not easily accessible. The FDD reported that the list of registered drugs is updated regularly and is available in hard copy for internal distribution only.

Interested external parties requiring access to the decisions on drug registration may submit a formal request to the FDD. In addition, the FDD distributes the list of registered products to selected sites and photocopying can be facilitated upon request from these sites.

Medicines quality control laboratory

Section 3.1 of the Food and Drug Act 1971 stipulates that the Minister shall cause there to be a Government Analyst with responsibility for conducting analyses of products covered under the Act. In addition, Section 20.1 states that the Minister may appoint persons as analysts, with such appointment to be published in the *Gazette* and such persons to be given a certificate of their

appointment. The legislation allows the regulatory quality control laboratory (RQCL) to perform quality testing of pharmaceutical products and to issue official results.

The FDD is deemed to be the Government Analyst under the Food and Drug Act and operates the medicines quality control laboratory (QCL). There is also a minilab under the supervision of the MMU at the Pharmacy Bond with the capability to do quality assurance testing of 40 products imported by that entity. There are plans to expand the capability to 60 products.

The functions of the QCL include the testing of collected and submitted samples of non-biological pharmaceutical products, including the testing of samples relating to applications for drug registration, and the provision of limited support to the research efforts of the University of Guyana. The QCL is not equipped to test biological products. The laboratory is reported to have the necessary facilities, material and resources to meet minimum requirements. It is equipped to do all types of chemical tests and assays; identification by infra-red spectrophotometry, thin layer chromatography, UV-visible spectrophotometry, polarimetry, high-performance liquid chromatography and atomic absorption spectrophotometry; disintegration tests; and dissolution tests. It is unable to conduct microbial limit tests for drugs, pyrogen tests, sterility tests and tests for toxicity. Samples are referred to the CRDTL for microbiological and sterility testing and in accordance with the CRDTL's quarterly sample testing schedule.

Data on samples submitted and/or collected and tested over the past two years were not provided and appeared not to be easily accessible. The MOH's Annual Report 2006 stated that the FDD had targeted 157 samples for analysis during that year; 125 were actually analyzed with 55 of these having unsatisfactory results. The 2007 report *"Assessment of the Pharmaceutical Sector in Guyana"* indicated that 163 samples were collected for regulatory purposes in 2006 of which only 14% were tested. There appears to be some discrepancy in reporting. The FDD collects samples for testing as part of a planned quality surveillance program for anti-malarials and anti-retrovirals, and in accordance with the CRDTL's quarterly schedule. The QCL participates in the WHO proficiency testing scheme.

The main constraint being experienced by both the QCL and the minilab located at the Pharmacy Bond is the lack of sufficient reference materials to facilitate the testing of drugs. There are also training requirements and the need for calibration of instruments. The laboratory suffers from a high turnover of staff.

Financing of drug regulation

There is no specific budget allocation by the GOG for drug regulation and data relating to the estimated expenditure by the country for drug regulation for the past three years were unavailable.

The FDD budget is part of the MOH's budget and the FDD Director promised to provide the budgetary information but this was not received up to the time of preparing this report. Expenditure information for FDD functions – licensing, inspection and medicines assessment and registration - were likewise unavailable.

Under the law, the FDD is allowed to collect fees for drug regulatory services. FDD has not customarily published increases in their fee schedule. Fees being levied are outlined in Table 3. Clients pay these fees directly to the MOH. Consequently, the FDD was unable to provide data on the amount of fees collected for the last three years. The fees are not made available for the FDD's use in defraying operational expenses. The FDD reported that there was no problem with financial sustainability.

Table 3: Schedule of Fees

Type of service provided	Fee charged	Currency
Registration of Drug	$2000	GYD
Import Permit	$1500	GYD
Manufacturer's License	$1500	GYD
Wholesaler's License	$1500	GYD
Free Sale Certificate	$1500	GYD
License for Patent Shops (Pharmacy & Poisons Board)	$500	GYD

Human resources (including training)

The two main entities involved in drug regulation – the FDD and the PPB - are currently staffed as documented in Table 4. Being under the Ministry of Health, the regulatory agencies do not have the power to hire or fire personnel.

Table 4: Staff complement of regulatory entities

Staff category	Food & Drug Department	Pharmacy & Poisons Board
Technical full time	11 (including 5 pharmacists, 2 analysts & 2 lab assistants)	1 (pharmacist)
Technical part time	0	0
Administrative full time	4	0
Administrative part time	0	0

Four of the full-time pharmacists employed to the FDD conduct the department's inspection and licensing activities, and also oversee the assessment and registration of pharmaceutical products. The fifth pharmacist is the Director. The single pharmacist at the PBB acts as the Registrar and conducts country wide inspections.

Both the FDD and the PPB reported a shortage of staff. FDD gave as the main reason the failure to keep pace with the increasing level of activity required in drug registration, pharmacovigilance and import control, which require not only an increase in the number of staff but staff with additional skills. A proposal for a new structure had been written and, at the time of the interview, was being reviewed by the relevant government officials. The PBB, which was reconstituted in 2007, should have a Registrar and 3 inspectors. There is difficulty attracting the required personnel due to the low salary being offered.

The staff shortage at the FDD was reported to be having a negative impact on efficiency. Targeted turnaround times for drug registration are not being achieved and inspections are not being conducted with sufficient frequency. Other critical functions such as pharmacovigilance, increased registration capacity to accommodate the registration of herbal medicines, regulation of internet pharmacies, and strengthened monitoring at importation points were being neglected.

The average net monthly salary of GYD 50,000 for a pharmacist utilized for GMP and distribution channel inspection was lower than that for a pharmacist working in a private retail pharmacy (GYD 60,000). Comparable salaries in the private wholesale trade were unavailable. Despite the lower salaries in the public sector, the FDD reported having low staff turnover. Benefits, such as leave, security of tenure and duty free importation of a vehicle were thought to compensate for the low salaries.

Each staff member working in drug regulation was reported to have a job description but it was recognized that these were in need of review.

Staff development planning takes place at the central level, namely the Ministry of the Public Service. The FDD has a small training budget that allows utilization of relevant resource persons to conduct minor technical training. Over the past three years, drug regulatory staff members have received training in quality assurance (2), GMP inspection (4), distribution channel inspection (4), product assessment and registration (3), and quality control of drugs (3 each on two separate occasions). Sources of financing for training were the government's budget, donors and PAHO.

Infrastructure

The FDD relocated its offices to the building of the Institute of Applied Science and Technology (IAST) at the University of Guyana in November 2008. Up to January 2009, computer cables had not been installed so although the FDD has dedicated computers and printers the staff has been unable to access the Internet or electronic mail. The Director of FDD reported that transport facilities for the department are inadequate.

The single pharmacist employed to the PPB was without a computer or printer at the time of the interview. He also reported that the home computer that he had been using had crashed and he had to be seeking outside help to prepare reports.

Discussion

Regrettably, much of the data required for an in-depth assessment, although promised by the FDD and the New GPC, did not materialize. Based on information from interviews and reference to previous reports, including the draft National Medicines Policy (NMP) and its supporting Implementation Plan, and the report *Assessment of the Pharmaceutical Sector in Guyana* (2007), the following strengths were ascertained:

- Policy makers recognize the importance of pharmacy to the delivery of quality health care.
- The development of a National Medicines Policy together with an Implementation Plan.
- Valuable technical assistance being given by SCMS in capacity building.
- Local manufacturing capacity, particularly of ARVs, to meet the country's requirements.

The implementation of the NMP seems to be taking longer than projected and needs to be fast tracked so that the constraints and consequent deficiencies in Guyana's drug regulatory system, which are having a negative impact on the government's ability to provide safe, effective and quality medicines for the population, can be addressed without further delay.

The NMP calls for the set-up of a single Pharmaceutical Authority that seeks to bring order in the situation of incomplete, fragmented and partly outdated legislation and regulations as well as the somewhat unclear and overlapping responsibilities of the existing institutions involved in medicines regulation.

Important requirements under the law are not being complied with such as the Drug Advisory Committee mentioned in the F&D Act, which may be regarded as the regulatory authority, has never been convened. In addition, over the years, the Pharmacy & Poisons Board has functioned on and off (currently on) and the MOH Materials Management Unit does not adhere to the Procurement Act 2002 with regards to procurement by international tender.

The following list outlines the main constraints and challenges being faced by Guyana's medicines regulatory system.

- no strategic plan for drug regulation and no specific staff development and training plan;
- outdated and deficient legislation;
- delay in implementation of the draft National Medicines Policy;
- role conflict and ambiguity due to overlapping functions and no organizational structure;
- inadequate numbers of adequately skilled technical staff;
- inadequate funding;
- improper deployment of technical staff within the system;
- lack of a fully automated drug assessment and registration system;
- inadequate office space and equipment for optimal performance;
- low salaries;
- lack of international competitive bidding for procurement of pharmaceuticals in contravention of the Procurement Act;
- poor information flow and general collaboration between the Customs Department and the FDD;
- weak data capture and retrieval systems;
- fines for violations are very low;
- inadequate training of personnel in technical aspects of drug regulation.

The negative consequences of these constraints include:

- multitasking of drug regulatory staff;
- poor monitoring and control of drug importation;.
- no regulation of herbal medicines, other alternative and complementary medicines, internet pharmacies or internet retailers;
- inadequate quality assurance of pharmaceutical products, including locally manufactured products;
- inadequate performance monitoring and evaluation systems;
- unavailability of critical data in an easily accessible form;
- lack of guidelines, standard operating procedures, and written criteria to guide decision making in many key areas;
- inadequate inspection;
- questionable rigor in the assessment of medicines for registration;
- no registration requirement for donated medicines;
- lack of transparency in the drug registration system;
- lengthy turnaround time for drug registration with no facility for fast tracking;
- no formal appeal system;
- inability of QCL to do comprehensive quality assurance testing;
- suboptimal performance of the QCL; and
- no system in place for pharmacovigilance.

Based on the foregoing, it can be concluded that Guyana is at risk for exposure to counterfeit and substandard medicines due to the inadequacies identified in its importation controls, its medicines registration system and quality assurance systems.

Recommendations

For small countries it is advised that one institution be responsible for all functions related to regulatory affairs in the pharmaceutical sector, i.e. registration of pharmaceutical products, licensing of pharmaceutical personnel and facilities (pharmacies, wholesale and manufacture), and inspection.

The National Medicines Policy proposes the establishment of a single agency with responsibility for medicines regulation in the form of a Pharmaceutical Authority. This implies the re-organization of the FDD to become a special branch of the Pharmaceutical Authority, and a review of the functions of the Pharmacy Council of Guyana to determine if it should remain or its functions be transferred to the Pharmaceutical Authority.

It is apparent that the Ministry of Health is very aware of the deficiencies of the medicines regulatory framework and has a willingness to implement the necessary strategies to bring about needed improvements to achieve its mandate of providing safe, efficacious and quality medicines for the people of Guyana. The medicines regulatory system is in need of a major overhaul. Transparency, compliance, monitoring and accountability must be integrated into any system that is implemented. Speedy implementation of the National Medicines Policy is critical as this will go a far way in addressing the identified shortcomings.

Haiti: Country Report

Country Background[19]

Haiti is located on the western half of the island Hispaniola, which it shares with the Dominican Republic. The country covers an area of 27,700 km², and has a population of 9.7 million with 47% living in urban areas (2008 estimates).

The country's Gross National Product was USD 430/capita in 2006 (current value) - the lowest figure amongst CARICOM member countries. The unemployment rate for the economically active population was estimated at 33% in 2003. The agricultural and related sectors provide the majority of formal employment, followed by the public service and wholesale and retail trade.

Public sector health care is provided by the Ministry of Health based on a basic package of care, and using a three-tier system: first level health centers, communal referral hospitals and departmental referral hospitals. This system is still in the process of being implemented. Under the previous system there were 402 dispensaries, 198 health centers without beds, 54 health centers with beds, and 63 hospitals. Ministry of Health staff is also working in private and NGO sector health facilities Existing health care infrastructure is divided between the public sector (35.7%), the not-for-profit sector (31.8%), and the private sector (31.5%).

In 2003, the main causes of death were diseases of the circulatory system, AIDS, infectious intestinal diseases, pneumonia and influenza, and malignant neoplasms[20]. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 50.4 years 63.2 years	2008
Infant mortality rate (per 1000 life births)	57	2006
Maternal mortality ratio (per 100,000 live births)	630	2006

Public sector health care is financed through the Ministry of Health budget, user fees, and external aid. The Minister of Health budget is extremely low, in terms of % of national budget (3.5% in 2004-2005) as well as in monetary terms. It is estimated that over 40% of the population do not have access to basic health care (geographical and financial reasons).

Pharmaceutical sector context

Haiti has a National Medicines Policy dated March 1997. Apparently the policy was never officially adopted by government. Attached to the policy is a costed log frame for the first 2 years. The policy foresees the establishment of a national commission to oversee implementation. Review of the medicines law, implementation of medicines registration and related quality assurance measures,

[19] Information in this section is sourced from 'Health in the Americas - Basic Indicators 2008' (PAHO 2008), 'Health in the Americas - Country Reports' (PAHO 2007), and information provided in the self administered survey questionnaire

[20] N.B. Recorded causes of death only cover a relatively small percentage of actual deaths.

price controls, and promotion of rational use of medicines are some of the key strategies. The policy is currently being revised.

There is an essential medicines and medical supplies list, differentiated by first and second level of care. Essential medicines are further described in the National Formulary published in 2007. The formulary contains 156 different substances (including combination of substances). Use of the essential medicines list is mandatory in the public sector only. Currently there are no active programs to promote use of generic medicines.

The State University of Haiti offers programs in medicine, pharmacy and nursing. Pharmacy training consists of a 5-year program. There is no program for the training of pharmacy assistants. The number of pharmacists practicing in Haiti was not available.

There are 3 officially authorized local pharmaceutical manufacturing companies, which produce multi-source (generic) medicines. The total market share of locally produced medicines has been estimated as 30 to 40% (Health in the Americas 2007 - Haiti country report / PAHO). Earlier publications do, however, state that market share dropped from 30-40% to 6-8% after the 1996 crisis related to intoxication by use of diethylene glycol for medicinal syrups[21].

In the private sector 38 import and distribution agencies, 181 retail pharmacies, and 21 pharmaceutical warehouses are operating with official authorization. The 'Programme Nationale des Médicaments Essentiels' (PROMESS)procures essential medicines mainly through international tender for sale on a cost recovery basis to public and private not-for profit sectors. PROMESS was established in 1992 with donor funds and under administration of PAHO/WHO and is now operating under the auspices of the Directorate for Pharmacy & Medicines and Traditional Medicine (DPM/TM) of the Ministry of Health.

The public sector operates 25 hospital pharmacies. Medicines are also provided in 631 health centers (public, private, 'mixed') and dispensaries. Seventeen supply centers are operating at departmental level.

In addition to the formal sectors, medicines are widely sold on the streets and markets by drug peddlers.

Legislative Provisions

Existing medicines legislation includes the Medicines and Pharmaceutical Products Act of 1948 and the Act of 1955, regulating the introduction, production, distribution and sale of pharmaceutical and biological products.

Haiti is party to the 1961 UN Single Convention on Narcotics and subsequent conventions on psychotropics, and has an Act providing for control and repression of the illegal traffic of drugs (Law of 24 September 2001).

Administration of the medicines laws in Haiti is vested in the Ministry of Health. The Ministry of Commerce is involved in the issuance of commercial licenses for pharmacy businesses and registration of trade marks as far as it relates to proprietary products.

Table 2 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

[21] Analyse du Secteur de la Santé pour la Réforme (Ministère de la Sante Publique et de la Population/2004)

Table 2 - Comprehensiveness of existing legislation (done)

Key regulatory function/provision	Covered in legislation	Comments
Licensing of		
Manufacturers	Yes	
Importers	Yes	
Wholesaler/Distributor	Yes	
Retailers/dispensing outlets	Yes	
Other	Yes	Ambulant sellers
Market Authorization	Yes	
Inspection of premises	Yes	
Establishment of Quality Control Laboratory	No	only required for manufacturing companies
Control of clinical trials	No	
Control of counterfeit medicines	No	sale of damaged, expired or defect products is prohibited
Control of imports and exports	Yes	partially (narcotics and controlled drugs)
Adverse drug reaction monitoring	No	
Control of product promotion and advertisement	Yes	In line with professional ethics and the information provided by the manufacturer
Provision for medicines distribution schedules/categories	Yes	Indirectly (prescription only, pharmacy only, free sale)
Control of narcotics and psychotropic substances	Yes	
Scope of regulated products	Yes	Human and veterinary drugs, medicated dressings, drains and sterilized sutures
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	
Power to make regulations	No	
Regulations made under the Act	No	draft norms and procedures are available

Generally, the laws are not comprehensive enough to provide for all the key regulatory functions. Provisions for counterfeit medicines, product promotion and advertising, clinical trials and safety monitoring of products, an independent quality control laboratory are either not specific enough or missing. The laws do not foresee the establishment of a registration commission or of expert panels for evaluating applications for registration. In the texts available to us accountability and transparency of the regulatory agency was not addressed, and provisions for appeal against decisions taken by the Ministry of Health were missing.

Licensing of manufacturers, importers, wholesalers, distributors, retail pharmacies: the Ministry of Health is responsible for issuance of licenses for the manufacture, importation, storage, and sale of narcotics and poisons. The Ministry of Health is the authority responsible for issuance of licenses for wholesale and retail pharmacy in line with requirements stated in the law.

The law also provides for sale of a restricted number of prescription medicines by other commercial businesses and for sale of a restricted number of non-prescription medicines by ambulant sellers. In both cases authorization from the Ministry of Health is required.

Internet pharmacies are not covered by the licensing system.

Inspection: For the purpose of enforcing the provisions of the medicines laws, officially empowered inspectors of the Ministry of Commerce, and pharmacy and health inspectors of the Ministry of Health are empowered to seizing samples if contravention of the law is suspected.

Medicines distribution categories impliedly include narcotics as per Narcotics Convention, and prescription and non-prescription medicines although there are no clear provisions for medicines schedules. The Ministry of Health defines the list of medicines that may be sold by ambulant vendors from within the category of non-prescription medicines.

Scope of regulated products includes human and veterinary medicines, medicated dressings, drains and sterilized sutures.

Administrative and legal sanctions are provided in respective laws.

Power to make regulations: in the texts available to us there were no provisions for making regulations.

Conclusion and recommendations: The existing laws are outdated and are missing important provisions. The language is not always clear and unambiguous. It is recommended to revise the existing medicines laws, considering that the main Act should provide the administrative set-up, basic requirements, and provisions for appeal, sanctions and penalties. Regulations to the Act should be formulated to prescribe the more detailed requirements for implementation of the Act.

We were informed that the medicines laws have been revised and a Draft Medicines and Pharmacy Bill dated 2003 is awaiting enactment by Parliament (Avant projet de loi sur les médicaments et la Pharmacie).

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section are reflecting the responses provided by the Director Pharmacy & Medicines on the self-administered questionnaire, and responses by the Directorate for Pharmacy, Medicines & Traditional Medicines staff on follow-up questions (facilitated by PAHO/CPC and PAHO/WHO Haiti).

Organizational structure

Medicines regulation is the responsibility of the Directorate for Pharmacy, Medicines & Traditional Medicines (DPM/MT) in the Ministry of Health. There are 4 departments under the DPM/MT: pharmaceutical inspection, registration, essential medicines, and narcotics.

Norms and procedures for medicines regulation are available at DPM/MT, including production, importation, registration, dispensing, and pharmacy (first edition 2003, second edition 2009). These documents have not been officially approved.

Licensing and inspection of community pharmacies is decentralized to the 'Departments'. Departmental pharmacists conduct inspections of public and private pharmacies and receive applications for their registration, which are forwarded to the DPM/MT for further processing. There is a direct line of communication between departmental pharmacists and the DPM/MT.

DPM/MT has a strategic and annual work plan. Monitoring and evaluation was last carried out in 2008.

Licensing

Licensing of Premises
Licensing of pharmacies, importers & wholesalers (pharmaceutical agencies), pharmaceutical depots, and manufacturers is done through the pharmaceutical inspection department. All these pharmaceutical establishments need to employ a full-time pharmacist to be able to operate.

Licenses are subject to annual renewal.

Import Permits
Import of pharmaceuticals by the private sector is subject to a license issued by the Ministry of Commerce. Prior approval by the Ministry of Health is necessary.

Inspection and Surveillance

Pre-license inspections and inspections based on complaints are done by the department of pharmaceutical inspection. Inspections of the distribution channel are also done by the department of essential medicines. The registration department works with customs officers to ensure that only medicines registered in Haiti are being imported.

GMP inspections of manufacturing plants are carried out, but GMP certificates are not issued. Guidelines used for GMP inspections are those developed within the framework of the Pan American Network for Drug Regulatory Harmonization.

During the previous 3 years approximately 10 contraventions of the law were registered, including illegal importation of medicines, sale of non-registered medicines, street sale, and counterfeit medicines. Sanctions applied were seizure of products and closure of premises.

