# SAINT LUCIA

# PHARMACEUTICAL COUNTRY PROFILE

# SAINT LUCIA Pharmaceutical Country Profile

Published by the Ministry of Health, Wellness, Human Services and Gender Relations in collaboration with the Pan American Health Organization/World Health Organization (PAHO/WHO)

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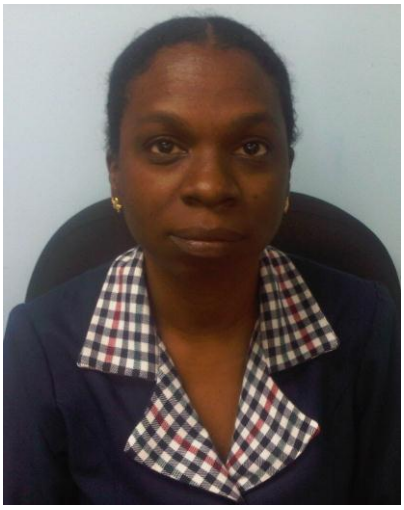
# Foreword



The 2012 Pharmaceutical Country Profile for Saint Lucia has been produced by the Ministry of Health, in collaboration with the Pan American Health Organization/World Health Organization (PAHO/WHO).

This document contains information on existing socio-economic and health-related conditions, resources; as well as on regulatory structures, processes and outcomes relating to the pharmaceutical sector in Saint Lucia. The compiled data comes from international sources, surveys conducted in the previous years and country level information collected in 2011. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

***On the behalf of the Ministry of Health, Wellness, Human Services and Gender Relations of Saint Lucia, I wish to express my appreciation to the following people for their contribution to the process of data collection and the development of this profile.***

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Donna Daniel (Chief Pharmacist)

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It is my hope that partners, researchers, policy-makers and all those who are interested in the Saint Lucia pharmaceutical sector will find this profile a useful tool to aid their activities.

Dr. Merlene Fredericks

**Chief Medical Officer** of Health Saint Lucia, West Indies


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# Acronyms and abbreviations

| | |
|---|---|
| ADR | Adverse Drug Reaction |
| CARICOM | Caribbean Community |
| CMS | Central Medical Store |
| CRDTL | Caribbean Regional Drug Testing Laboratory |
| DTC | Drug and Therapeutics Committee |
| EC$ | East Caribbean Dollar |
| EML | Drug and Therapeutics Committee |
| EPI | Expanded Programme on Immunization |
| GDP | Gross Domestic Product |
| GGHE | General Government Health Expenditure |
| GMP | Good Manufacturing Practices |
| HQ | Headquarters |
| ISO | International Organization for Standardization |
| MOH | Ministry of Health |
| MRA | Medicines Regulatory Authority |
| NHA | National Health Account |
| NHP | National Health Policy |
| NMP | National Medicines Policy |
| OECC | Office of Eastern Caribbean Countries |
| OECS | Organization of Eastern Caribbean States |
| OMF | OECS Medicines Formulary |
| PAHO | Pan American Health Organization |
| PPS | Pharmaceutical Procurement Service |
| STG | Standard Treatment Guideline |
| THE | Total Health Expenditure |
| TPE | Total Pharmaceutical Expenditure |
| TRIPS | Trade-Related Aspects of Intellectual Property Rights |
| UMC | Uppsala Monitoring Centre |
| USD | United States Dollar |
| WHO | World Health Organization |
| WTO | World Trade Organization |
| XCD | East Caribbean Dollar |


# Introduction

This Pharmaceutical Country Profile provides data on existing socio-economic and health-related conditions, resources, regulatory structures, processes and outcomes relating to the pharmaceutical sector of Saint Lucia. The aim of this document is to compile all relevant, existing information on the pharmaceutical sector and make it available to the public in a user-friendly format. In 2010, the country profiles project was piloted in 13 countries (http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html). During 2011, the World Health Organization has supported all WHO Member States to develop similar comprehensive pharmaceutical country profiles.

The information is categorized in 8 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy issues, (4) Medicines Trade and Production (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical procurement and distribution, and (8) Selection and rational use. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). This narrative profile is based on data derived from both the core and supplementary indicators. The tables in the annexes also present all data collected for each of the indicators in the original survey form. For each piece of information, the year and source of the data are indicated; these have been used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links have been provided to the source documents so that users can easily access these documents.


The selection of indicators for the profiles has involved all technical units working in the Essential Medicines Department of the World Health Organization (WHO), as well as experts from WHO Regional and Country Offices, Harvard Medical School, Oswaldo Cruz Foundation (known as Fiocruz), University of Utrecht, the Austrian Federal Institute for Health Care and representatives from 13 pilot countries.

Data collection in all 193 member states has been conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information. To facilitate the work of national counterparts, the questionnaires were pre-filled at WHO HQ using all publicly-available data and before being sent out to each country by the WHO Regional Office. A coordinator was nominated for each of the member states. The coordinator for Saint Lucia was Donna Daniel (Chief Pharmacist), with support of Adriana Mitsue Ivama and the PAHO/WHO team.

The completed questionnaires were then used to generate individual country profiles. In order to do this in a structured and efficient manner, a text template was developed. Experts from member states took part in the development of the profile and, once the final document was ready, an officer from the Ministry of Health certified the quality of the information and gave formal permission to publish the profile on the WHO web site.


This profile will be regularly updated by the Pan American Health Organization/World Health Organization. Comments, suggestions or corrections may be sent