Counterfeit and substandard products are a problem. Examples given are Anti-tetanus serum and Pentazocin. Both cases involved the death of patients.

Problems of illegal medicine imports exist mainly along the boarder with the Dominican Republic.

Product Assessment and Registration

Product registration has been foreseen in the legislation since 1955, but in practice only started in 1997. Since then, only medicines registered in Haiti can be legally imported, distributed, or sold. Registrations are subject to renewal every 5 years.

To date 3,926 products are registered, 10% of them registered by generic name (N.B. this figure does not include branded generics).

The registration department in the DPM/MT is responsible for evaluation of applications and issuing of marketing authorization. The Director of DPM//MT is the authority to approve or disapprove applications.

There are standard applications forms and standard operating procedures for regulatory staff. Formal procedures to fast-track assessment of applications for priority medicines are available for vaccines. Documentation requirements for application for registration of new and known (multi-source / generic) products are the same.

Product dossiers submitted with applications for registration for imported products need to include

- Product characteristics and label
- Profile of the manufacturer
- Technical product file (chemical/pharmaceutical, clinical, pharmacological/toxicological, bioavailability, and stability data; information regarding manufacturing process)
- Product samples

There are no expert committees for assessing product dossiers and no formal commission that decides on approval or rejection of the application. Respondents reported that the average time to process a complete application for registration varies between 4 to 6 months for new products and known (multi-source generic) products. The law does not specify a maximum time allowed for processing applications.

Registration numbers are not issued, and updated lists of registered products are not made available to the interested public.

During the previous year 287 applications for registration for a pharmaceutical products were submitted, 17 were processed and approved, and 262 dossiers are waiting assessment.

Availability of registered products for the 29 different medicines included in the survey basket is summarized in Table 3.

Table 3 - Availability of basket medicines (registered products)

Total number of drugs in basket	**29**
Number with 3 alternative products registered	13
Number with 2 alternative products registered	4
Number with 1 product registered	3
Number with no product registered	9
Number where only the originator brand is registered	2

Items for which no registered product is available are Amitryptiline, Lamivudine, Efavirenz, Didanosine, Tenofovir, Levofloxin, Fluconazole, Valganciclovir, and Clopidogrel. For Lopinavir + Ritonavir and Imatinib mesylate only the originator products are registered.

Medicines quality control laboratory

The regulatory authorities reported not to have access to a quality control laboratory.

Financing of drug regulation

Regulatory activities are financed through the general Ministry of Health budget and through fees collected. Table 3 provides an overview of fees charged for different regulatory services.

Table 3 - Regulatory Fees

Type of Service	Frequency	Amount in Gourdes	Amount in USD
Registration of speciality product	once	5,000	128
Renewal of registration speciality product	every 5 years	2,500	64
Registration of generic product	once	2,500	64
Renewal of registration generic product	every 5 years	1,250	32
Opening of pharmacy	once	7,500	192
Renewal of pharmacy license	annually	1,000	26
Opening of import/wholesale business	once	15,000	385
Renewal of import/wholesale license	annually	1,500	39
Opening of private depot	once	10,000	260
Renewal of private depot license	annually	1,250	32
Opening of manufacturing premises	once	50,000	1,285
Renewal of manufacturing license	annually	10,000	260
Authorization of destruction of unusable medicines	per lot and product	100	3

In addition, fees for narcotics permits, sale of narcotics prescription blocks, and dangerous drugs books are collected.

Financial means to perform all regulatory activities are felt to be insufficient. This has a negative impact especially on inspection activities.

Human resources (including training)

At central Ministry of Health level 5 pharmacists are employed, the Director DPM/TM and one for each DPM/TM department.

Human resources available for regulatory activities are inadequate. The shortage of human resources was said to be due to insufficient government budget.

Training has been provided during the past three years, financed by government and international institutions, as follows:

- Quality assurance: 6 staff
- Good Manufacturing Inspection Practices: 6 staff
- Distribution channel inspections: 6 staff
- Assessment of applications for registration: 6 staff

Infrastructure

Office space, computer equipment, and communication infrastructure available at the DPM/TM are felt to be adequate. Means for transport are insufficient.

Discussion

Haiti is one of the 5 CARICOM member states that do have an operational registration system for medicines. However, the legal framework is outdated and inadequate, and human and financial capacity is limited. The latter is particularly affecting enforcement of legal provisions through planned inspections. This was also noted by respondents as main weakness.

Consequently there are cases where pharmaceutical businesses operate illegally, i.e. without authorization by the Ministry of Health. In 2004, 500 pharmacies were listed in Haiti, but only 198 of them were officially authorized by the Ministry of Health[22].

Respondents also noted the challenge of dossier assessment in the context of inadequate human capacity, and stated that enforcement mechanisms were poor.

The revised legislation has been available since 2003. The reasons for delay in enactment were not stated.

Recommendations

The brief assessment done in the context of this study does not provide the level of information required for developing detailed recommendations. However, for addressing some of the identified constraints in the short to medium term the following could be considered:

For the Government / Ministry of Health

- ensure that the draft legislation is being presented to Parliament
- increase human and financial resources available to the DPM/TM (could be in the context of a comprehensive program to strengthen the public pharmaceutical sector with support from cooperating partners)
- establish relationships with quality control laboratories in the region (e.g. Dominican Republic, Jamaica)

[22] Analyse du Secteur de la Santé pour la Réforme (Ministère de la Sante Publique et de la Population/2004)

Jamaica: Country Report

Country Background

Jamaica is the largest English-speaking island in the Caribbean Sea. It is located 150km south of Cuba and 160 km west of Haiti and covers an area of 11,424 km². It is divided into 14 parishes. There are two main cities – Kingston, the capital, and Montego Bay. The total population in 2008 was 2.728 million. Fifty-six % of the population lives in urban areas.

The country's Gross National Product was USD 10,120 Million in 2007, representing USD 3,710/capita[23]. Tourism, bauxite mining and primary agriculture exports, including sugar and bananas, are the traditional mainstays of the economy. Private remittances from abroad continue to play an increasingly important role in the country's economy.

The Ministry of Health's central office is responsible for policies, standard setting, inspection and monitoring, and program development. Decentralization of the health sector began in 1996 with the creation of 4 Regional Health Authorities. Thus, decision-making capacity was removed from individual hospitals and parishes and vested in the Authorities. Some central level functions were devolved to the Authorities. The health system offers primary, secondary, and tertiary care. Ambulatory care at the community level is delivered through a network of 343 health centers. Secondary and tertiary care are offered via 23 government hospitals and the teaching hospital of the University of the West Indies. Private sector health services are provided through an extensive network of professionals offering specialist services and by family doctors throughout the island. There is also a strong private sector network of diagnostic laboratories, pharmacies and hospitals. Non-governmental organizations also provide ambulatory health care, targeting the poorer segments of the population.

The main causes of death are cancer, cerebrovascular diseases, heart disease, and diabetes. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 70.1 years 75.3 years	2008
Infant mortality rate (per 1000 life births)	19.9	2006
Maternal mortality ratio (per 100,000 live births)	94.8	2006

Financing of the health sector comes primarily from governmental budgetary allocations that until recently were supplemented by user fees. Financial support also comes from inputs by non-governmental organizations and international development partners. Since April 1, 2008, user fees were abolished and all health care services offered in the public sector are free of cost. Pharmaceutical expenses are, on average, 20% of total health expenditure. Government expenditure on health was 56.7% of total health expenditure while private sector expenditure accounted for 43.3%. Net out-of-pocket household expenses for health care were 63.6% of private health expenditures in 2004-2005.

[23] Health Situation in the Americas - Basic Indicators 2008 (PAHO 2008)

Pharmaceutical sector context

Jamaica has no National Medicines Policy. The Central Drug and Therapeutics Committee under the chairmanship of the Director, Standards and Regulation Division of the Ministry of Health & Environment (MOH&E) has responsibility for the development of the List of Vital Essential and Necessary (VEN) Drugs and Medical Sundries for Public Health Institutions. The latest version of the VEN List (5th edition) is dated 2008.

Jamaica has one medical school and a number of nursing schools. In 2005, there were 2,320 physicians and 220 dentists. Pharmacists are trained to the Baccalaureate degree level at the University of Technology, Jamaica and are required to complete a one-year internship program before they are eligible to be licensed to practice. There were 742 registered pharmacists at the end of 2008. The University Hospital of the West Indies (UHWI) has a training program for Pharmacy Technicians. It is estimated that there are 50 locally trained pharmacy technicians in the country.

There are 29 licensed private sector pharmaceutical distributors and a government owned procurement agency – Health Corporation Limited (HCL) – that procures, stores and distributes essential medicines for the public health facilities. HCL imported medicines valued at approximately USD 7.8 Million in 2008. Figures for the value of imports made by private sector distributors were unavailable. The total value of government pharmaceutical expenditure for HCL-sourced pharmaceuticals and medical supplies was J$ 841 Million (USD 9.89 Million).

There are 7 licensed pharmaceutical manufacturers that are all privately owned and operated. The total value of domestic pharmaceutical production and the value of imports of pharmaceutical active ingredients were unavailable. Jamaica has no research based pharmaceutical industry.

At the end of 2008, there were 394 registered retail pharmacies, including 5 private hospital pharmacies and 10 HCL-operated pharmacies. Four of the HCL-operated pharmacies are government hospital pharmacies operated on a contractual basis for the Southern Regional Authority and the South East Regional Health Authority and 2 are located in government health centers. The 19 government hospital pharmacies and 71 government health centre pharmacies not operated by HCL are not required to be licensed as they only dispense prescriptions for patients with public sector generated prescriptions. Retail pharmacies are to be found in every major town throughout the island, with the majority being concentrated in Kingston. Most of these private for-profit pharmacies are registered with the National Health Fund and can therefore provide medicines for its members. In addition, there are dispensaries affiliated with churches and the military that are authorized to sell a limited number of medicines.

Legislative Provisions

Existing medicines legislation includes the Dangerous Drugs Act, 1948; the Dangerous Drugs (Authorization Conditions) Regulations, 1948; the Pharmacy Act, 1975 and the National Health Services Act, 1997. In as far as the Food and Drugs Act, is concerned, the copies made available for review were the Food and Drugs Act of 1975 and the Food and Drugs Regulations, 1975. The Food and Drugs Act of 1964 and its corresponding amendments were not available for assessment.

Administration of medicine legislation is done by the Pharmacy Council which is established under section 3 the Pharmacy Act. The Pharmacy Council is responsible for control of the pharmacy profession and to ensure maintenance of proper standards of practice, to register persons as authorized seller of poisons and to regulate the training of pharmaceutical students.

On the other hand, the Drug Advisory Committee is established under section 24(b) of the Food and Drugs Act to assist and advise the Minister with respect to drug standards, conditions of sale of drugs and any other matters connected therewith in the interest of, and for the protection of the public health.

Autonomy of the drug regulatory body: the Minister is responsible for implementation of the Food and Drugs Act assisted by the Drug Advisory Committee and with powers delegated to drug inspectors.

The Pharmacy Council is a semi-autonomous body with powers to collect and utilize fees for regulatory functions for which it is mandated. It has powers under section 5 to appoint and employ the Registrar, inspectors and any other officers for the purpose of proper carrying out of provisions of the Pharmacy Act.

In as far as delegation of regulatory function is concerned the Food and Drugs Act, gives powers for the inspectors and/or analysts to conduct inspection and take food and drug samples for analysis while Committees established by the Pharmacy Council may also perform some delegated functions.

Table 2 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 2 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of:		
Manufacturers	Yes	Food and Drugs Act
Importers	Yes	
Wholesalers/Distributors	Yes	Pharmacy Act
Retailers/dispensing outlets	Yes	Pharmacy Act
Other	Yes	
Market Authorization	Yes	Food and Drugs Act
Inspection of premises and manufacturing sites	Yes	
Establishment of Quality Control Laboratory	(Yes)	Signatory to Agreement establishing the CRDTL
Control of clinical trials	No	
Control of counterfeit medicines	No	
Control of imports	Yes	
Adverse drug reaction monitoring	(Yes)	Art 70 of the Food & Drugs Regulations provides for reports on adverse drug reactions on 'new drugs' (passive only)
Control of product promotion and advertisement	Yes	Food and Drugs Act
Provision for medicines distribution schedules/categories	No	
Control of narcotics and psychotropic substances	Yes	
Scope of regulated products	Yes	

Key regulatory function/provision	Covered in legislation	Comments
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	
Power to make regulations	Yes	Minister empowered to make Regulations
Regulations made under the Act	Yes	The Dangerous Drugs (Authorization Conditions) Regulations, 1948; the Food and Drugs Regulations, 1975.

Licensing of manufacturers, importers, wholesalers, distributors, retail pharmacies:
The Food and Drugs Act provides for licensing of manufacturers and importers, registration of drugs and control of product promotion and advertising, while the Pharmacy Act provides for licensing of premises for storing for sale (wholesaler/distributor) and retail.

Marketing Authorization: All medicines must be registered under the Food and Drugs Act, the relevant authority being the Minister. The Minister can exempt any product of person from the provisions of the Act. 'New drugs' must be licensed instead and specific information requirements are provided in the regulations to the Act.

Quality Control may be done using the Caribbean Regional Drug Testing Laboratory which has been established under the Act and is in force in 14 countries namely Barbados, Guyana, Jamaica, Trinidad and Tobago, Antigua and Barbuda, Belize, Bahamas, British Virgin Islands, Dominica, Grenada, Montserrat, St Christopher-Nevis-Anguilla, St Lucia and St Vincent.

Medicines distribution categories are not clearly stipulated in the Acts.

Scope of products regulated includes food, drugs, poisons, cosmetics and medical devices, narcotic drugs and psychotropic substances.

Administrative and legal sanctions provided in different laws depending on gravity of offences.

Power to make regulations is vested on Minister empowered under section 21 of the Food and Drugs Act, while section 25 of the Pharmacy Act empowers the Council, with the approval of the Minister to make Regulations for the proper carrying out the provisions and purposes of the Act.

Available Regulations include the Dangerous Drugs (Authorization Conditions) Regulations, 1948 and the Food and Drugs Regulations, 1975.

Conclusion and Recommendation: There are no proceedings prescribed for the Drug Advisory Committee (including number of members, conditions and terms of office, decision making procedures, or addressing conflict of interest), and there is no provision for a Registrar/Secretary for this Committee. The legislation is not very clear about the organizational set up of the authority responsible for registration of medicines. Any revision of the existing Acts should consider establishing a dedicated authority (either within the Ministry of Health or outside) responsible for dealing with product registration and working procedures for the drug advisory committee should be specified in a regulation.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section reflect the outcome of interviews conducted with the Director of Standards and Regulations, Deputy Registrar of the Pharmacy Council, Chief Dangerous Drug Inspector, Acting Director of Pharmaceutical and Regulatory Affairs, the Government Chemist, Senior Analyst of the CRDTL, the Director, Purchasing of Health Corporation Limited and President of the Pharmaceutical Society of Jamaica (PSJ). Interviews were based on the approved assessment instrument.

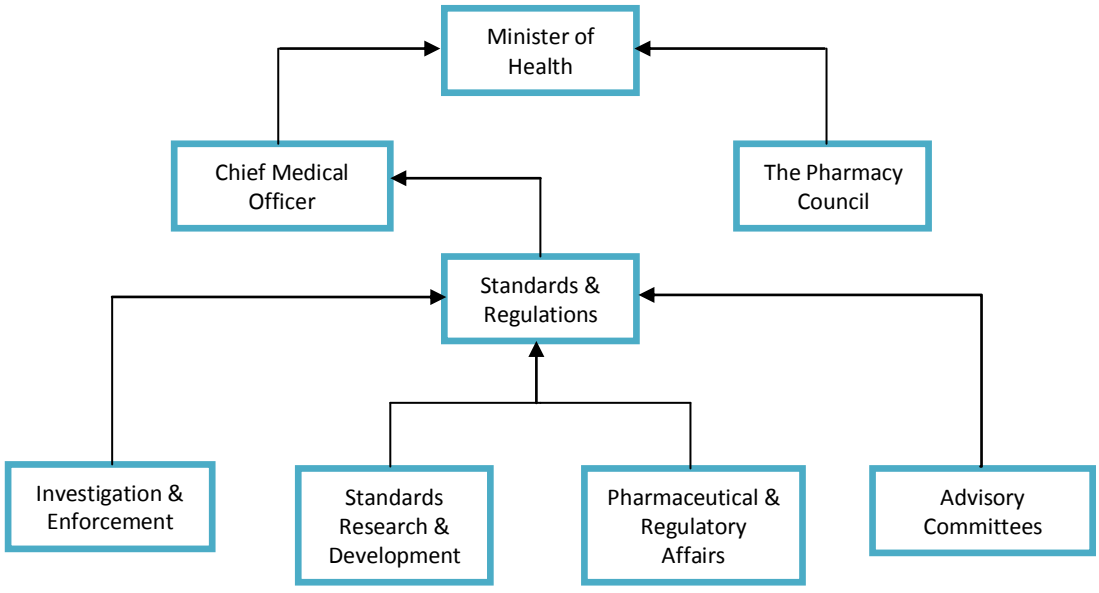
Organizational structure

In Jamaica, medicines regulation responsibilities are divided between two entities, the Pharmaceutical and Regulatory Affairs Branch (PRAB), which is a unit of the Standards and Regulations Division of the MOH&E, and the Pharmacy Council of Jamaica. The Director, Standards and Regulations reports to the Chief Medical Officer and the Chairman of the Pharmacy Council is appointed for a 3-year term by and reports to the Minister of Health. The organizational structure of the Medicines Regulation system is outlined in Figure 1 with the key players highlighted.

The PRAB, with the support of a Drug Registration Committee, is the body that issues marketing approval for medicines. The PRAB is also responsible for GMP inspections, issuing import permits, and the development of the VEN List, with the support of the Central Drugs and Therapeutic Committee. The Food and Drug Act 1964 and its Regulations 1971 are the governing legislation for the PRAB.

The Pharmacy Council of Jamaica is a statutory body established under the Pharmacy Act 1975. It has responsibility for establishing and monitoring the standards for the professional practice of pharmacy, which includes inspection and licensing of premises, and the registration of pharmacists, pharmacy students, pharmacy owners and authorized sellers of poisons. The Pharmacy Council operates as a semi-autonomous agency. In addition to appointed Council members, the Council has a full-time staff including a Registrar and Drug Inspectors.

Figure 1: Organizational Set-up of Medicines Regulation



Licensing

Licensing of Premises

The Pharmacy Council issues licenses to pharmaceutical manufacturers, local pharmaceutical distributors (including the government's procurement and distribution agency – HCL), private for-profit pharmacies and authorized sellers of poisons. GMP inspection, conducted by Drug Inspectors employed to the PRAB, is a requirement for licensing of manufacturers and distributors, although the PRAB admitted that sometimes inspections are not conducted for renewal of licenses.

The Pharmacy Council meets at least once per month to approve licenses based, in part, on the inspection reports submitted by the Council's Drug Inspectors. Premises licensed to store, distribute and sell pharmaceuticals must be under the control of a registered pharmacist. Importers are not licensed but all persons and establishments importing pharmaceuticals must apply for an import permit from the PRAB.

Guidelines and criteria on pre-licensing requirements are published and known by applicants. Some of the criteria are defined in the legislation and some are the result of specifications set by the Pharmacy Council from time to time. Licenses are not issued for dispensing doctors.

Lists of licensed pharmaceutical establishments are published in the Official Gazette and will be distributed upon request. Revoked licenses are also published but there is no publication of applications not granted. Details of licenses issued for the past two years are outlined in Table 3.

Table 3: Licensing of premises activity

Action	Year: 2007	Year: 2008
New license issued	50	50
License renewal	1,060	1,119
License suspended	Nil	Nil
License revoked	Nil	Nil

Respondents felt that it is quite likely that there are unlicensed establishments engaged in the importation of medicines and confirmed that there are persons engaged in selling medicines outside of licensed premises (i.e. peddlers/hawkers). Respondents were unaware of any unlicensed pharmaceutical manufacturing or distribution operations, but indicated that there are a limited number of unlicensed drug outlets, such as those operated by churches, which need to be regulated. The level of illegal/unlicensed activity overall was not known. If illegal operations or selling of medicines are found the authorities have the power vested in them to seize the drugs. Further actions are processed through the penal system.

Internet pharmacies and distributors of herbal remedies and alternative medicines are not yet covered by the licensing system. Legislation is being amended to address these new entities.

Import Permits

Medicines cannot be imported into Jamaica without an import permit issued by the PRAB. The PRAB has decentralized the issuing of import permits with the Western Regional Authority also fulfilling that function on behalf of the PRAB. Unregistered medicines cannot be imported into the island except for limited amounts imported by HCL for emergency use in the public sector or in accordance with a special request from a physician for one-off emergency use by an individual patient. In such cases, a Certificate of Analysis for the product must be submitted as a requirement for issuing the import permit. Investigational products require import permits. Requirements for importation of

drugs, including a flow chart outlining the process for application of an import permit, are published on the MOH's website.

For 2006 and 2007, there was approximately 18,000 and 20,000 import permits issued, respectively. There were in excess of 18,000 permits issued during 2008. There were no revocations or withdrawal of permits for the past three years.

Licensing of Persons

The Pharmacy Council has responsibility for annual licensing of pharmacists, pharmacy owners and authorized sellers of poisons, and maintains a register of pharmacy students and pharmacy interns. Annual re-licensure of pharmacists is based on the successful completion of 12 continuing education (CE) credits, with a minimum of 6 CE credits to be obtained in face-to-face sessions. The PCJ has an accreditation scheme for approval of CE sessions and assigning credit scores. The PCJ also holds a semi-annual examination for foreign based pharmacists wishing to practice in Jamaica.

Inspection and Surveillance

GMP Inspection

There is no GMP inspectorate. GMP inspection is conducted by Drug Inspectors of the PRAB, Ministry of Health. No GMP certificates are issued as none of the local manufacturers are exporters. GMP inspection reports are provided to the Pharmacy Council to facilitate licensing of manufacturers and distributors. There have been a limited number of GMP inspections of overseas manufacturers for the purpose of ensuring compliance.

The written GMP guidelines are extracts from the WHO GMP guidelines. The guidelines have not been enacted as a law although the Food and Drug Act has some stipulated requirements. There are also manuals for GMP inspectors; the last one is dated 2001 and is a WHO manual. Samples are not collected as part of the inspection requirements for manufacturers but are collected during GMP inspection of distributors. Samples may be collected from manufacturers if there are complaints. Products failing laboratory tests are recalled or product registration is withheld.

There are 6 pharmacists involved in inspection but they also have other duties related to drug regulation. These 6 officials are responsible for conducting inspections in the whole country (no decentralization). GMP training was conducted by WHO five years ago but has not been ongoing.

There are no fees for GMP inspection.

Planned 'preventive' inspections are not being conducted due to a shortage of staff but an attempt is made to conduct an inspection of each facility at least annually as a prerequisite for license renewal. For 2008, all 7 manufacturers were inspected and a total of 23 inspections were conducted. There were no violations registered during the past 2 years. If there are minor violations, manufacturers and distributors are usually allowed time to make the required adjustments to become compliant.

Distribution Channel Inspection

There is no dedicated distribution channel inspectorate. Distributors are inspected by the 4 full time Pharmacy Council Drug Inspectors as part of the Council's licensing responsibility. These same inspectors also inspect retail pharmacies, private hospital pharmacies and authorized sellers of poisons. They do inspection for the whole country (no decentralization).

There are written guidelines for Good Distribution Practices based on the WHO guidelines. There are, however, no written inspection guidelines or standard operating procedures for the inspectors. The inspectors have not received training in distribution channel inspection.

A processing fee of J$2,500 is levied for each inspection.

There were 78 distribution channel inspections planned annually for 2007 and 2008. Approximately 39 inspections were actually conducted for each of these two years. There were no violations detected during these two years.

Pharmacy Council inspectors do not collect samples during distribution channel inspections. Inspectors from the PRAB collect samples from distributors in response to complaints or for ad hoc testing. Details of the number of samples collected are outlined in Table 4. Samples are collected in accordance with a quarterly schedule issued by the CRDTL. Test results were unavailable from the PRAB but overall quality assurance activities and results were obtained from the Government Chemist and can be seen in the 'Medicines quality control laboratory' section of this report. The PRAB institutes product recalls when a product fails laboratory testing.

Table 4: Sample Collection from Distributors

Samples collected in connection with:	Number of Samples Collected Year: 06/07	Year 07/08
Planned quality surveillance	0	0
Follow-up of complaints	7	4
Target testing/risk assessment	57	75

There were no cases of counterfeit medicines detected, however, in 2006/07 and 2007/08 there were 2 cases and 1 case, respectively, of expired products being sold and on a few occasions distributors were found operating with expired licenses. Additionally, there were times when products were found to be stored under improper conditions and distributors were found to be selling products not authorized to be sold. The number of violations was unavailable.

Product Assessment and Registration

There is an operational product assessment and registration system in Jamaica as stipulated under the Food and Drug Act 1964, the Food & Drug Regulations 1975 and other gazetted amendments. This applies for all medicines for human and veterinary use. Herbal medicines and medical devices and applications were recently included as items requiring registration. Donated pharmaceuticals must meet registration requirements.

Enforcement of medicines registration started prior to 1975 although records only started to be maintained in that year. As at February 2009, there were 12,124 medicines on the register. It is not known how many of those products are actually marketed in Jamaica. The proportion of the registered products that are generic products could not be easily determined.

Availability of registered products for the 29 different medicines included in the survey basket is summarized in Table 5.

Table 5 - Availability of basket medicines (registered products)

Total number of drugs in basket	29
Number with 3 alternative products registered	23
Number with 2 alternative products registered	1
Number with 1 product registered	5
Number where only the originator brand is registered	4
Number with no registered product	0

Basket medicines for which only the originator brand is registered are all anti-retrovirals – Lopinavir + Ritonavir, Tenofovir, Valganciclovir and Imatinib mesylate.

Applications for registration are submitted using standard application forms that are available at the PRAB and online from the MOH's website. The same form is used for both new products and known products. The list of requirements for assessment purposes are:

1) Three copies of a summarized statement (not package insert) giving on:
   a. All ingredients present in the formulation;
   b. Dose, dose schedule, route of administration;
   c. Therapeutic / diagnostic claims;
   d. Description of dosage form being registered;
   e. Contraindication / precautions;
   f. Side effects;
   g. Toxic effects, and protocol for treating toxicity or where applicable, antidote.
2) Details of the tests conducted to control the potency, purity, and stability.
3) Summary of:
   a. Clinical pharmacology: pharmacodynamics; pharmacokinetics; bioavailability. Bioequivalence studies including not less than twelve (12) subjects for all generic preparations.
   b. Efficacy: controlled studies; uncontrolled studies;
   c. Safety: adverse drug reactions in volunteers and where a new chemical moiety has been marketed for less than five (5) years, adverse drug reactions in patients.
4) A Certificate of analysis (original, not photocopy) or certified report containing:
   a. Assay report on a recent batch of the product analyzed;
   b. The method of analysis used.
5) Five (5) copies of a draft of every label bearing the address of the manufacturer proposed to be used in connection with the product, a batch/lot number and expiry date of the product.
6) Five (5) samples of the new drug in the finished pharmaceutical form in which it is to be sold along with adequate amounts of appropriate chemical and / or biological reference standards of active ingredients necessary to perform analyses described in three (b).
7) A "Certificate of a Pharmaceutical Product" (original, not photocopy) bearing information as recommended by W.H.O. from the competent health authority in the country of manufacture (authenticated by the Jamaican Embassy or Jamaican Consulate in the country) certifying that the drug is approved for use and registered in that country and the conditions under which it may be sold in that country.

8) A statement showing:
   a. The countries in which the product is approved for sale other than the country in which it is manufactured.
   b. Any country in which the product has been refused registration and the reasons for refusal.
9) Any other relevant information.

There are draft standard operating procedures but these have not been fully implemented for use by the 5 technical PRAB staff (pharmacists) involved in drug registration. A flow chart of the process is available but could not be accessed. There is a standing multi-disciplinary Drug Registration Committee that functions in an advisory capacity for the approval of products and use classification. In addition, medical specialists are requested to conduct peer reviews. Criteria for granting marketing authorization include safety, quality, and efficacy. This is clearly stated on the application

form. Cost-benefit analysis does not play a role in the decision making process. Final approval of registration applications rests with the Director, Standards and Regulations on behalf of the Minister of Health.

Five drug schedules exist: narcotic, specialist only, prescription only, OTC pharmacy only, and OTC non-pharmacy. The first three schedules fall under the oversight of the Drug Registration Committee while the latter two are based on determination of the Pharmacy Council's List Committee (a sub-committee of Council members).

The PRAB does not consider patent status during the registration process, nor does it have any links with the patent office. The registration application form does, however, require that generic companies indicate the expiry date of the patent on the product being submitted for registration. In addition, the registration certificate reminds the registrant of a generic product to ensure that the innovator's patent has expired before placing the product on the market. Special data exclusivity clauses are applied.

If the application is approved, a Registration Certificate is issued. Certificates are color coded to differentiate between List 4 (prescription only), List 2 (over-the-counter products for sale only in pharmacies) and List 1 (over-the-counter products that may be sold in shops other than pharmacies). Manufacturers are not required to print the unique registration number on packages, package inserts or labels of their products marketed in Jamaica. There is no periodic renewal of registration but there are plans to possibly introduce this requirement in the near future. This could have implications for continued access to some low volume medicines. Currently, any adjustment to the product or to the site of manufacture requires re-registration of the product.

There is a one-time registration fee of J$5,000 (USD 58) per product that is collected by the PRAB and forwarded to the Ministry of Finance and the Public Service for deposit to the government's Consolidated Fund. An increase in the registration fee to J$30,000 is due to be gazetted shortly. This increase could have negative implications for access to low volume medicines.

During 2008, the PRAB received 342 applications for registration. As there were applications outstanding from 2007, in 2008 there were 408 applications processed, of which 40 were refused authorization. In addition, 531 other products (nutritional and herbal products, cosmetics, energy drinks, etc.) were evaluated.

There is no independent appellate body. Appeals can be lodged with the PRAB for referral to the Drug Registration Committee who will determine whether a review of the decision is warranted. Sometimes a peer review is done by an external specialist. There was no data available on the number of decisions appealed.

The average time taken and the maximum time for evaluation of an application for registration are 90 days for generic products, 120 days for innovator products and 60 days for fast-track products. There are no consequences if maximum time limits are exceeded. The fast-track system prioritizes applications in cases where drugs are required for life threatening illnesses, such as HIV/AIDS and cancer or for use in a national emergency.

The registration system has only recently been partially automated in keeping with attempts by the MOH to automate its import permit system. The list of registered drugs is updated regularly and hardcopies are provided to interested parties upon request.

Medicines quality control laboratory

The existing law does not provide for the establishment of a regulatory quality control laboratory. The legislation does, however, make provision for the appointment of analysts under the Evidence Act and the Food and Drug Act, sections 5.17 and 33. Additionally, under Section 24 of the Pharmacy Act quality testing of pharmaceutical products is allowed together with the issue of official results. The Government Chemist, a department of the Ministry of Health, is utilized for drug testing although it is not a dedicated drug testing facility. In addition, drug samples are referred for testing to the Caribbean Drug Testing Laboratory (CRDTL), which is housed at the same complex as the Government Chemist and has as its Director the head of the Government Chemist Department. The PRAB sends samples for testing to both the Government Chemist and the CRDTL in accordance with the CRDTL's quarterly testing schedule, in response to complaints and to facilitate the drug registration assessment process.

The functions of the Government Chemist Department are carried out by 13 full time and 1 part time administration/management staff, 4 full time degree level technical staff and 1 full time technician/assistant. The laboratory has to capacity to test samples of non-biological pharmaceutical products. It does not conduct testing of biological products, nor does it participate in the inspection of industry quality control laboratories, research or the training of analysts. The laboratory is reported to lack the necessary facilities, material and resources to conduct microbiological testing, which is therefore referred to the CRDTL, when required. It is equipped to do all types of chemical tests and assays, and identification by infra-red spectrophotometry, thin layer chromatography, UV-visible spectrophotometry and high-performance liquid chromatography. In addition to microbiological testing, disintegration tests, dissolution tests, and sterility tests are referred to the CRDTL. Neither laboratory has the capacity to conduct polarimetry, atomic absorption spectrophotometry, testing for pyrogens nor toxicity testing.

As it is a department of the Ministry of Health, the Government Chemist receives budgetary funding from the government of Jamaica's budget. The laboratory does not charge fees as it does not generally conduct testing for private clients. Details of the laboratory's budget for the past two years are outlined in Table 6.

Table 6: Government Chemist budget details (Million Jamaican $)

Budget section	Year: 2007/08	Year: 2008/09
Capital budget		5.0
Salaries	14.3	14.0
Miscellaneous	2.7	4.0
TOTAL	17.0	23.0

Data on samples submitted and/or collected and tested over the past two years are outlined in Table 7 and Table 8. The Government Chemist Department collects samples for testing on behalf of the CRDTL as part of a planned quality surveillance program for all countries in the CARICOM region. It is felt that the general level of substandard products in Jamaica is not known due to insufficient random sample testing. The Government Chemist laboratory does not participate in any proficiency testing scheme.

Table 7: Samples submitted/collected for testing

Test Requested By	Year: 2006/07	Year: 2007/08
Government drug inspectors		
Drug registration authority	34	25
Manufacturers	47	92
Private importers/wholesalers		
Public sector procurement agencies		
Hospitals, clinics		
Individuals		
Police/MOH**	32	20
TOTAL	113	137

** Investigation of breaches

Table 8: Government Chemist laboratory activity

Activities	Year: 2006/07	Year: 2007/08
Total number of drug products submitted for quality control (QC)*	81	117
Total number of drug products on which QC was performed	108	132
Total number of drug products that failed QC	12	13
Total number of products that passed the tests	96	119
Total number of samples on which QC could not be performed (because of lack of reagents, reference standards, procedures, expertise, equipment, etc.)**	13	15

* Excludes samples submitted for investigation of breaches

** Lack of equipment, procedures and reference standards most common

One main constraint in the registration process that was mentioned by the Director Standards and Regulations is the lengthy turnaround time for test results. The Government Chemist Department advised that a contributing factor to the turnaround time is failure to submit the required procedures and reference standards with the samples. Additional constraints being faced by the laboratory are insufficient funds, lack of equipment and lack of notice regarding submission of samples, which in turn has a negative impact on the ability to plan. The proficiency of the staff was cited as a major strength.

Financing of drug regulation

The PRAB is funded via the overall budget for the Standards & Regulations Division but there is no amount designated specifically for drug regulatory activities. PRAB was unable to provide information on estimated expenditure on regulatory activities for the past two years. The PRAB collects fees for import permits (J$200/10 items), Dangerous Drugs import permits (J$200 per item) and for drug product registration (J$5,000 per application). It is estimated that these fees amount to J$6 -7 million annually. These fees are remitted to the government's Consolidated Fund.

The Pharmacy Council is funded through the government's budget and fee collection. The Pharmacy Council levies a wide variety of fees for services provided. The Schedule of Fees levied by the Pharmacy Council is attached. The fees collected are retained by the Council to supplement government budgetary funding of its activities, as authorized under Sections 6 and 7 of the Pharmacy Act. Funding information for the Pharmacy Council for the past 3 years is outlined in Table 9. The Pharmacy Council stated that financial sustainability is a problem.

Table 9: Pharmacy Council Financial Activity (Million Jamaican $)

Financial Activity	Year: 2006/07	Year: 2007/08	Year: 2008/09
Government funding	5.0	8.2	10.2
Fees collected	13.0	15.2	17.8
Expenditure	21.4	19.9	20.7

The Ministry of Health has an internal audit system whereas the Pharmacy Council has none. Both entities are subject to external audit by the Auditor General's Department.

Human resources (including training)

The staff involved in drug regulation at the PRAB and the Pharmacy Council is documented in Table 10.

Table 10: Staff complement of regulatory entities

Staff category	Pharmaceutical & Regularity Affairs Branch	Pharmacy Council
Technical full time	14 pharmacists	7 pharmacists
Technical part time	0	0
Administrative full time	6	6
Administrative part time	0	0
TOTAL	**20**	**13**

Being under the Ministry of Health, and therefore part of central government, the PRAB does not have the authority to hire or fire personnel. The Pharmacy Council is a statutory body and has the power to hire and dismiss staff as stipulated in Section 5 of the Pharmacy Act.

The technical staff of both the PRAB and the Pharmacy Council has multiple tasks to perform within the sphere of drug regulation and is not dedicated to any one specific function. Both entities confirmed that there is a shortage of staff. The PRAB reported that a new structure is awaiting approval and the Pharmacy Council advised that its staff shortage is due to insufficient funds to recruit the additional staff that is needed. The general staff shortage is resulting in insufficient monitoring of unregistered dispensers/sellers of medicines e.g. church clinics, gas stations, supermarkets; slow revision of legislation to incorporate pharmacy technicians; inability to attend committee meetings; and delay in completing some important activities or those activities remaining undone.

Pharmacists' average annual net salaries in the private sector are, in some cases, the same as that of a government drug inspector but are most times higher, even with the same years of experience. Details of comparative salaries are outlined in Table 11. Both entities reported low staff turnover.

Table 11: Comparative salaries

Categories	Salary (Million Jamaican $)
Government drug inspector	1.3 – 1.4
Pharmacist working in a private retail pharmacy**	1.4
Head of production in a private pharmaceutical plant	2.5
Person releasing batches of finished product in a plant	2.0
Pharmacist working in a private hospital pharmacy	1.4
Pharmacist working with a distributor	1.8

All staff working in medicines regulation at the PRAB and the Pharmacy Council has a written job description. Staff is appointed based on defined level of education and experience requirements.

The Pharmacy Council has no written staff development plan and no training budget. No staff member has been trained in the last 3 years. The PRAB's staff development plan is part of the MOH's overall Manpower and Development Plan. The PRAB makes an annual budget submission to the MOH's Finance Division, which includes funding for training. It, therefore, has no separate training budget. Three PRAB persons were trained in the identification of illicit drugs by the Drug Enforcement Authority of the local Police Department. All but 2 PRAB persons, who are relatively new, have received GMP and quality control training over 5 years ago.

Infrastructure

Both the PRAB and the Pharmacy Council have dedicated office space, computers, printers, internet and e-mail access. Officers assigned to these entities utilize their own automobiles and are reimbursed with a motor vehicle upkeep and mileage. The PRAB has office space constraints and needs to find alternative methods of filing the voluminous dossiers submitted with registration applications. The Pharmacy Council recently relocated its offices and although this has resulted in additional office space it has been unable to refurbish the new offices due to limited funds.

Discussion

Jamaica is one of the 5 CARICOM countries with an operational registration system for medicines and a relatively rigorous drug regulatory system. This system is, however, working under major constraints such as

- shortage of human resources in the PRAB and the Pharmacy Council;
- inadequate structure of the Standards and Regulations Division;
- limited financial resources;
- inadequate office space and furniture;
- insufficient automation of the registration system;
- lack of remuneration to specialists requested to do peer reviews for drug registration;
- unavailability of procedures and reference standards;
- under equipped quality control laboratory; and
- no formal Appellate Body to support the registration system.

These constraints have contributed to some of the following reported and observed weaknesses in the country's drug regulation system:

- no National Medicines Policy or Implementation Plan;
- absence of strategic planning;
- no staff development or training plans;
- no internal audit of Pharmacy Council operations;
- poor record keeping systems;
- lack of cost data for drug regulation activities;
- lack of written code of conduct for external committees;
- multitasking of officers involved in drug regulation;
- inadequate inspections;
- limited training of staff in past 2 years;
- lack of trained distribution channel inspectors;
- no written guidelines or SOPs for distribution channel inspection;
- draft SOPs for registration not yet implemented;

- relatively long turnaround time for drug assessment and registration;
- no legal provisions for licensing of internet pharmacies or internet retailers;
- delay in enacting legislation to regulate pharmacy technician practitioners;
- delay in bringing church clinics, gas stations and supermarkets under stricter regulation;
- insufficient random sample testing;
- lengthy turnaround time for quality assurance testing; and
- inability to do comprehensive quality assurance of drugs sent for testing;

Within this context, the proficiency and experience of the PRAB and Pharmacy Council staff is a real strength. The existence of a registration system, albeit in need of improvement, and the availability of information on the registration and import permit processes on the MOH'S website are additional positive aspects. The intention to increase the medicines registration fee and to require re-registration might have a negative impact on the willingness of some suppliers to trade with Jamaica. This could in turn affect the price of products as well as the availability of some low volume medicines. Opportunities to further develop the existing medicines regulatory system and to improve its efficiency and effectiveness exist.

Recommendations

The brief assessment done in the context of this study does not provide the level of information required for developing detailed recommendations. However, for addressing some of the identified constraints in the short to medium term the following could be considered:

For the Ministry of Health:

- draft a National Medicines Policy and an Implementation Plan;
- ensure adequate funding of the medicines regulatory system;
- provide funds under the capital budget to properly equip the Government Chemist Department;
- treat medicines regulation as a cost centre to better assess cost efficiency;
- review and approve the restructuring of the Standards & Regulations Division;
- provide additional funding to the Pharmacy Council to undertake refurbishing of its offices and employment of additional officers;
- lobby with the Ministry of Finance and the Public Service for the PRAB to retain collected fees to assist with improving its systems e.g. automation of the drug registration system;
- with stakeholders, identify medicines regulatory specific training courses (e.g. inspection, prevention of counterfeit drugs, assessment of applications for registration), identify funding and participants.

For the Pharmaceutical and Regulatory Affairs Branch:

- prepare a strategic plan, including staff development;
- document in writing terms of reference, code of conduct and standard operating procedures for expert committees;
- implement an effective record-keeping and data retrieval system;
- include remuneration of peer review specialists in budget submission;
- implement draft SOPs for registration;
- fully automate the medicines assessment and registration system;
- establish a formal Appellate Body to support the registration system;
- shorten processing time for registration of medicines through automation;
- upgrade to online or CD-rom registration application to decrease space required for storage of dossiers;
- establish criteria for deciding whether a product is OTC, pharmacy only or prescription only;

- implement stricter GMP inspection;
- develop and implement notification system with Government Chemist Department to facilitate planning for testing of samples;
- submit required procedures and reference standards when sending samples for testing to Government Chemist Department; and
- increase the collection of samples for random testing.

For the Pharmacy Council:

- prepare a strategic plan, including a staff development plan;
- implement an internal audit system;
- prepare a training budget;
- document written guidelines or SOPs for distribution channel inspection;
- enact regulation of internet pharmacies;
- enact regulation of pharmacy technicians;
- implement licensing and strengthen monitoring of church clinic pharmacies and entities selling OTC medicines.

Montserrat: Country Report

Country Background[24]

Montserrat is located between Guadeloupe and Saint Kitts and Nevis. The island covers a surface area of 102 km². It is of volcanic origin and after eruption of the Soufriere Hills Volcano in 2000 and the loss of Plymouth and other important urban and agricultural areas, more than half of the 12,000 inhabitants left Montserrat. For 2008 the total population has been estimated to be 4,875. The Gross National Product was EC$ 24,692/capita in 2007.

Montserrat is a British overseas territory with its own government, consisting of the Chief Minister, 3 other elected Ministers, the Governor (representing the Queen), the Attorney General and the Finance Secretary.

Within the Ministry of Education, Health, and Community Services, headquarters are responsible for policy and planning and review of legislation. The Department of Health is providing primary and secondary health care and facilitates access of the population to tertiary care in other countries in the region. There are four primary care clinics. Secondary care is provided in the 30-bed Glendon Hospital.

The leading causes of death are hypertension, diabetes, chronic respiratory diseases, and malignant neoplasms. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 76.9 years 81.5 years	2008
Infant mortality rate (per 1000 life births)	23.3	2007
Maternal mortality ratio (per 100,000 live births)	0	2007

Public health care is financed through the government budget and user fees. Total recurrent expenditure during 2005 was USD 4.6 million.

Pharmaceutical sector context

Montserrat does not have National Medicines Policy nor is generic prescribing and dispensing regulated. In practice, generic substitution is done. The OECS/PPS essential medicines list is used as a reference for the public sector. Provision of medicines in the public sector is highly subsidized with a large part of the population being exempt from payments (e.g. prisoners, pregnant women, children, patients over 60 years, medicines for chronic diseases).

There are no medical or pharmacy training institutions.

[24] Information in this section is sourced from 'Health in the Americas - Basic Indicators 2008' (PAHO 2008), 'Health in the Americas - Country Reports' (PAHO 2007), and telephonic interviews completing the assessment instrument.

Pharmaceutical manufacturing is not present in the country. There are no private pharmaceutical importers or wholesalers. The public sector is using the pooled procurement mechanism for pharmaceutical supplies provided by OECS/PPS. For additional procurement supplies are being sourced mainly from the United Kingdom and Barbados.

There is one private retail pharmacy importing its own products. Some medicines are also being sold in supermarkets. There are 5 pharmacists, 3 working in the public sector and 2 in the private sector.

Legislative Provisions

Existing medicines legislation: respondents were not aware of existing medicines legislation.

Pharmacists are registered at the Magistrate Court and their registration is published in the government gazette.

Conclusion: There is a clear lack of medicines legislation which may affect quality, efficacy, and safety of medicines - particularly those circulating in the private sector.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section are reflecting the outcome of interviews conducted with the Chief Pharmacist.

Organizational structure

There is no National Medicines Regulatory authority and no drug inspectorate.

Licensing

Licensing of Premises
Premises that deal with pharmaceuticals are only being licensed as businesses.

Import Permits
Import permits are issued for controlled drugs only.

Inspection and Surveillance

There are no provisions for pharmaceutical inspections, and they are not being conducted.

No examples were given for counterfeit medicines.

Product Assessment and Registration

This function is not foreseen in the legislative system.

For the public sector, OECS/PPS is expected to employ adequate measures that ensure quality of medicines procured through that system.

Medicines quality control laboratory

Montserrat is one of the 14 countries that established and are funding the Caribbean Regional Drug Testing Laboratory in Jamaica. From time to time medicines from the public sector suspected to be substandard are sent to this laboratory for testing. This happens approximately 3 times per year.

Financing of drug regulation

There are no special funds for financing of drug regulation.

Human resources (including training)

There are no public sector staff members assigned to drug regulatory activities.

Ministry of Health pharmacy staff did not attend any specific training related to regulatory functions.

Discussion

Montserrat is one of the 10 CARICOM member states that do not have an operational registration system for medicines. As is the case for the other 6 CARICOM member states that are at the same time members of the Organization of Eastern Caribbean States (OECS) quality assurance for medicines provided through the public health sector has been largely delegated to the OECS/PPS that conducts pooled procurement of pharmaceuticals for OECS members. However, the quality of medicines imported by the private sector is not controlled.

Considering the small market size and the human and financial resources requirements it might not be viable for Montserrat to develop and implement legislation that requires in-country assessment of product dossiers for issuing of marketing authorizations.

Montserrat could benefit from a regional assessment/registration system that would improve on the current quality assurance measures provided through OECS/PPS and also extend to the private pharmaceutical sector.

Recommendations

The brief assessment done in the context of this study does not provide the level of information required for developing detailed recommendations. However, for addressing some of the identified constraints in the short to medium term the following could be considered:

For the Government / Ministry of Health

- Develop a National Medicines Policy stating government commitment to ensuring safety, efficacy and quality of medicines available in the country.
- Draft a Medicines Bill that provides for (regional) marketing authorization, scheduling of medicines, and a drug inspectorate
- Seek support from OECS/PPS for conducting pharmaceutical inspections of public and private sector facilities where medicines are kept and sold.

St Kitts & Nevis: Country Report

Country Background[25]

The federation of St. Kitts and Nevis consists of the islands of St. Kitts with a surface area of 176.12 km² and Nevis with a surface area of 93.2 km². The islands are located west of Antigua and Barbuda and northwest of Montserrat. The total population was estimated to be 48,781 in 2005, 36,676 living on St Kitts and 12,105 on Nevis.

Through the constitution Nevis is guaranteed full autonomy and the island is governed by the Nevis Island Administration headed by the Premier. St Kitts is the seat of the federal government headed by the Prime Minister. Inter-island transport is mainly through 6 ferries and transit time is 40 minutes.

The country's Gross National Product was USD 12,440/capita in 2006 (ppp). The main sectors contributing to the Gross National Product are services (including tourism), manufacturing and construction.

Public policy states that all residents of St Kitts & Nevis should have equitable access to quality health care. Priority areas identified in the 2006-2011 National Health Plan include HIV/AIDS/STIs, chronic non-communicable diseases and family health services. Priority areas are quite similar to those identified for the Caribbean Cooperation in Health Phase III.

Each of the two islands has a Ministry of Health in charge of public health services. Regular meeting between the two Ministers are conducted to ensure that policies are harmonized. In St Kitts there are 11 community clinics, and in Nevis 6. Secondary and tertiary care is being provided in the Joseph N. France General Hospital and 2 former cottage hospitals in St Kitts and the Alexandra Hospital in Nevis. There are no private hospitals. In the public sector services are either highly subsidized or provided free to patients.

During the period 2002-2004 the 5 main causes of death were cerebrovascular diseases, ischemic heart disease, septicemia, influenza and pneumonia, and cardiac arrest. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 70.1 years 76 years	2008
Infant mortality rate (per 1000 life births)	16.2	2001 - 2005
Maternal mortality ratio (per 100,000 live births)	2 deaths reported in 2003	2001 - 2005

[25] Information in this section is sourced from 'Health in the Americas - Basic Indicators 2008' (PAHO 2008), 'Health in the Americas - Volume II - Countries' (PAHO 2007), and the completed assessment instrument.

Pharmaceutical sector context

St Kitts and Nevis does not have a National Medicines Policy. The OECS/PPS essential medicines list is used as a reference for the public sector. National treatment guidelines exist for some priority health conditions. The use of generic medicines is neither actively promoted nor is it regulated. However, prescription forms are designed in a way that the prescriber needs to indicate that substitution should not be done.

Medical schools are 'offshore' campuses of American universities. One of these offers pharmacy training. However, pharmacists are usually being trained in neighboring countries. There are approximately 12 pharmacists in St Kitts (8 in public and 4 in private sector), and around 5 in Nevis. Auxiliary pharmacy staff is being trained on the job.

Pharmaceutical manufacturing is not present in the country. There are no private sector importers or wholesalers. The local retail pharmacies import individually and also sell certain OTC medicines to shops. For the public sector Central Medical Stores is procuring pharmaceuticals mainly through the pooled procurement mechanism managed by OECS/PPS.

There are 5 private retail pharmacies on St Kitts (numbers for Nevis were not available). In the public sector pharmaceutical services are provided in 7 health centers / hospital pharmacies.

Legislative Provisions

Existing medicines legislation includes the Medical Act of 1938 and the Drug (Prevention and Misuse) Act of 1986. A Pharmacy Bill has been available since 2000, but a copy was unfortunately not available to us.

Apart from the Drug (Prevention of Misuse) Act, there are no legal provisions available that regulate the marketing and distribution & sale of medicines or the pharmacy profession. Pharmacists are, however, registered with the Medical Board under the Ministry of Health (the Medical Act provides for registration of chemists and druggists).

Conclusion and recommendations: There is a clear lack of medicines legislation which may affect quality, efficacy, and safety of medicines - particularly those circulating in the private sector. The government should make it a priority to pass the Pharmacy Bill.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section are reflecting the outcome of interviews conducted with respondents to the assessment instrument.

Organizational structure

There is no National Medicines Regulatory authority and no drug inspectorate.

Licensing

Licensing of Premises
Premises that deal with pharmaceuticals are only being licensed as businesses.

Import Permits
Import permits are issued for narcotics and controlled drugs only.

Inspection and Surveillance

There are no provisions for pharmaceutical inspections, and they are not being conducted.

No examples were given for counterfeit medicines. Respondents are, however, aware of the threat and did attend an orientation session conducted by OECS/PPS.

Product Assessment and Registration

This function is not foreseen in the legislative system.

For the public sector, OECS/PPS is expected to employ adequate measures that ensure quality of medicines procured through that system.

Medicines quality control laboratory

St Kitts and Nevis belong to the 14 countries that established and are funding the Caribbean Regional Drug Testing Laboratory in Jamaica. From time to time medicines from the public sector are sent to this laboratory for testing (mainly through OECS/PPS).

Financing of drug regulation

There are no special funds for financing of drug regulation.

Human resources (including training)

There is no public sector staff assigned to medicines regulatory activities. Quality assurance activities are being conducted within the context of central medical stores operations.

Public sector salaries for pharmaceutical professional staff are lower than in the private sector.

Ministry of Health pharmacy staff did not attend any specific training related to regulatory functions.

Discussion

St Kitts and Nevis is one of the 10 CARICOM member states that do not have an operational registration system for medicines. As is the case for the other 6 CARICOM member states that are at the same time members of the Organization of Eastern Caribbean States (OECS) quality assurance for medicines provided through the public health sector has been largely delegated to the OECS/PPS that conducts pooled procurement of pharmaceuticals for OECS members.

The quality of medicines imported by the private sector is not controlled at all. Except for controlled medicines there are no formal schedules that establish which products are prescription-only, pharmacy- only or for general sale.

Considering the small market size and the human and financial resources requirements it might not be viable for St Kitts and Nevis to develop and implement legislation that requires in-country assessment of product dossiers for issuing of marketing authorizations.

The country could benefit from a regional assessment/registration system that would improve on the current quality assurance measures provided through OECS/PPS and also extend to the private pharmaceutical sector.

Recommendations

The brief assessment done in the context of this study does not provide the level of information required for developing detailed recommendations. However, for addressing some of the identified constraints in the short to medium term the following could be considered:

For the Government / Ministry of Health

- Develop a National Medicines Policy including government policy and commitment towards regulation of medicines
- Develop a policy implementation plan
- Ensure processing of the Pharmacy Bill
- Support training of drug inspectors

St. Lucia: Country Report

Country Background

Saint Lucia is an island nation in the eastern Caribbean Sea on the boundary with the Atlantic Ocean. Part of the Lesser Antilles, it is one of the Windward Islands and is located north/northeast of the islands of Saint Vincent and the Grenadines, northwest of Barbados and south of Martinique. It has a land area of approximately 620 km^2 and had a total population of 170,000 in 2008. Its capital is Castries where more than one-third of the population lives.

In 2007, St. Lucia had a Gross Domestic Product of USD 960 Million, which translated into USD 8,500 per capita (PPP).[26] The country's economy is based mainly on offshore banking, tourism, manufacturing and agriculture.

Primary health care services are mainly provided at the 34 health centers and 2 district hospitals. In addition to routine general medicine clinics, special services are offered in obstetrics/gynecology, pediatrics, surgery, sexually transmitted infections and mental health. Special clinics and basic services are offered to diabetic and hypertensive clients at the primary care facilities. Secondary and specialized care and services are provided at the 3 general hospitals and the psychiatric hospital. Although clients may seek care at any facility, the administration and management of health facilities are based on the catchment population.

The private health care market in St. Lucia is comprised of many medical and dental practitioners some of whom work in both the public and private sectors. Nurses are also employed in the hotel industry and in private home nursing care. The main types of health insurance are private health insurance for individuals and groups, and coverage by the National Insurance Scheme.

The main causes of death are circulatory system diseases, neoplasms, and injuries due to violence and accidents. External causes of death are more than three times greater for males than females. In 2008, the life expectancy of males was 72.0 years while that for females was 75.8 years. In 2005, St. Lucia had an infant mortality rate of 15 per 1000 live births. Information on the country's maternal mortality rate was not available.

Primary sources of funding for the Government health sector recurrent expenditure comprise taxes and user fees. The National Insurance Scheme makes an annual contribution to the consolidated fund to cover in-patient hospital expenses. St Lucia's health sector receives technical and financial assistance from several external agencies and governments. The execution of many major capital projects has relied heavily on international aid. In 2005, health expenditure was 10.3% of total government expenditure. Total health expenditure per capita was US$421 in 2006. Private health expenditure was 43.8% of total health expenditure in 2005. Of this, 94.3% was paid out-of-pocket.

Pharmaceutical sector context

St. Lucia has no National Medicines Policy. There is an Essential Medicines List (information on the most current edition was not supplied) but there is no National Medicines Formulary. The formulary provided by OECS/PPS is used. The utilization of the Essential Medicines List is mandatory within the public sector but not in the private sector. There are official national treatment guidelines for

[26] Health Situation in the Americas: Basic Indicators 2008 (PAHO 2008).

priority health conditions. The drug law makes provision for different schedules for pharmaceutical products, as follows:

- First Schedule: Controlled Drugs
- Second Schedule: Over the Counter Medicines and Diagnostics
- Third Schedule: Pharmacist Assisted Drugs
- Fourth Schedule: Prescription only drugs

The assignment of a pharmaceutical product to a particular schedule is based on drug classification, pharmacological effect, dosage strength and dosage form.

There are provisions under the law promoting the use of generic medicines. Generic prescribing is mandatory in both the public and private sectors.

The pharmaceutical delivery system is comprised of 3 government hospital pharmacies, 25 private for-profit retail pharmacies and 33 government health centre pharmacies. Only the private sector pharmacies are required to be licensed.

At the end of 2008, St. Lucia had 70 registered pharmacists and no formally trained pharmacy auxiliary personnel. There is no local training of pharmacists. There were 108 licensed physicians, 28 dentists and 14 veterinarians practicing in St. Lucia in 2008. There is no local training facility to train medical personnel.

There are 5 pharmaceutical wholesalers/distributors and no locally based pharmaceutical manufacturer. The OECS/PPS has responsibility for procurement of pharmaceuticals for the country. Total government pharmaceutical expenditure was ECD 3.2M (USD 1.6M approximately) in 2007/2008. All vaccines used in the public sector are procured through PAHO's Revolving Fund. A National Procurement Committee is in place to coordinate the procurement of biomedical equipment. Importation, storage and distribution of pharmaceuticals on behalf of the public sector is done by Central Procurement.

Legislative Provisions

Existing medicines legislation includes the Pharmacy Act No. 8 of 2003; the Pharmacy (Forms and fess) Regulations 2006 and the Pharmacy Regulations 2007.

Administration of medicine legislation is done by the Pharmacy Council established under the Pharmacy Act, 2003. The Council is responsible for regulating the pharmacy practice including registration of pharmacists, pharmacies and sellers of poisons.

Pharmacy Council is empowered to collect and utilize fees to perform regulatory functions hence exercising some level of autonomy in execution of drug regulatory functions.

In as far as delegation of drug regulatory functions is concerned, the Pharmacy Act, 2003 provides for delegation of exercise of any of the powers of the Pharmacy Council or performance of any duty vested on it under the Act to either a Committee or to a member of the Pharmacy Council.

Table 1 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 1 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of:		
Manufacturers	No	
Importers	No	
Wholesalers/Distributors	No	
Retailers/dispensing outlets	Yes	
Other	Yes	Authorized sellers of poisons
Market Authorization	No	
Inspection of premises and manufacturing sites	Yes	
Establishment of Quality Control Laboratory	No	but St Lucia is signatory to the Agreement establishing the CRDTL
Control of clinical trials	No	
Control of counterfeit medicines	No	
Adverse drug reaction monitoring	No	
Control of product promotion and advertisement	No	
Provision for medicines distribution schedules/categories	No	
Control of narcotics and psychotropic substances	Yes	
Scope of regulated products	Yes	
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	
Power to make regulations	Yes	Vested on the Minister upon consultation with the Pharmacy Council
Regulations made under the Act	Yes	

Licensing of manufacturers, importers, wholesalers, distributors, retail pharmacies:
The Pharmacy Act, 2003 provides for registration of pharmacists, pharmacies, and authorized seller of poisons, regulation of the supply of drugs and poisons to the public and for related matters. In as far as the practice of pharmacy is concerned, it includes (a) the supply of drugs or poisons in accordance with a prescription given by a duly registered doctor, dentist, veterinarian, or any other authorized person; (b) the compounding, packaging, labeling, storage and dispensing of drugs; (c) the provision of non-prescription drugs; (d) the provision of health care aids and devices; and (e) the provision of information related to drug use. Provisions do not include wholesale business.

One of the functions of the Pharmacy Council provided for under section 13 of the Act is to advise the Minister on the management and control of the pharmaceutical industry in general, including importation of drugs and poisons and their wholesale to private pharmacies.

There are, however, no specific provisions for issuance of license for manufacture, importation, wholesale, market authorization of medicines, control of clinical trials and counterfeit products, control of product promotion and advertising and safety monitoring of products.

Quality Control is done using the Caribbean Regional Drug Testing Laboratory which has been established under an Agreement signed by 14 countries namely Barbados, Guyana, Jamaica, Trinidad and Tobago, Antigua and Barbuda, Belize, Bahamas, British Virgin Islands, Dominica, Grenada, Montserrat, St Christopher-Nevis-Anguilla, St Lucia and St Vincent.

Medicines distribution categories are the First, Second, Third and Fourth schedules: controlled drugs, over the counter medicines and diagnostics, pharmacist assisted drugs and prescription only drugs respectively.

Scope of products regulated includes drugs and poisons, narcotic drugs and psychotropic substances.

Administrative and legal sanctions include general penalty under the Pharmacy Act, for unspecified offences whereby an offender is liable upon conviction to a fine not exceeding five thousand EC dollars or to imprisonment for a term not exceeding one year or to both. For specified offences, an offender is liable on conviction to a fine of five thousand dollars or to imprisonment for a term not exceeding one year or both.

Power to make regulations is vested on the Minister, after consultation with the Pharmacy Council.

Available regulations include the Pharmacy (Forms and fess) Regulations 2006 and the Pharmacy Regulations 2007.

Conclusion and recommendation: There is need to review the functions of the Pharmacy Council in order to provide for licensing and inspection of wholesalers/distributors and manufacturers (although there is currently no industrial pharmaceutical manufacturing). It is important to ensure that all the core medicines regulatory functions namely licensing the manufacture, importation, wholesale, market authorization of medicines circulating in the market, control of clinical trials and counterfeit products, control of product promotion and advertising and safety monitoring of products, are provided for. However, any law requiring registration of medicines should make provision for the possibility to delegate part of the responsibilities related to this function to a (sub)-regional authority.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section reflect responses on the self-administered questionnaire completed by the Chief Pharmacist with input from the Medical Supplies Officer, Ministry of Health.

Organizational structure

There is no dedicated medicines regulatory body charged with responsibility for all critical regulatory functions. Hence, there is no licensing of pharmaceutical manufacturers, pharmaceutical importers or pharmaceutical wholesalers. In addition, there is no product assessment and registration system, or Good Manufacturing Practices (GMP) inspection or inspection of distribution channels.

The Pharmacy Council is an autonomous body responsible for registering private retail pharmacies, pharmacists and authorized sellers of poisons under the Pharmacy (Forms and Fees) Regulations 2006.

Licensing

Licensing of Premises

The Pharmacy Council issues certificates of registration for pharmacies in the private sector and for authorized sellers of poisons. Renewal of registration is required annually. Lists of licensed pharmaceutical establishments are not published. However, the Pharmacy Council website provides information on registered pharmacists. Conditions and guidelines for registration of pharmacists, pharmacies and registration of sellers of poisons are also published on the website (www.pharmacycouncilslu.org).

Import Permits

There is no requirement for importers to apply for an import permit to authorize the importation of pharmaceutical products. There appears to be no monitoring of imports generally.

Inspection and Surveillance

There are no GMP inspections or inspections of distribution channels. A Drug Inspector assigned to the Office of the Chief Pharmacist is yet to be appointed (the Pharmacy Act provides for appointment of Pharmacy Inspectors by the Minister of Health).

There was no indication whether the country experiences problems with counterfeit medicines. As there is no stringent monitoring of imports and inspections appear to be minimal and are restricted to retail pharmacies, the chances of identifying counterfeit products are relatively low and St. Lucia is at risk.

Product Assessment and Registration

There is no operational product assessment and registration system in St. Lucia. There was no indication of the measures taken to ensure efficacy, safety and quality of pharmaceutical products marketed in St. Lucia, other than those provided by OECS/PPS in the context of pooled procurement for the public sector.

There was no available data on the total number of pharmaceutical products for human use being marketed in the country or the proportion of marketed pharmaceutical products in the country that are generic products.

The information on the availability of 29 medicines included in the survey basket is summarized in Table 2. It has to be noted that the information relates to what is available in the public sector. Therefore, the majority of products had only one manufacturer's product available in the market.

Table 2 - Availability of basket medicines

Total number of drugs in basket	29
Number with 3 alternative products	1
Number with 2 alternative products	2
Number with 1 product	25
Number where only the originator brand is available	5
Number with no listed supplier	1

Medicines quality control laboratory

It was reported that random testing of medicines in the public sector system is done annually through the OECS/PPS. In addition, there is quality control of samples during tender evaluation and samples are collected from distributors in accordance with the CRDTL's quarterly testing schedule.

Financing of drug regulation

There is no specific budget allocation by the government for medicines regulation. However, the Pharmacy Council receives a government subvention of EC$ 8,000/month.

Human resources (including training)

There was no staffing information provided for the Office of the Chief Pharmacist. The Pharmacy Council is currently operating with 4 appointed members (6 foreseen) with the Chief Pharmacist as Secretary.

Discussion

The lack of a drug regulatory body and the consequent lack of licensing, inspection or market authorization poses great concerns as the safety, efficacy and quality of drugs is not being properly monitored. The OECS/PPS only purchases pharmaceuticals from pre-qualified suppliers but once the medicines arrive in St. Lucia there are no formal mechanisms to ensure that they are meeting quality standards. In addition, medicines are being imported by private sector wholesalers with no monitoring of the product, the storage conditions or the conditions of distribution. Based on the foregoing, it can be concluded that St. Lucia is at risk for exposure to counterfeit and substandard drugs.

Recommendations

The Ministry of Health needs to develop a National Medicines Policy. The Office of the Chief Pharmacist supported the idea of a harmonized system for medicines regulation for the CARICOM region. Priority regulatory issues that would benefit from regional harmonization were deemed to be medicines registration, development of essential medicines lists, inspection of manufacturing premises, and data collection on medicines activities such as sales and distribution.

The government should attempt to determine which aspects of medicines regulation should be implemented locally and which via regional collaboration in order to address the deficiencies that currently exist. The attendant legislative framework must also be put in place.

St Vincent and the Grenadines: Country Report

Country Background[27]

Saint Vincent and the Grenadines (SVG) is located at the southern end of the Windward Islands, between Saint Lucia and Grenada. The country comprises the island of Saint Vincent and seven smaller inhabited islands and islets that together constitute the Grenadines; altogether, the islands cover 349 km^2. The Grenadines extend south 45 miles and include the inhabited islands of Bequia, Mustique, Myreau, Canouan, Union Island and Palm Island. Forty-four percent (44%) of the population resides in urban and sub-urban communities. Most of the land area and 91% of the country's 2008-estimated population of 121,000 are on the mainland St. Vincent. Mainland St. Vincent is linked to the Grenadines by sea as well as air transport. Docking facilities are available on all inhabited Grenadine Islands, while airport facilities are present on four islands.

In 2005, SVG had a Gross National Product of USD 430 Million, which translated into USD 3,613 per capita (USD 6,220 PPP[28] in 2006). The country's economy is based mainly on agriculture and tourism, with a small manufacturing industry, which is mostly for export. The main export product is bananas.

Health services are offered at the primary and secondary levels. Thirty-eight (38) health centers in 9 health districts facilitate the delivery of primary care. Each health center is required to have a minimum complement of a staff nurse/midwife, a nursing assistant and a community health aide. The health team also includes the district medical officer, environmental health officer, family life educator, social worker and pharmacist. Secondary care is offered at Kingstown General Hospital, a 209-bed referral hospital offering various categories of specialist care. Acute care, not requiring specialist intervention, is also provided by 5 rural hospitals with a combined capacity of 58 beds. Acute and chronic psychiatric care is provided through the Mental Health Centre, which has the capacity to house 120 inpatients.

All public health care facilities are owned and operated by the Government through the Ministry of Health, who sets the standards for care and regulates practice within the health sector. The Ministry of Health, and more particularly the Chief Medical Officer, guides the operations of private health care facilities. Auxiliary diagnostic services are offered mainly through the main referral hospital. There are two privately operated clinical laboratories, which offer services to the public.

The main causes of death are diseases of the circulatory system, cancers, external causes and communicable diseases (mainly HIV/AIDS). In 2008, the life expectancy of males was 69.7 years while that for females was 74.0 years. In 2006, SVG had an infant mortality rate of 17 per 1000 live births. Information on the country's maternal mortality rate was not available.

Health care services in SVG are financed through government expenditure on publicly provided services, out-of-pocket payments and private health insurance. The National Health Insurance Program (NHIP) was created to provide access to a comprehensive package of health care services. During the period 2001-2005 public health expenditure was 3.86% of the country's GDP.

[27] Information in this section is based on the assessment instrument and 'Health in the Americas - Country Reports' (PAHO 2007)

[28] Source: 'Health in the Americas - basic indicators 2008' (PAHO 2008)

Pharmaceutical sector context

SVG has no National Medicines Policy. Additionally, there is no Essential Medicines List and no National Medicines Formulary. The country is guided by the list produced by the OECS/PPS and by the British National Formulary. There are partial national treatment guidelines for HIV/AIDS and *H. Pylori*.

There is legislative provision for different schedules for pharmaceutical products, which are prescription only, controlled substances, medicines that do not need to be sold in a pharmacy, and poisons. Safety, risk and the ability to be used by non-professionals are the criteria used to assign pharmaceutical products to the different schedules. There are no legislative provisions promoting the use of generic medicines.

There is no strategic plan for medicines regulation but the Pharmacy Council and the MOH Drug Inspector prepare annual work plans. There is, however, no monitoring or evaluation system carried out to assess performance of the medicines regulatory functions.

The pharmaceutical delivery system is comprised of 6 government hospital pharmacies, 15 private for-profit retail pharmacies and 38 government health center pharmacies. Only the private sector pharmacies are required to be licensed.

At the beginning of 2009, SVG had approximately 43 registered pharmacists and no formally trained pharmacy auxiliary personnel. Two persons were reported to be receiving pharmacy training overseas. There is no local training of pharmacists. There were 94 licensed physicians practicing in SVG in 2008. There is an off-shore training facility for medical doctors. In the same year, there were 17 dentists, 9 family nurse practitioners and 9 veterinarians also licensed to practice.

Data on the total number of importers and wholesalers of medicines were unavailable. There is no local manufacturer of pharmaceutical products. The Central Medical Stores has responsibility for procurement of pharmaceuticals. SVG procures all drugs and equipment from the OECS/PPS. Vaccines are accessed through the PAHO revolving fund. SVG imported EC$4 M (USD2 M) worth of pharmaceuticals in 2008. Total government pharmaceutical expenditure was EC$4 Million (USD2 Million) for the financial year 2007/8.

Legislative Provisions

Existing medicines legislation includes the Pharmacy Act No. 54 of 2002, the Drug (prevention of misuse) Act of 1998, the Chemical (precursor chemicals) Act No. 2 of 2003, the Penicillin (control) Regulation of 1947, and the Sulphonamide Regulation of 1949 (amended 1991). Only the Pharmacy Act could be made available to us.

Administration of medicine legislation is done by the Pharmacy Council established under section 3 of the Pharmacy Act, 2003. The Council is responsible for regulating the pharmacy profession, the practice of pharmacy and pharmaceutical products.

The Pharmacy Council is empowered to collect and utilize fees to perform regulatory functions hence exercising some level of autonomy in execution of its regulatory functions

In as far as delegation of drug regulatory functions is concerned, the Pharmacy Act, 2002 provides for delegation of the Pharmacy Council functions to a Committee as it considers necessary.

Table 1 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 1 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of: Manufacturers	Yes	
Importers	Yes	
Wholesalers/Distributors	Yes	
Retailers/dispensing outlets	Yes	
Other	Yes	Sellers of poisons
Market Authorization	Yes	
Inspection of premises and manufacturing sites	Yes	
Establishment of Quality Control Laboratory	(Yes)	Indirectly through being signatory to the Agreement establishing the CRDTL
Control of clinical trials	No	
Control of imports	Yes	
Control of counterfeit medicines	No	
Adverse drug reaction monitoring	No	
Control of product promotion and advertisement	No	
Provision for medicines distribution schedules/categories	Yes	
Control of narcotics and psychotropic substances	Yes	
Scope of regulated products	Yes	
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	
Power to make regulations	Yes	Vested on the Minister upon recommendations of the Pharmacy Council
Regulations made under the Act	?	not up to date; decision on draft submitted in 2006 outstanding

Licensing of manufacturers, importers, wholesalers, distributors, and retail pharmacies: The Pharmacy Act, 2002 provides for registration of pharmacists, pharmacy students, pharmacist's assistants, pharmacies and pharmacy owners. It also provides for issuance of licenses for manufacture, importation and wholesale.

Marketing Authorization for all medicines imported for the purpose of sale is required in Section 27 (6). The authority to register medicines is the Pharmacy Council.

Quality Control may be done using the Caribbean Regional Drug Testing Laboratory which has been established under an Agreement signed by 14 countries namely Barbados, Guyana, Jamaica, Trinidad

and Tobago, Antigua and Barbuda, Belize, Bahamas, British Virgin Islands, Dominica, Grenada, Montserrat, St Kitts and Nevis, St Lucia and SVG.

Medicines distribution categories are divided in 4 lists: List 1 comprises 'free sale' OTC products; List 2 contains drugs that require an import license issued by the Council; List 3 includes poisons, and List 4 consists of prescription only medicines.

The scope of products regulated under the Pharmacy Act extends to drugs for human and animal use, and poisons.

Administrative and legal sanctions are so far restricted to offences defined in Section 35 of the Pharmacy Act.

Power to make regulations is vested on the Minister, after consultation with the Pharmacy Council. Apparently regulations are not yet updated and in line with the new Pharmacy Act.

Conclusion and recommendation: The Pharmacy Council has been mandated to regulate both the profession and the products, which might be appropriate for a small country like SVG. With regard to registration of medicines an amendment is recommended that would provide authority to the Pharmacy Council to delegate related functions to a (sub-)regional body that might be established.

There are no specific provisions for issuance of license for control of clinical trials, the prohibition of counterfeit products, control of product promotion and advertising and adverse drug reaction monitoring of products. It is important to ensure that all the core medicines regulatory functions are provided for.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section reflect responses on the self-administered questionnaire completed by the Chief Pharmacist, who is also the Chairperson of the Pharmacy Council, with input from the Drug Inspector, Ministry of Health.

Organizational structure

The legislation does provide for the establishment of a Pharmacy Council, which could be interpreted as being the National Medicines Regulatory Authority. It was reported that the Ministry of Health coordinates drug regulation centrally at the national level. The SVG Pharmacy Council, appointed by the Minister of Health and the Drug Inspector at the Ministry of Health have responsibility for the existing drug regulatory functions. There is no support through Expert Committees, but the Pharmacy Act provides for establishment of committees under the Pharmacy Council.

Licensing

The SVG issues licenses for pharmaceutical imports, wholesalers/distributors, pharmacies, pharmacists, pharmacy owners, pharmacy students, and pharmacy assistants. Licensing of authorized sellers of poisons is provided for in the law but not yet being implemented.

The legislation specifies that any establishment operating as a pharmaceutical establishment must be under the charge of a registered pharmacist.

Inspection and Surveillance

There is no organization responsible for conducting Good Manufacturing Practices (GMP) inspections. This may be due to the lack of local manufacturing of pharmaceuticals. A Drug Inspector assigned to the Ministry of Health conducts inspection of distribution channels.

Under the law, obstruction of a Drug Inspector attracts a fine of EC$2,500 or up to 12 months in jail. Similar sanctions are provided for violations of any other provision of the Pharmacy Act. There were reported to be 4 offences during the past three years, which resulted in the issuing of warning letters by the Pharmacy Council.

It is not known whether SVG experiences problems with counterfeit pharmaceutical products. There was one reported incident of a substandard pharmaceutical product, namely, Nelfinavir, which was recalled. There is no information on problems with the control of imports not purchased through formal distribution channels such as internet purchasing and suitcase traders.

Product Assessment and Registration

The product assessment and registration system provided for in the Pharmacy Act is not yet operational. The lists foreseen in the legislation to categorize medicines according the 4 distribution schedules have not yet been published.

There are no measures taken in the private sector to ensure safety, efficacy and quality of the pharmaceutical products available in the country besides licensing of premises. Within the public sector, the only measure taken is centralized procurement by the Central Medical Stores mainly using the OECS/PPS pooled procurement services.

There was no available data on the total number of pharmaceutical products for human use being marketed in the country or the proportion of marketed pharmaceutical products in the country that are generic products.

The information on the availability of the 29 medicines included in the survey basket was not provided. There was, however, data on the availability of 27 anti retroviral (ARV) medicines. In relation to current suppliers, all items were being procured from only one supplier, except for 2 items that were not being procured – IDV 400mg and 3TC/D4T/NVP 150mg/40mg/200mg. Ten of the sole source items were from the originator of the product. Five of the items were obtained through donations from Brazil and one item was procured through the Clinton Foundation. Information was also provided on the number of possible suppliers for each of the 27 listed items, which is summarized in Table 2.

Table 2 – Potential availability of ARV medicines

Total number of drugs in basket	27
Number with 5 alternative suppliers	5
Number with 4 alternative suppliers	0
Number with 3 alternative suppliers	4
Number with 2 alternative suppliers	10
Number with 1 available supplier	7
Number where only the originator brand is available	5
Number of items without an identified supplier & not being procured	1

Medicines quality control laboratory

The existing law does not provide for the establishment of a regulatory quality control laboratory. There is no local testing of pharmaceutical products. It is not clear whether it is the Pharmacy Council, the Ministry of Health's Drug Inspector or both that are responsible for collection of samples to be sent to the Caribbean Regional Drug Testing Laboratory (CRDTL) in Jamaica for testing. The OECS/PPS sends samples to the CRDTL for testing during tender evaluation and also has a minilab to do limited testing of random samples.

Financing of drug regulation

There is no specific budget allocation by the government for drug regulation. These activities are financed via the Medical Administration Budget. The schedule of fees levied by the SVG Pharmacy Council for drug regulation services are outlined in Table 3.

Table 3 - Schedule of Fees

Type of service provided	Fee charged	Currency
Annual Registration of Pharmacists	$100	EC$
Registration of Pharmacies/Pharmacy Owners	$200	EC$
Registration of wholesale premises/owners of wholesale pharmacies	$300	EC$

Human resources (including training)

There are six persons working in medicines regulation in SVG – 1 Drug Inspector (MOH, full time) and 5 part-time Pharmacy Council members. None of these persons have been trained in any area relating to medicines regulation during the past three years.

There is perceived to be a shortage of both technical and administrative staff to perform regulatory functions. The main reason given for the shortage is the lack of funding. The staff shortage was reported to be contributing to the inability to start medicines registration activities.

The salary of the technical staff working in medicines regulation in the public sector was reported to be similar to that of persons with the same qualifications/functions but working in the private sector.

Infrastructure

There is no adequate office space, but there are dedicated computers, printers, internet and e-mail access, and adequate transport facilities.

Discussion

The main strengths of the medicines regulation system in SVG were cited to be the autonomy of the Pharmacy Council, the technical level of the personnel and the promulgation of the new Pharmacy Act. Outdated regulations, insufficient inspectors, the lack of a medicines registration system, and the lack of a quality control drug testing laboratory were deemed to be the major weaknesses. It was also felt that the staff is not sufficiently competent to administer a medicines registration system. Additionally, it was noted that information on legislation, regulations, procedures and guidelines relating to medicines regulatory activities cannot be publicly accessed on websites or other media channels.

Recommendations

The brief assessment done in the context of this study does not provide the level of information required for developing detailed recommendations. However, for addressing some of the identified constraints in the short to medium term the following could be considered:

- The Ministry of Health should consider developing a National Medicines Policy. If the required expertise is unavailable locally to determine those aspects of drug regulation to be implemented locally and those to be accessed via regional collaboration, such expertise must be identified and recruited to address the deficiencies that currently exist.
- The Ministry of Health should ensure that the draft regulations to the Pharmacy Act are been approved.
- For implementation of the medicines registration system (foreseen in the Pharmacy Act) an amendment to the Pharmacy Act could provide for delegating authority for assessment of applications to a (sub)-regional body.

Suriname: Country Report

Country Background[29]

Suriname is located on the north east coast of South America covering a surface of 163,820 square kilometers. The country shares boarders with Guyana to the west, Brazil to the south, and French Guyana to the east. The total population in 2006 was 504,257 (estimate from 2004 census). Eighty-nine % of the population live along the coastal strip (59.4% urban, 29.6% rural), which makes up 10% of the land surface. The remaining 10% of the population live in the interior that is characterized by rainforest vegetation.

The country's Gross National Product was USD 1.6 Billion in 2006, equaling USD 3,173/capita[30]. The economy is mainly based on the mining, agriculture, and manufacturing sectors.

The Ministry of Health central office, Inspectorate, and the Bureau of Public Health are responsible for policies, standard setting, inspection and monitoring, and program development. Primary health care is provided on behalf of government by the Regional Health Services (state foundation) and the Medical Mission (NGO). Private sector primary health care is mainly provided by private medical practitioners. Four public (including 1 psychiatric center) and 2 private hospitals provide secondary and specialist care. In addition, the military hospital caters for the military and their dependants.

The main cause of death is cerebrovascular disease, followed by conditions related to the peri-natal period, ischemic heart disease, HIV/AIDS, and diabetes. Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 67.2 years 73.7 year	2008
Infant mortality rate (per 1000 life births)	19.1	2006
Maternal mortality ratio (per 100,000 live births)	110	2006

Health care financing is separate from health care provision. Approximately 31% of the population - 'the under-privileged' - are covered through the Ministry of Social Affairs and Housing; 26% through the State Health Insurance Fund (government employees); 8% by the Medical Mission (communities in the interior; Ministry of Health subsidized); and 34% are covered by private health insurance, company plans, or pay out-of-pocket.

Pharmaceutical sector context

Suriname has an officially approved National Medicines Policy dated 2005, and an implementation plan covering the period 2005 to 2008. The multi-stakeholder 'Board for the National Essential Medicines Program' - established my Ministerial Decree and appointed by the Minister of Health - is responsible for implementation of the National Medicines Policy, and (through subcommittees) for

[29] If not indicated otherwise, Information in this section is sourced from 'Health in the Americas - Volume II - Countries' (PAHO 2007), and the completed assessment instrument.

[30] In 'Health in the Americas - Basic Indicators 2008' (PAHO 2008) GNP/capita in 2006 is estimated as USD 7,720 (PPP).

maintaining the essential medicines list and developing standard treatment guidelines. The latest version of the national essential medicines list (4th edition) is dated October 2004. Addenda were published in 2007, 2008, and 2009, and a complete review is foreseen for 2009/10.

Suriname has one medical school and one nursing school, but graduate pharmacists cannot be trained in-country. There is one vocational 3-4 year pharmacy assistant training program. There are plans for upgrading the program.

The number of pharmacists is 31, out of which 8 are currently not engaged in pharmacy practice. There are 332 registered physicians, 42 dentists, and 127 medical specialists that are authorized to prescribe medicines.

There are 26 licensed pharmaceutical importers, the largest being the government owned Drug Supply Company Suriname (BGVS). For BGVS the value of imported medicines was approximately USD 5 Million in 2007. Figures for the other importers were not available from the Pharmaceutical Inspectorate. Based on estimates that BGVS has a market share of around 30 to 50% the total value of imported medicines could be around USD 10 Million[31].

There are 3 pharmaceutical manufacturers including BGVS. Export of locally manufactured medicines is not done, and there is no research based pharmaceutical industry. For BGVS the manufacturing arm is apparently not a substantial part of their operations. In 2007, BGVS sales of manufactured medicines amounted to USD 300,000 (preliminary figures).

Twenty-eight pharmacies are licensed. This number includes the pharmacies operating in the public (3) and private hospitals (2), and the Regional Health Services pharmacy. Retail pharmacies are concentrated in the urban areas of Paramaribo and Nickerie (2) and Commewijne (1). Most of them provide services to clients registered with the State Health Insurance Fund, who are also served by the government hospital pharmacies and Regional Health Services clinics. In addition, there are dispensaries (e.g. Military Hospital, Regional Health Services and Medical Mission clinics) and drug stores authorized to sell a limited number of non-prescription medicines.

Legislative Provisions

Existing medicines legislation is based on the Pharmaceutical Act of 1896 (Wet op de uitoefening van de artsenijbereidkunst; Gouverneur van Suriname 1896), which has been revised and supplemented by numerous complementary Acts and Decrees. The most important amendments include

- The Packed Medicine or Registration Act of 1973 (Besluit Verpakte Geneesmiddelen GB 1973 no. 155), providing for amongst others the registration committee and regulating mandatory registration and exemptions.
- The Government Order of 29 December 1980, enforcing the provisions of the Packed Medicines Act of 1973 as per 1 January 1981
- The Government Order of 26 May 1981, regarding registration of pharmaceutical preparations
- The Government Order of 4 September 1986, amending the Packed Medicines Act by giving authority for simplified registration procedures if medicines are registered in certain countries
- The Government Order of 31 March 1999 (Besluit Negatieve Lijst), liberalizing imports but providing for import certificates to be issued for medicines

[31] N.B.: Mark-up on landed costs was 15% at BGVS (2008). Other importers/wholesalers are probably applying the legally allowed 22% mark-up.

- The Government Decree of 4 February 1983, establishing the Medicines Supply Company Suriname (BGVS);

Suriname is signatory to the narcotic and psychotropic drug treaties of the United Nations (1961, 1971 and 1988). Dangerous drugs are dealt with under the Illicit Drugs Act of 1999.

Authority to administer the medicines laws are centralized with Ministry of Health executives overseeing regulation (drug registration, licensing) and enforcement (inspectorate). The compulsory registration of medicines as mentioned in the law since 1973 came into operation in 1981. The Drug Registration Committee is responsible to assess products. There is no separate body to regulate pharmacy practices; there is a Council for the Essential Drugs Program (REG) chaired by the Director of Health. The responsibilities of the council include advising the Minister of Health, developing guidelines for the Essential Drugs Program, and implementing the program.

In as far as **delegation of regulatory functions** is concerned, registration of medicines is delegated to Registration Committee.

Table 2 documents the provisions made in the existing medicines related legislation, by providing information on which key regulatory functions are covered.

Table 2 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of:		
Manufacturers	Yes	
Importers	Yes	
Wholesalers	No	Treated same as importer/ distributor
Distributors	Yes	By law distribution is (was) one of the key responsibilities of BGVS
Retailers/dispensing outlets	Yes	Pharmacies
Others	Yes	shops selling a limited number (officially approved) of OTC medicines
Market Authorization	Yes	
Inspection of premises and manufacturing sites	Yes	The Director of Health (previously 'Medical Inspector') as responsible authority
Establishment of Medicines Quality Control Laboratory	No	The BGVS statute foresees establishment of a QC laboratory; however this is not strictly speaking a Regulatory QC laboratory
Control of clinical trials	No	
Control of counterfeit medicines incl. smuggling	No	Decree against smuggling (SB 1986 No.3) lays down rules for the prevention of smuggling
Adverse drug reaction monitoring	No	
Control of product promotion and advertisement	Yes	
Provision for medicines distribution schedules/categories	Yes	prescription only, pharmacy only, OTC, Schedules as per Narcotics Conventions
Control of narcotics and psychotropic substances	Yes	
Scope of regulated products	Yes	'Packed' medicines products for human use; narcotic and psychotropic raw materials

Key regulatory function/provision	Covered in legislation	Comments
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	
Power to make regulations	?	
Regulations made under the Act	No	Many regulations, orders, and decrees since 1896

Generally, the law is not comprehensive enough to provide for all the key regulatory functions. Missing provisions include control of clinical trials and safety monitoring of products. Provisions for medicines distribution schedules are not clearly stipulated. Powers delegated to pharmaceutical inspectors under the medicines laws are not specific and comprehensive. Below is a summary of specific provisions as they relate to medicines legislations.

Licensing of manufacturers, importers, retail pharmacies, shops: The law provides for issuing of commercial licenses on recommendation of the Ministry of Health. The law does not provide for safety monitoring of products nor for control of clinical trials and counterfeit products. However, ad hoc decisions on clinical trials take place.

Marketing Authorization: The 'Packed Medicines Act' provides for registration of medicines. Exemptions are provided for, and unregistered medicines can be authorized for distribution by the Director of Health. The registration committee is the authority to assess and decide on applications for registration.

Inspection: The powers and duties of the Pharmaceutical Inspectorate are not established by law. Currently activities are carried out on behalf of the Director of Health (previously the 'Medical Inspector' with defined duties for inspection of pharmacies under the 'Supervision of Public Health' Act of 1938). Powers and role of inspectors are also mentioned in the new Standards Act of 2004.

Quality Control of imported products (including medicines) is mentioned in the Government Decree no. 172 of 1981. The Standards Act of 2004 (SB 2004 no. 121) and the related Bureau of Standards (Act no. 30 of 2006) provide for standardizing technical practices and criteria, performing inspections/sampling (powers and role of inspectors) and testing, and for accreditation of laboratories.

Medicines distribution categories are addressed in the Government Order no 70 of 1973 which mentions that medicines (as defined in paragraph 2 of the order) can only be sold by registered pharmacists. Government Decree no. 4668 of 1981 defines the 'free sale' list, also mentioned in Government Decree no. 85 of 1981.

Administrative and legal sanctions include imprisonment and fines and are already mentioned in the main Pharmacy Act of 1896. Recent updates on fines have been made, e.g. in the "General Fine Act" (no. 73 of 2002).

Power to make Regulation: lower regulations are passed by the Minister of Health but authority/power of the Minister/Director of Health executives is not specifically addressed in the legislation available to us.

Regulations made under the Act: there are many amendment Acts, Decrees, and Orders that affect execution of the Pharmacy Act. It is not clear whether these provide the detailed guidance usually found in regulations.

Conclusion: the current main Pharmaceutical Act is outdated. The practice followed over the years to update provisions in the Act by issuing Decrees, Orders, and new Acts without repealing and replacing the whole of the Pharmaceutical Act of 1896 has led to a situation that is very confusing for regulators as well as for those who are regulated.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section are reflecting the outcome of interviews conducted with the Head Pharmaceutical Inspection, the Acting President of the Registration Committee, the Managing Director of BGVS, and the Pharmacy Policy Coordinator. Interviews were based on the approved assessment instrument.

Organizational structure

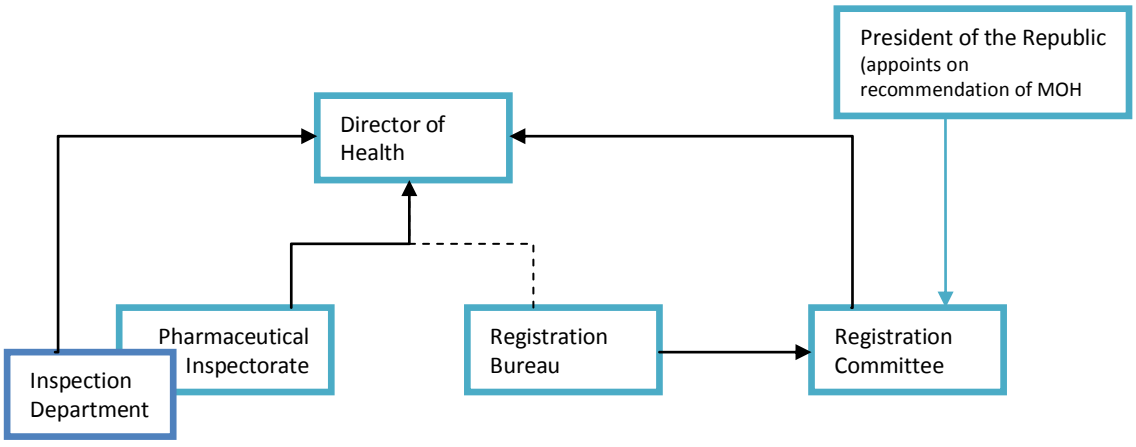
In Suriname medicines regulation responsibilities are currently divided between two entities, the Pharmaceutical Inspectorate and the Registration Committee.

The Registration Committee is the body that issues marketing approval for medicines. As stipulated in the Act of 1973[32], members are appointed by the President of the Republic of Suriname on recommendation of the Ministry of Health. The Registration Committee reports to the Director of Health but is otherwise independent.

The Registration Bureau under the Ministry of Health provides the administrative infrastructure for the Registration Committee. The chairperson of the Registration Committee acts as the head of the Registration Bureau, but is not a Registration Bureau staff member.

The Pharmaceutical Inspectorate is a division of the Ministry of Health Inspection Department. It is tasked with the supervision and enforcement of compliance with medicine related legislation and regulation. In practice the Pharmaceutical Inspectorate is responsible for issuing import permits and recommendations regarding pharmaceutical licenses, and for inspection of distribution channels. The head of the Pharmaceutical Inspectorate reports to the Director of Health.

Figure 1: Organizational Set-up of Medicines Regulation



[32] Besluit Verpakte Geneesmiddelen; Gouverneur van Suriname 1973

Licensing

Licensing of Premises

The Ministry of Trade and Industry issues business licenses for pharmaceutical importers and manufacturers, while licensing for pharmacies and drug stores is done by the District Commissioner. In both cases, the Pharmaceutical Inspectorate is consulted and provides recommendations on which the licensing decision will be based. There are no specific licenses for pharmaceutical wholesalers/distributors, which are licensed as importers only. Distribution to unauthorized retailers is prohibited.

Recommendations are based on inspections, but inspection reports are usually not produced. Guidelines and criteria on pre-license requirements are not published, but being explained to applicants. Some of the criteria are defined in the laws and some result from specifications set by the Pharmaceutical Inspectorate from time to time (e.g. pharmacies should be physically separated by at least 3 km). As a principle, licenses for dispensing doctors are not issued.

Lists of licensed pharmaceutical establishments are not published.

Existing legal requirements with regard to the type of professional qualifications needed to operate different pharmaceutical establishments are not comprehensive. However, a license is only recommended if the following professionals are in place

- Manufacturers: pharmacist
- Importers: pharmacist consultant (i.e. part time)
- Retail pharmacy: pharmacist
- Hospital pharmacy: pharmacist
- Dispensaries: pharmacy assistant
- Drug stores: pharmacy assistant

Respondents confirmed that there are businesses engaged in unlicensed pharmaceutical operations, such as

- manufacturing of 'home remedies'[33] (to be sold in unlicensed establishments)
- importation (e.g. from Guyana, Brazil; imports without import permit by licensed importers; medicines hidden in consignments of other supplies)
- retail (e.g. unauthorized sale of medicines in supermarkets)

The extent of these illegal operations is not known. If illegal consignments are found they can be confiscated. Further actions are processed through the penal system.

Internet pharmacies are not covered by the licensing system. Respondents felt that this is not yet a major problem for Suriname, because the use of credit cards (usually mandatory for payment of internet purchases) is not wide-spread. This may change in the future.

Import Permits

Medicines can only be imported into Suriname with an import permit. This is currently being endorsed by the Pharmaceutical Inspectorate. Issuing of the import permit is subject to submission of a pro-forma invoice, an original copy of the registration certificate, and product samples. The Pharmaceutical Inspectorate issues additional requirements from time to time, e.g. suppliers need to certify on the pro-forma invoice that actual import will happen within a specified period (currently 3 months).

[33] mainly traditional medicines products

Import of unregistered medicines is subject to a waiver issued by the Pharmaceutical Inspectorate on behalf of the Director of Health. Waivers are usually granted to BGVS for imports of unregistered medicines that are included in the essential medicines list. The law makes provision for waivers for unregistered products for individual use, and for investigational products.

The Pharmaceutical Inspectorate is also keeping a register of pharmacy professionals.

Inspection and Surveillance

All inspections of the distribution channel are done through the Pharmaceutical Inspectorate. There is no specific GMP inspectorate, and GMP certificates are not issued.

There are no guidelines for good distribution practices to be adhered to by importers and pharmacies. However, checklists are used during inspections.

There are 2 inspectors (pharmacists) who are also working in the licensing section. These 2 officials are responsible for conducting inspections in the whole country (no decentralization). Specific training has not yet been provided.

Enforcement measures that can be applied by the Pharmaceutical Inspectorate are confiscation of medicines and closure of premises. The office of the Director of Health would follow up on the processes required to impose legal sanctions (prosecution). A disciplinary Board operates under the office of the Public Prosecutor.

Planned 'preventive' inspections are not being conducted due to shortage of staff, and there were no violations registered during the past 2 years. It is intended to start with planned inspections by April 2009. The weaknesses of the existing inspection system are obvious to the division.

Up till now, no counterfeit medicines have been identified on the Surinamese market. However, as inspections are mainly conducted for licensing purposes and specific strategies for combating counterfeit products are not in place, the chances of identifying any counterfeit products that might be circulating are relatively low.

Product Assessment and Registration

In principle, all medicines marketed in Suriname need to be registered (Besluit Verpakte Geneesmiddelen; AB 1973 No 155). Waivers can be granted in specific cases by the Director of Health.

Enforcement of medicines registration started in 1981 and by January 2009 the medicines register listed 2,635 products. It is not known, how many of those products are actually marketed in Suriname.

Availability of registered products for the 29 different medicines included in the survey basket is summarized in Table 3.

Table 3 - Availability of basket medicines (registered products)

Total number of drugs in basket	29
Number with 3 alternative products registered	15
Number with 2 alternative products registered	2
Number with 1 product registered	7
Number where only the originator brand is registered	1
Number with no registered product	5

Basket medicines for which no product is registered are some anti-retrovirals, Levofloxin, Valganciclovir, and Imatinib mesylate.

Except for veterinary products all classes of medicinal products are subject to registration. Biological products are currently not assessed (Vaccines are under the jurisdiction of the Bureau of Public Health and imported using the PAHO Revolving Fund for Vaccines mechanism).

The Registration Committee (RC) is the body responsible for evaluation of applications for registration and for deciding whether marketing approval will be granted. The RC has three sections: pharmaceutical, pharmacological, and medical. In principle, there should be two committee members appointed for each of the sections. Presently the RC has four active members (1 physician, 2 pharmacologists and 1 pharmacist). Work for the RC is done in addition to other full time jobs. RC members are supposed to receive financial compensation from the Ministry of Health. This has, however, not materialized for some years[34]. The RC is supported administratively by the Registration Bureau under the Ministry of Health.

Applications for registration are submitted using standard application forms that are available at the Registration Bureau. The same forms are used for new products and known products, but efficacy and safety studies only need to be submitted for new products. The following information needs to be included in the submitted dossiers (as per State Ordinance of 4 January 1973, Article 3c, Section1):

10) Appendix A: description of composition (quantitative)
11) Appendix B: abbreviated description of manufacturing procedure (master formula), including all substances with quantities and quality used
12) Appendix C1: prescribed testing for finished product
13) Appendix C2: prescribed testing for substances included in the finished product, including quality specifications
14) Appendix D: information regarding stability under tropical conditions (stability tests)
15) Appendix E: description of effects and side effects, indication for use, contra-indications, way of administration, dosage, and other relevant details
16) Appendix F: reports, publications, scientific data related to the active substance and product relevant for evaluation of the application (only required for substances/combinations without sufficient general knowledge regarding their mode of action)
17) Appendix G: marketed packaging and contents
18) Appendix H: samples of labels, packing material and related documents (including designs)
19) Appendix I: description of closure system
20) Appendix J: samples of finished dosage form and active ingredients (sufficient quantities for analysis)

[34] This is apparently due to the fact that for some time RC members were not officially installed in their positions. This has recently been rectified and payment of allowances is expected to be resumed.

21) Appendix K: statement by the competent authority of the country of manufacture that the finished product has been produced as per legal requirements and has received marketing authorization (also include in which other countries the product is legally marketed, including registration numbers). For this it is mandatory to provide a WHO Model Certificate of a Pharmaceutical Product (CPP).

There are no standard operating procedures or written criteria to be applied during the registration process. Usually one dossier is being evaluated independently by two RC members considering safety, efficacy and quality. There are no standing expert committees but specialists might be consulted if needed. The law specifies that products that are registered in the Netherlands, France, Belgium, Switzerland, England, West Germany, Sweden, Norway, Denmark, Canada or the United States of America can be evaluated using a simplified procedure[35]. From the responses received it was not clear whether this has been formally implemented and what the 'simplified procedure' would be. In practice, however, marketing authorization is given based on the WHO CPP stating that the product is approved for use in the country of origin, and on submission of a sample.

Based on the evaluators' recommendations the application is either granted, rejected or referred pending the provision of further information by the applicant. The law specifies that decisions are taken by voting, with the President of the RC having a casting vote. In practice, decisions are always taken by consensus.

During the evaluation process the RC decides on 'qualification of delivery', specifying the prescription status of the product. For this the 'old' schedules published in 1986, other countries' practices, literature, and Surinamese expert opinions are considered. Three schedules exist: OTC for sale in general drug stores, UA for pharmacy only, and UT for prescription only. In the copy of the register made available to us scheduling is not always consistent. E.g. for acetylsalicylic acid tablets (Aspirin) some registered products are scheduled as OTC and some as prescription only; albendazole 200mg tablets are scheduled as prescription only except for one product that is scheduled as pharmacy only.

The RC does not consider patent status during the registration process, nor does it (or the Registration Bureau) have any links with the patent office. No special data exclusivity clauses are applied.

If the application is approved a letter of approval and a registration certificate are issued. Manufacturers are not required to print the registration number on packages and / or package inserts of their products marketed in Suriname.

The following fees are charged (paid directly into the government account / Ministry of Finance):

- Application fee (includes processing): equivalent of USD 18
- Annual retention fee: equivalent of USD 9
- Application for variations (includes processing): equivalent of USD 18

There is no independent appellate body. Complaints can be lodged with the Director of Health. However, companies usually raise any complaints directly with the Registration Bureau.

The maximum time for evaluation of an application for registration is set by law at 6 months. If dossiers are complete the average time taken to decide on an application for registration for interchangeable multi-source products was said to be around 4 weeks.

[35] Staatsbesluit van 4 september 1986, tot wijziging van het Besluit Verpakte Geneesmiddelen (GB 1973 no. 155) SB 1986 no. 56

There is no fast-track system to prioritize applications according to set (public health) criteria. However, if the Ministry of Health requests priority attention to an application for an urgently needed product this request is usually granted.

During 2008 the Registration Bureau received 245 applications for registration. Approximately 75% were approved, while the remaining 25% were either rejected or are still under consideration.

The Registration Bureau keeps a computerized database of registered products (MS Access based). Hardcopies can be collected by interested persons. There are plans to develop a webpage under the Ministry of Health website containing the register and relevant forms and guidelines.

Medicines quality control laboratory

The existing law does not provide for the establishment of a regulatory quality control laboratory. The only medicines quality control laboratory in Suriname is established at BGVS with the main purpose of ensuring quality of products manufactured and imported by BGVS. This laboratory is also used by BGVS for quality control of procured products. The Pharmaceutical Inspection sends samples for testing to the BGVS laboratory. Due to time limitations we could not visit the BGVS laboratory.

One main constraint in the registration process that was mentioned by the respondent is access to a reliable and affordable quality control laboratory. The BGVS quality control laboratory is not used for this purpose, and there are no contacts with and/or access to existing laboratories in the region (e.g. the Caribbean Regional Drug Testing Laboratory in Jamaica). For samples that have to be submitted with the application for registration only organoleptic tests are applied (appearance, packaging, labeling etc.).

Financing of drug regulation

The two existing structures, i.e. Pharmaceutical Inspection and Registration Bureau, are fully financed through the Ministry of Health budget. Both offices did not know their annual budgets. Operational expenditure information was obtained from the Ministry of Health for the last financial year: USD 22,800 (Pharmaceutical Inspection), and USD 13,100 (Registration Bureau).

For licensing and inspection activities done by the Pharmaceutical Inspectorate no fees are to be paid. Registration related fees are not retained by the Registration Bureau.

Recently external funding was provided through an Inter-American Development Bank funded health project, mainly for updating computer hardware. Under the same project funding is being provided for a medium-term quality assurance consultancy that will include recommendations for updating existing legislations, the organization of bodies and departments responsible for ensuring quality of medicines, and the upgrading/establishment of an independent regulatory quality control laboratory.

Human resources (including training)

The current staffing situation at the Pharmaceutical Inspectorate and the Registration Bureau is documented in Table 4.

Table 4: Staff complement of regulatory entities

Staff category	Pharmaceutical Inspectorate	Registration Bureau
Technical full time	3 pharmacists	0
Technical part time	0	1 pharmacologist
Administrative full time	0	2
Administrative part time	2 (intermediate professional training)	0

Being under the Ministry of Health the regulatory agencies do not have power to hire or fire personnel.

Two of the technical staff members of the Pharmaceutical Inspectorate are involved in both, licensing and inspection activities. The chairperson of the Registration Committee is acting head of the Registration Bureau and provides part-time management support.

Both entities confirmed that there is a shortage of staff. For the Registration Bureau it was said that the current structure does not provide for an adequate staff establishment, that there was no interest by professionals, and that there was a lack of adequately qualified candidates.

Pharmacists' starting salaries in the private sector are nearly three times higher than public sector salaries. This was said to be one major reason for the difficulties in finding additional staff for the Pharmaceutical Inspectorate. It was also noted that requests for additional administrative staff were not made. Lack of staff was reported to have a very negative impact on regulatory operations (e.g. inspections are not being conducted as necessary).

Except for the administrative staff working in the Registration Bureau there are no written job descriptions, but it was noted that individual staff members are clear about their roles and responsibilities.

There are no specific training plans, and none of the staff members has recently attended specific training courses related to their areas of work (such as quality assurance, GMP or distribution channel inspection, product assessment and registration, or administration and management).

Infrastructure

Both, the Pharmaceutical Inspectorate and the Registration Bureau perceive that they have adequate infrastructure to support their work (office space, computers, printers, internet and e-mail access).

The Pharmaceutical Inspectorate has one dedicated car, while the Registration Bureau has to request transport from the Ministry of Health transport pool.

Discussion

Suriname is one of the five CARICOM countries with an operational registration system for medicines. This system is, however, working under severe constraints such as

- outdated legislation with numerous amendments that were never consolidated into one comprehensive law
- shortage of qualified human resources in the Registration Committee and Registration Bureau
- inadequate structure of the Registration Bureau (e.g. no full-time head/registrar)

- limited financial resources
- no access to independent medicines quality control laboratory

These constraints contribute to some of the reported weaknesses, e.g. lack of written procedures and criteria for evaluation of applications for registration (including fast track procedures for priority medicines) or for deciding on the scheduling status; inadequate communication with applicants and Pharmaceutical Inspectorate; absence of strategic planning, monitoring and evaluation.

Within this context the commitment of the Registration Committee members is a real strength. The existence of the registration data base is another positive aspect.

It has been reported that of the 421 items (including different strengths/dosage forms) included in the national essential medicines list about 100 do not have a single corresponding product that is registered in Suriname[36]. Consequently legal import of nearly one third of the essential medicine products can only be done by obtaining a waiver. This puts additional strain on the Pharmaceutical Inspectorate and is expected to lead to delays in processing shipments of needed medicines. It is also not clear what criteria are used for deciding whether to grant a waiver for import of non-registered medicines.

An earlier study done in 2003 found that in a sample of private sector pharmaceutical establishments only 25% of products corresponding to one of 20 basket medicines were registered. It was not established whether the remaining 75% were legally imported through the waiver mechanism or whether they were imported illegally[37]. Whatever the case, the fact that for a considerable number of essential medicines no products are registered negatively affects access to and availability of quality assured essential medicines.

The general lack of written procedures and guidelines poses a threat especially to the operations of the Pharmaceutical Inspectorate, where the institutional memory could be lost if the head of the division decided to leave her position.

Opportunities to further develop the existing medicines regulatory systems and to improve their efficiency and effectiveness exist. The National Medicines Policy identifies four relevant strategies under the section 'Medicines Law and Regulations':

- Updating of the obsolete law and regulations with regard to medicines from prescription up to delivery and use.
- Strengthening of the registration of medicines with priority setting within the registration on basis of rational needs and with quick but careful procedures for essential medicines. The medicines regulating authority will collaborate with counterpart-organizations in other CARICOM countries towards harmonization of control, registration requirements, and exchange of information and ratification of international conventions.
- Strengthening of the Pharmaceutical Inspection.
- Setting up of a quality monitoring laboratory for medicines or delegate these tasks to an existing laboratory establishing the necessary infrastructure to this end.

In this context the 'Strengthening of Pharmaceutical Quality Assurance & Legislation for the Ministry of Health in Suriname' project is currently being implemented. The expected outcomes include a

[36] Analysis done in early 2008 for the draft inception report of the ongoing project 'Strengthening of Pharmaceutical Quality Assurance & Legislation for the Ministry of Health in Suriname'

[37] Lee et al: Suriname Study on Public Sector Drug Procurement (MSH 2003)

quality assurance policy, proposals for a new comprehensive medicines law, and recommendations for adequate structures for the medicines regulatory system.

Recommendations

There is no doubt that reform of the current medicines legislation should have - and in practice already has - priority. This reform will most probably require the re-structuring of the current regulatory system in line with the new legal provisions. It is beyond the scope of this study to make specific recommendations in this regard.

For addressing some of the identified constraints in the short to medium term we recommend the following:

For the Ministry of Health

- Ensure remuneration of Registration Committee members
- Provide for employment of full-time head of the Registration Bureau
- With stakeholders develop strategies to ensure that for all essential medicines an adequate range of registered products is available
- With stakeholders identify medicines regulatory specific training courses (e.g. inspection, prevention of counterfeit drugs, assessment of applications for registration), identify funding and participants

For the Registration Bureau/Registration Committee

- Document in writing the working procedures of the Registration Committee (e.g. assessment criteria, assessment process; meeting procedures) - make these procedures publicly available
- Develop procedures for communicating with applicants
- Make more use of the registration database (e.g. for monitoring time needed for processing applications)
- Establish criteria for deciding whether a product is OTC, pharmacy only or prescription only
- Establish contact with other regulatory agencies in the region for information exchange
- Make use of established guidelines (e.g. PANDRH guidelines, WHO guidelines, other established agencies' guidelines)

For the Pharmaceutical Inspection

- Document in writing the procedures and criteria applied for providing import licenses
- Document in writing the conditions that need to be met for issuing of waivers for import of unregistered medicines
- Document in writing the licensing requirements for pharmacies, drug stores, importers and wholesalers (make use of existing guidelines, e.g. good distribution practices, good pharmacy practice)
- Make the above publicly available
- Using the existing inspection check-list develop an inspection report format and use this to produce inspection reports (provide inspection reports to the inspected premises)
- Develop and maintain simple data bases for licensed premises and professionals
- Implement planned inspection

Trinidad & Tobago: Country Report

Country Background

Information in this section mainly draws on 'Health in the Americas 2007 - Country Reports' (PAHO 2007) and our assessment findings.

Trinidad & Tobago is the most southern territory of the West Indies, with a tropical climate and one rainy and one dry season. The territory covers 5,128 km², of which the smaller island of Tobago covers 300 km². The total population for 2008 is estimated at 1.34 Million[38], with 96% residing in Trinidad.

The country's Gross National Product reached USD 16.800/capita (PPP) in 2006. The economy is driven by energy exports, while agricultural production is on the decline.

Public sector health services are purchased by the Ministry of Health from the 5 Regional Health Authorities (established by law), who in turn are responsible for managing and organizing health services in their regions. In addition, the Ministry of Health implements several vertical programs (e.g. the National Aids Program, National Tuberculosis Program, or Chronic Disease Assistance Program). In total there are 9 public hospitals, 7 district health facilities, and 97 health centers[39].

The main cause of death is ischemic heart disease followed by diabetes, malignant neoplasms, cerebrovascular diseases and external causes (2001). Basic health related indicators are summarized in Table 1.

Table 1 - Basic health related indicators

Indicator description	Indicator value	Year
Life expectancy at birth: **male** **female**	 68.2 72.1	2008
Infant mortality rate (per 1000 life births)	17	2004[40]
Maternal mortality ratio (per 100,000 live births)	39	2001

Public sector health care financing is tax based. In 2005 government expenditure on health care accounted for 53.7% of all health expenditure. Eighty-eight (88) % of private health care expenditure is out-of pocket. Total health expenditure/capita at average exchange rate was USD 513 in 2005.[41]

Pharmaceutical sector context

Trinidad & Tobago has an officially approved National Medicines Policy dated 1998. An implementation plan is not available. The policy specifies that the Ministry of Health is the lead agency for monitoring and evaluation of the policy, but no dedicated committee to be in charge of this process is identified. There is no essential medicines list, but a 'VEN' list that includes the medicines available for public sector use prioritized as 'vital', 'essential' or 'necessary'. The most

38 'Health in the Americas - Basic Indicators 2008' (PAHO 2008)
39 see www.health.gov.tt
40 see footnote 1
41 World Health Statistics 2008 (WHO 2008)

recent list dated 24 November 2008 contains 1,346 products (different strengths, dosage forms, and pack sizes are counted).

The University of the West Indies offers medical, nursing and pharmacy training. Pharmacy training is at the level of Bachelor of Science. The College of Science, Technology & The Arts of Trinidad and Tobago offers a one-year pharmacist assistant training program. It is estimated that around 500 pharmacists are registered with the Pharmacy Board.

There are 2 main local companies manufacturing generic pharmaceutical products for sale locally and for export in the region. In addition, there are 10-12 smaller establishments with a limited range of simple products. The total number of pharmaceutical importers and wholesalers was not available.

All 113 public health facilities offer pharmacy services. Medicines in the public sector are provided free of charge. There are 232 retail pharmacies and pharmacy ownership is not restricted to pharmacists. In addition, licensed shops are allowed to sell a restricted number of OTC medicines. Medical doctors are only allowed to dispense/sell medicines in emergency cases. Respondents stated that in practice there are many medical doctors who sell medicines on a larger scale to their patients.

Procurement of pharmaceutical supplies for the public sector is centralized and contracted out to the National Insurance Property Development Company (NIPDEC). The value of tenders awarded for 2009 was USD 39.5 Million for general pharmaceutical supplies, USD 8.9 Million for anti-retrovirals, and USD 18.6 Million for cancer related medicines. Brand name products accounted for 78.3%, 85.9%, and 82% respectively of total contract values[42].

Legislative Provisions

Existing medicines legislation include

- the Pharmacy Board Act, 1961 with its corresponding Amendments and Schedules;
- the Pharmacy Board Regulations of 1988
- the Food and Drugs Act, 1965 with its corresponding Amendments;
- the Food and Drugs Regulations with corresponding Amendments
- the Antibiotics Act No. 14, 1948 with its corresponding Amendments and Cap 30-02, Antibiotics (Conditions for Use) Order; Cap 30-02 Approved Pharmaceutical Firms Order;
- the Dangerous Drugs Act of 1991 with its corresponding Amendments

Administration of medicine legislation is entrusted to

- The Council of the Pharmacy Board established under section 7 of the Pharmacy Board Act. The Council is responsible for control of the pharmacy profession and the maintenance of proper standards of practice including sell of poisons and prescribing rules and discipline in respect of pharmaceutical students and professionals.
- Inspectors and a Drug Advisory Committee appointed by the Minister of Health under the Food and Drugs Act
- Inspectors and the Antibiotics Control Committee established under the Antibiotics Act

The Council of the Pharmacy Board is an autonomous body with powers to collect and utilize fees for regulatory functions for which it is mandated. The status of the Drug Advisory Committee and Antibiotics Control Committee is not specified in the Acts.

[42] Information provided by NIPDEC; it is not clear whether brand name products include branded generics.

In as far as **delegation of regulatory function** is concerned section 20 of the Food and Drugs Act provides that the Minister may appoint one or more persons to be analysts or inspectors for the purpose of enforcement of the Act. The Act gives powers to the authorized officer to conduct inspection and take food and drug samples for analysis.

Functions of the Council of the Pharmacy Board may be delegated to Committees appointed by the Council.

Table 2 documents the provisions made in the existing medicines related legislation focusing on key regulatory functions.

Table 2 - Comprehensiveness of existing legislation

Key regulatory function/provision	Covered in legislation	Comments
Licensing of: **Manufacturers**	Yes	Food and Drugs & Antibiotics Acts
Importers	Yes	
Wholesalers/Distributors	Yes	Food and Drugs, Antibiotics & Pharmacy Board Acts
Retailers/dispensing outlets	Yes	Food and Drugs, Antibiotics & Pharmacy Board Acts
Other	Yes	shops selling Schedule 2 medicines (Pharmacy Act)
Market Authorization	Yes	Food and Drugs & Antibiotics Acts
Inspection of premises and manufacturing sites	Yes	
Establishment of Quality Control Laboratory	(Yes)	Appointment of analyst but no explicit reference to regulatory QC laboratory
Control of clinical trials	No	
Control of counterfeit medicines	(Yes)	indirectly F&D
Adverse drug reaction monitoring	No	
Control of product promotion and advertisement	Yes	Food and Drugs Act
Provision for medicines distribution schedules/categories	Yes	
Control of narcotics and psychotropic substances	Yes	
Scope of regulated products	Yes	
Administrative and legal sanctions e.g. suspension or revocation of licenses or fines/imprisonment	Yes	
Power to make regulations	Yes	Minister empowered to make Regulations
Regulations made under the Act	Yes	

Licensing of manufacturers, importers, wholesalers, distributors, retail pharmacies:
The Food and Drugs Act provides for licensing of manufacturers, and imports, wholesalers and retailers who handle controlled drugs. Under the Antibiotics Act imports, manufacture, wholesale and retail of antibiotics is licensed. The Pharmacy Act provides for licensing of premises for storing for sale (wholesaler/distributor) and retail.

Marketing Authorization:
Registration of antibiotics is required under the Antibiotics Act. Registration of controlled and other medicines is regulated under the Food and Drugs Act.

Inspection: Inspectors are to be appointed under Section 20 of the Food & Drugs Act. The Antibiotics Act (Sections 12 and 14) provides for persons that can be appointed by the Antibiotics Control Committee for carrying out inspections. The Pharmacy Act and regulations refer to inspections only in the fee schedules.

Quality Control is covered in the Food and Drugs Act by provision in Section 20 for the appointment of analysts. Quality control certificates issued by an appointed analyst are admissible as evidence in court. Trinidad & Tobago is also signatory to the Agreement establishing the Caribbean Regional Drug Testing Laboratory.

Safety monitoring (post-marketing surveillance) is mentioned in the Food & Drugs Regulations (page 109) as the responsibility of the registration holder only.

Medicines distribution categories divided in

- narcotics (defined in the Schedule to the Narcotic Control Ordinance)
- controlled drugs (Second Schedule, Division 2 - Food & Drugs Act)
- prescription only (Third schedule drugs as per Second Schedule, Division 1 - Food & Drugs Act)
- Antibiotics as specified under the Schedule to the Antibiotics Act.

Scope of products regulated includes food, drugs for human and animal use, cosmetics, and devices under the Food & Drugs Act ; compounds of and medicinal preparations containing Antibiotics as specified under the Antibiotics Act; and devices, drugs for human and animal use, and poisons under the Pharmacy Act.

Administrative and legal sanctions are provided in different laws. The severity of sanctions depends on the gravity of offences.

Power to make regulations is vested on the Minister of Health under Section 25 of the Food and Drugs Act, Section 22 of the Antibiotics Act, and Section 40 of the Pharmacy Board Act.

Regulations made include Antibiotics (Conditions for Use) Order; Approved Pharmaceutical Firms Order; Food and Drugs Regulations; and the Pharmacy Board Regulations.

Conclusion and Recommendation: There is need to harmonize the laws regulating medicines in order to have one comprehensive legislation providing for regulation of all medicines and related products as well as for one National Regulatory Authority responsible for implementation of the law. Regulation of pharmacy profession and practice could remain separate and under the responsibility of the Pharmacy Council.

Assessment Findings - Regulatory Institutional Capacity, Procedures and Processes

If not indicated otherwise, the findings reported in this section are reflecting the outcome of interviews conducted with the stakeholders of the Ministry of Health Drug Inspectorate and Chemistry, Food & Drugs divisions including the Food & Drugs laboratory, and the Manager/Senior Pharmacist NIPDEC. Interviews were based on the approved assessment instrument. Due to time constraints interviews held with the Drug Inspectorate were less extensive than those with the Chemistry, Food & Drugs division. More detailed information has therefore been collected related to medicines regulation under the Food & Drugs Act.

Organizational structure

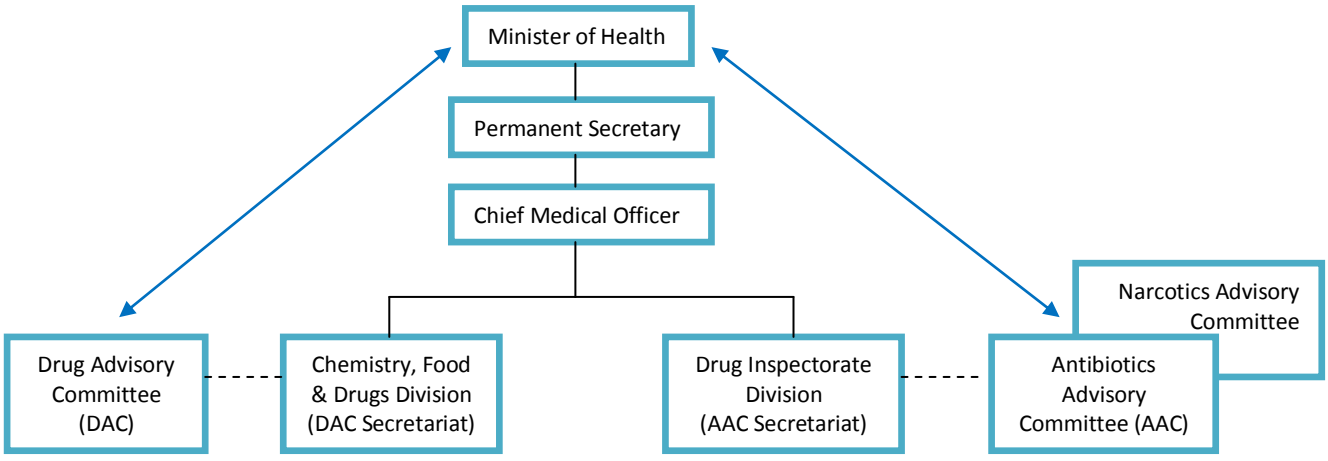
In Trinidad and Tobago medicines regulation responsibilities are divided between two Ministry of Health divisions, the Drug Inspectorate and the Chemistry, Food & Drug division. The Pharmacy Board through the Pharmacy Council regulates the pharmacy profession and the operation of pharmacies.

The Drug Inspectorate division is dealing with registration of antibiotics, issuing import licenses for antibiotics, and inspection and licensing of premises where antibiotics are kept as per Antibiotics Act. The division is also responsible for registration of narcotics, issuing related licenses and monitoring adherence to regulations as per Dangerous Drugs Act.

The Chemistry, Food and Drugs division is dealing with registration of all other medicines, including controlled medicines that are not narcotics, and with inspection and licensing of manufacturers, importers and wholesalers as per Food and Drugs Act. Both divisions report to the Chief Medical Officer.

For both entities advisory committees are established under the Acts by the Minister. These committees are responsible for assessing applications for registration.

Figure 1: Organizational Set-up of Medicines Regulation



From the Organogram in Figure 1 it becomes clear that there is no formal direct link between the two divisions charged with medicines regulation. The Drug Inspectorate is, however, represented in the Drug Advisory Committee. Inadequate communication between the divisions was mentioned by respondents as a constraint.

Licensing

Licensing of Premises

License requirements and licensing body depend on the type of medicinal product (i.e. narcotics, antibiotics, controlled drugs, other medicines, or unscheduled drugs), and the type of pharmaceutical establishment (i.e. pharmacy, drugstore or others). Table 3 lists the licenses currently being issued to premises and the licensing body.

Table 3 - Licenses issued to pharmaceutical businesses

Establishment being licensed	License issued by Drug Inspectorate	License issued by Director Chemistry, Food & Drug division	License issued by Pharmacy Council
Manufacturers	not applicable *	√	
Importers	√ (for narcotics & antibiotics)	√ (for controlled drugs)	
Wholesalers	√ (for narcotics & antibiotics)	√ (for controlled drugs)	√
Retail Pharmacy	√ (for narcotics & antibiotics)	√ (for controlled drugs)	√
Other retail outlets (unscheduled drugs only)			√ (recommends to County Medical Officer of Health)

* There are currently no manufacturers of antibiotics or narcotics.

Issuing of licenses (certificates) is based on inspections. Licensing requirements are described in the relevant Acts and regulations. They are also included in the certificates. Licenses are subject to annual renewal.

Only licenses issued by the Pharmacy Council are subject to payment of licensing and retention fees.

Except for retail pharmacies (232) we were not able to obtain the numbers of currently licensed pharmaceutical establishments. The registers of all licensed pharmacists and pharmaceutical businesses are to be made available to the general public. However, no mechanism exists as yet. There are plans to publish the related registers on a webpage.

Existing legal requirements with regard to the type of professional qualifications needed to operate different pharmaceutical establishments are not comprehensive. However, a license is only recommended if the following professionals are in place

- Manufacturer: pharmacist (only if dealing with antibiotics, narcotics, or controlled drugs)
- Wholesaler/distributor: pharmacist (only if dealing with antibiotics, narcotics, or controlled drugs
- Retail pharmacy: pharmacist
- Hospital pharmacy: pharmacist
- Dispensaries: pharmacist

According to respondents the main cases of operating an unlicensed pharmaceutical business are those where a licensed pharmacy does not pay the annual retention fee. Sale of pharmaceuticals outside licensed premises does not usually occur. Respondents noted that the public is well educated regarding the related risks.

Internet pharmacies are not covered by the licensing system.

Import Permits

Import permits need to be obtained by licensed importers for each consignment of antibiotics, controlled drugs or narcotics.

Import of unregistered products is only possible for investigational use or submission of samples for the registration process. In both cases import permits need to be obtained.

Inspection and Surveillance

Inspection and surveillance is centralized and done from the respective Ministry of Health Divisions. Inspectors are empowered by the respective laws, and can collect samples, seize products suspicious of contravening the prescriptions of the law, and demand access to documents.

Chemistry, Food & Drugs Division
The Division is in charge of inspection of manufacturers and of distribution channels, where controlled drugs are sold.

Inspection of manufacturers is based on the prescriptions in the regulations to the Food & Drugs Act. Respondents reported that these were in line with WHO good manufacturing practices guidelines. Currently inspections are done annually and a certificate is being issued. The division issues Free Sale certificates for export, but no WHO type Certificate of Pharmaceutical Product. Inspections of the smaller manufacturing companies are less detailed and focus on the basic structures and requirements.

Inspectors of the Division are 'shared' and are responsible for both, food and drug related inspections. Inspectors are also present at the eight stations where imports are processing through customs.

There are currently no planned preventive inspections of the distribution channel.

Drug Inspectorate Division
The Division is responsible for inspections of distribution channels where antibiotics and narcotics are handled. Inspection reports are produced and copies provided to the inspected facilities.

During the previous year 21 pharmacies and 18 other pharmaceutical businesses were inspected. In 3 cases storage of unregistered antibiotics was detected, and in 1 case records were not kept according to the regulations.

Previous surveys found that violations detected during inspection of private pharmacies were related to inadequate documentation of prescriptions and of receipt of stock. Sale of prescription only medicines without a prescription was also reported[43]. One respondent stated that there are unregistered medicines for sale in retail pharmacy (mainly OTC products).

Counterfeit medicines are not considered to be a big problem. This is partly attributed to inspection activities taking place at entry points.

Product Assessment and Registration

Chemistry, Food & Drugs Division
All medicines marketed in Trinidad and Tobago need to be registered under the Food & Drugs Act. Exceptions are antibiotics (registered under the Antibiotics Act), narcotics (approved by the Minister of Health under the Narcotics Control Ordinance), medicines for investigational use, and product

43 PAHO/WHO Level I indicator survey 2005 and "Improving Access to Pharmaceutical Drug Therapy in Trinidad and Tobago: Pharmaceutical Services Reform" (R Bacovsky/Integra Consulting Ltd/Canada/2003)

samples to be submitted with the application for registration. There is no provision for issuing of waivers for e.g. emergency procurement.

Registration began in 1960. It is not known how many medicines are currently registered under the Food & Drugs Act. Because there is no data base of registered medicines and time was limited, it could neither be established whether there are registered products for each of the medicines of the survey basket, nor whether registered basket medicines include at least two alternative generic products[44].

All classes of medicinal products are being assessed for registration, including biological and veterinary products. The Drug Advisory Committee (DAC) is responsible for assessment of applications for registration and recommends to the Minister of Health to either approve or reject the application. The DAC consists of 18 members, including the Chief Medical Officer, Chief Chemist, Chief Pharmacist, Drug Analyst, Pharmacy Board, veterinarians, business community, medical profession and university pharmacy specialists. Additional specialist advice is sought when required. DAC members do not receive financial compensation for their work.

There are no formal procedures in place to avoid conflict of interest when appointing DAC members, and there is no written code of ethics. Possible conflict of interest is however considered before DAC meetings, and affected members would not attend.

Applications for registration are submitted using standard application forms that are available on the internet (http://www.ttconnect.gov.tt/Egov/Portal/citizen/service.aspx?id={53B951EE-2213-4896-ADD7-BFE682368841}). The following information/documentation is required to accompany the application:

- Original Free Sales Certificate or Certificate of Pharmaceutical Product (imported products)
- Certificates of marketing authorization from the relevant regulatory authorities in USA, Canada, United Kingdom, Australia, Belgium, Netherlands, France, Denmark, or Sweden)
- Chemical documentation
  A: Finished product (specification, methods of analysis, original certificate of analysis, stability data, disintegration, dissolution profile, 3 samples)
  B: Active ingredients (specifications, methods of analysis, original certificates of analysis, sample)
- Pharmaceutical documentation
  A: Pharmacodynamic data (general pharmacology, tests supporting efficacy)
  B: Pharmacokinetic data (distribution, metabolism, excretion, biological equivalence
  C: Pharmacotherapeutic data (therapeutic uses, clinical trials, therapeutic equivalence)
  D: Toxicity data
- Manufacturing details (formula, procedure, controls, sampling and testing procedures, GMP certificate)
- Packaging materials (description, compositions, size & dimensions), color, processes ensuring suitability for pharmaceutical purposes, samples)
- Ink and printing (color, chemical composition of ink, description of inc, other characteristics, printing)
- Package insert (for prescription medicines only)

[44] Screening of the latest Ministry of Health pharmaceutical price list indicates that for most VEN medicines generic products are procured, sometimes from different manufacturers, and sometimes in addition to originator products. This indicates availability of registered generic products on the market.

There are no standard operating procedures or written criteria to be applied during the registration process, except for the (detailed) criteria specified in the regulations to the Food & Drugs Act. The Act specifies that decisions on approval or rejection of applications need to be taken within 120 days from submission of the application. The DAC is meeting every 2 months. Box 1 explains the registration process.

BOX 1 - Processing of applications for registration

For each cycle there is a specified 2-weeks period during which applications can be submitted to the Chemistry, Food & Drugs division. These are immediately screened for completeness, and then sent to DAC members for assessment (at least 2 members to assess one application). At the same time samples are sent to the Food & Drugs Laboratory for testing. Assessment reports should be completed within 2 to 3 weeks and sample testing within 2 months. Assessment reports and testing results are discussed at the next meeting of the DAC and decisions are taken by consensus.

During the evaluation, registration status with other reputable regulatory agencies or WHO pre-qualification are not considered as important criteria for approval, but may increase confidence in case decisions are not straightforward.

Conditions of sale are 'Free Sale', 'Prescription', and 'Controlled'. Except for some defined medicines of the 'Free Sale' category, all medicines can only be sold in pharmacies. In principle, prescription only medicines are those used to treat diseases specified in the First Schedule of the Food & Drugs Act, and they are listed in the Third Schedule. However, these Schedules are outdated and have been updated by the DAC 'internally'.

The DAC does not consider patent status during the registration process, nor does it have any links with the patent office.

If the application is approved a note of approval and a registration number are issued. Registered products are also published in the official Government Gazette. Manufacturers are not required to print the registration number on packages and / or package inserts of their products marketed in Trinidad and Tobago.

Product registration is not subject to re-evaluation. However, registrations might be cancelled.

There is no independent appellate body. Complaints are sometimes received by the DAC (approximately 2 during the previous year).

The following fees are charged (paid directly into the consolidated fund at Treasury):

- Application fee (includes processing): TTD 750 (USD 123)
- Application for variations (includes processing): TTD 100 (USD 16)

There is no fast-track system to prioritize applications according to set (public health) criteria. Respondents felt that this was not necessary, because the current system performs well and is fast enough. In addition, respondents noted that it is important to properly evaluate each application for registration, and that decisions on applications for multi-source products are more frequently deferred because they do not comply with the requirements. It was also said that there are a sufficient number of generic products on the market[45].

The Secretariat to the DAC keeps a MS Word file of new applications for registration. The complete register is kept manually. It was therefore neither possible to determine the total number of registered medicinal products, nor to do any specific analysis. Information was made available

[45] There seems to be a general mistrust towards the quality of generic pharmaceutical products amongst public sector officials, within the private sector, and amongst patients.

related to the next planned DAC meeting: 93 applications were to be discussed, out of which 64 were applications for new drugs (including 10 herbal products). The remaining ones were either applications for approval of variations or deferred cases from previous meetings. We were informed that deferral does occur because of inadequate submissions, but also because at times DAC members cannot complete revision of assigned applications in time. There were examples where final decisions on application for registration had not been made after 1 year of submission.

Drug Inspectorate Division

Related to the registration of antibiotics under the Antibiotics Act, 36 applications for registration were received during the previous year (including 1 for a veterinary product). All applications were processed, but in 8 cases additional information had to be sought from the applicants.

The Drug Inspectorate Division does not have an automated system for regulatory data management that would allow a more detailed analysis of registration activities and outcomes. However, information on the number of ever registered products was available: during the period 1969 to 2009 2,377 medicinal products containing antibiotics were registered. It is not known how many of these are (still) on the market in Trinidad & Tobago.

Medicines quality control laboratory

The Food & Drugs Laboratory is established within the Chemicals, Food and Drugs division of the Ministry of Health. The Act also makes provision for the appointment of analysts. Certificates of Analysis provided by the Food & Drugs Laboratory can be presented as evidence in court. The drug analyst is a member of the DAC.

The drug laboratory is separate from the food laboratory. Tests are done on pharmaceutical products; biological products are not tested.

In addition to wet chemistry, the drug laboratory uses the following analytical methods: UV visible spectrophotometry, polarimetry, HPLC, atomic absorption spectrophotometry, and disintegration and dissolution tests. Thin layer chromatography is not performed because there is no source from which coating material could be procured. Microbial and sterility test are done at the food laboratory. Sterility testing is also sometimes referred to the Caribbean Regional Drug Testing Laboratory in Jamaica. Table 4 provides an overview of analyzed samples during 2007 as documented in the laboratory's annual report.

Table 4 - Samples analyzed by the Drug Laboratory during 2007

Submitting authority / purpose of testing	Number of samples analyzed
Government drug inspectors	59
DAC for registration purposes (new drugs)	126
Procurement agency (NIPDEC)	23
Public sector hospitals / 'complaint samples'	8

NIPDEC routinely sends samples of medicines provided under the chronic disease assistance program; tuberculosis medicines are being tested annually.

In addition, testing of samples is sometimes requested by the private sector, e.g. small manufacturers that are not required to have their own laboratory. For processing of these 'unofficial' samples fees in the range of 50 to 100 TTD (8 to 16 USD) are being charged.

The drug laboratory attempts to complete analysis of samples within 2 months for the DAC, within 2 weeks for hospitals in case of complaint samples, and within 2 weeks for NIPDEC.

The drug laboratory does not currently collect samples for testing, but market surveys, where samples will be bought in retail pharmacies for testing purposes, are planned.

Approximately 10% of tests conducted fail (including inadequate labeling or packaging); 1% of products do not finally pass quality control in the drug laboratory.

Performance of the drug laboratory is checked by re-testing of samples, and sometimes samples are sent for cross-analysis to the regional quality control laboratory in Jamaica.

Financing of drug regulation

The three existing bodies, i.e. Chemistry, Food & Drugs division, the Food & Drug Laboratory, and the Drug Inspectorate, are fully financed through the Ministry of Health budget. Officials in charge of the divisions did not know their annual budgets. Expenditure information could not be obtained.

Fees charged for registration and for analysis of samples submitted by the private sector are not retained.

Human resources (including training)

The current staffing situation of Chemistry, Food & Drugs division departments responsible for medicines regulation is documented in Table 5.

Table 5 - Staff complement of drug regulatory entities within the Chemistry, Food & Drugs Division

Staff category	Inspectorate	DAC Secretariat	Drug Laboratory
Technical	13 employed, but only 8 physically in place	1 pharmacologist (also working as inspector)	2 supervisors (Masters degree or higher) 4 technicians 1 laboratory assistant
Administrative	?	2	tasks done by technical staff

The staff establishment of the Drug Inspectorate Division was reported to be 13 technical (pharmacists) and 2 support staff.

Being under the Ministry of Health the regulatory agencies do not have power to hire or fire personnel. Promotion of staff is based on seniority. Salaries for technical pharmaceutical staff in the Ministry of Health were said to be much lower than those paid in the private sector.

Shortage of staff was noted in relation to number of inspectors and for the laboratory.

The regulatory bodies within the Ministry of Health do not have dedicated training budgets. Requests for training are submitted and budgets might be made available centrally. In practice there was no specific formal medicines regulatory training provided during the past 3 years. Inspectors and laboratory technicians are being trained on the job. Government did sponsor staff to attend conferences. Sometimes PAHO and pharmaceutical companies financially support training related activities.

Infrastructure

Office space available for the Chemistry, Food & Drug division appeared to be satisfactory. However, the number of computers and printers is insufficient, and there is no reliable internet connection. The official e-mail address is not working. The Drug Inspectorate division does not have adequate office space, but sufficient computers and printers. Internet access is unreliable.

Both divisions do not have dedicated cars and drivers. However, inspectors are considered as 'travelling officers', which implies a transport allowance to compensate for the use of private cars.

Discussion

Trinidad and Tobago is one of the five CARICOM countries with an operational registration system for medicines. Performance of this system is, however, constrained by

- Division of regulatory responsibilities (antibiotics, other pharmaceuticals)
- Shortage of human resources in the inspectorates and the laboratory
- Inadequate specialist training opportunities
- Inadequate infrastructure

These constraints contribute to some of the reported weaknesses, e.g. lack of written procedures and criteria for evaluation of applications for registration (including fast track procedures for priority medicines) or for deciding on the conditions for sale; absence of electronic database for medicines registered under the Food & Drugs and Antibiotic Acts; inadequate communication and collaboration between the two divisions and the drug laboratory; and absence of strategic planning, monitoring and evaluation.

Within the context of health sector reform the Ministry of Health intends to restructure the Chemistry, Food and Drug division and the Drug Inspectorate division[46]. While this causes some insecurity amongst staff members it also provides an opportunity for improving efficiency related to medicines regulation if restructuring is accompanied by legislative reform ('merging' of the Antibiotics and Food and Drug Acts).

Although respondents noted that clients trust the decisions made by the DAC there seems to be a general mistrust towards generic products, including among the public. Access to the more affordable generic products is further constrained by the fact that there is no legal provision allowing pharmacists in the private sector to substitute a prescribed originator brand product with the equivalent generic one. Within the context of drug shortages in the public sector, access to needed medication might therefore be compromised. It is noteworthy that the National Drug Policy of 1998 does not refer to affordability of medicines, and does not include strategies to promote the use of generic medicines.

Recommendations

It is beyond the scope of this assessment to provide a comprehensive set of recommendations for the improvement of the medicines regulatory system in Trinidad and Tobago. However, for addressing some of the challenges identified in the short to medium term we recommend the following:

[46] Ministry of Health Corporate Plan 2006 - 2009

For the Ministry of Health

- With stakeholders identify medicines regulatory specific training courses (e.g. GMP inspection, distribution channel inspection, prevention of counterfeit drugs, assessment of applications for registration), identify funding and participants
- Within the framework of restructuring consider merging the Drug Inspectorates at the Food and Drug Division and the Drug Inspectorate Division, and merging of the DAC and the Antibiotics Advisory Committee and the respective Secretariats
- Ensure that adequate office space, and working and communication tools (telephone, internet) are made available to the medicines regulatory entities
- Consider widening the scope of the Food and Drugs Act to include antibiotics
- Consider legislative reform providing for generic substitution in the private sector
- Initiate the process to review the National Drug Policy of 1998 ensuring (amongst others) that affordability of medicines and promotion of generics feature prominently

For the Drug Advisory Committee and Secretariat

- Document in writing the working procedures of the DAC (e.g. assessment process; meeting procedures) - make these procedures publicly available
- Develop a code of conduct and conflict of interest guidelines for the DAC members and external assessors
- Increase efficiency by establishing specific abbreviated evaluation procedures for applications for registration of generic products that are registered with other reputable regulatory agencies or pre-qualified by WHO; review in vivo bioequivalence study requirements using a risk based approach.
- Together with the Drug Inspectorate division seek assistance for the implementation of a searchable registration database where information for registered products can be recorded and easily be evaluated for various purposes
- Seek contact with other regulatory agencies in the region for information exchange and professional development

Caribbean Regional Drug Testing Laboratory (CRDTL)

The CRDTL was established as a CARICOM regional drug testing laboratory by written agreement dated June 1975. Article 4 of the agreement makes provision for the appointment of analysts and outlines their jurisdiction. Article 11 allows the CRDTL to perform quality testing of pharmaceutical products for the CARICOM region and to issue official results.

The CRDTL is located in Jamaica, where it occupies the same complex as the Government Chemist and has as its Director the head of the Government Chemist Department.

The functions of the CRDTL are carried out by 10 full time staff (4 administrative and 6 technical) and 1 part time technician. The laboratory is equipped to do all types of chemical tests and assays; identification by infra-red spectrophotometry, thin layer chromatography, UV-visible spectrophotometry and high-performance liquid chromatography; microbiological testing; disintegration tests; dissolution tests; and sterility tests. It does not have the capacity to conduct polarimetry, atomic absorption spectrophotometry, testing for pyrogens and toxicity testing. The laboratory tests non-biological pharmaceutical products, including samples submitted by the Ministry of Health (MOH) in Jamaica as part of drug assessment for registration.

The laboratory's operation is funded by annual grants from the governments of CARICOM countries. Some countries fail to make the agreed contributions, which has resulted in the laboratory not being fully equipped to fulfill its functions efficiently. The laboratory charges fees for tests done for private sector clients. The fee schedule is attached. Details of the laboratory's budget for the past two years are outlined in Table 1.

Table 1: CRDTL budget details

Budget section	Year: 2007/08	Year: 2008/09
	USD	USD
Capital budget		
Salaries	197,750	200,000
Miscellaneous	91,705	151,740
TOTAL	289,455	351,740

Data on samples submitted and tested over the past two years are outlined in Table 2 and Table 3. The Government Chemist Department collects samples for testing on behalf of the CRDTL as part of a planned quality surveillance program for all countries in the CARICOM region. The CRDTL participates in the WHO proficiency testing scheme. A breakout of the samples submitted by country source is attached.

Table 2: Samples submitted/collected for testing

Test Requested By	Year: 2006/07	Year: 2007/08
Government drug inspectors (complaints)	7	4
Drug registration authority	40	251
Manufacturers	15	16
Private importers/wholesalers	5	1
Public sector procurement agencies**	106	20
Hospitals, clinics	2	
Individuals		
Routine analysis	57	75
Police investigation		2
TOTAL	113	137

** OECS/PPS

Table 3: CRDTL laboratory activity

Activities	Year: 2006/07	Year: 2007/08
Total number of drug products submitted for quality control (QC)	348	453
Total number of drug products on which QC was performed	349**	291
Total number of drug products that failed QC	36	53
Total number of products that passed the tests	313	238
Total number of samples on which QC could not be performed (because of lack of reagents, reference standards, procedures, expertise, equipment, etc.)**	19	70
Total to be analyzed	38	92

** 58 from 2005/06

Various factors prevented the CRDTL being able to analyze all the samples received. Factors included insufficient sample quantities for testing, no monographs, lack of equipment, insufficient instruction from the agent, no reference material, training required and duplication submissions. An additional constraint being faced by the laboratory is insufficient notice regarding submission of samples, which in turn has a negative impact on the ability to plan. The proficiency of the staff was cited as a major strength.

RECOMMENDATIONS

Based on the foregoing, it is evident that the CRDTL needs to be properly equipped if it is to have the capability to conduct comprehensive quality assurance testing for the entire region. In light of the recognition that many countries in the region do not have their own regulatory quality control laboratory, and that even those that do may only be able to do limited types of test, the CRDTL should be upgraded to fill this gap. The increasing risk to the region of the effects of counterfeit and substandard pharmaceutical products, the escalation of internet pharmacies and untested alternative medicines all speak to the urgent need for the region to be adequately equipped to detect medicines that may cause harm and even death to citizens.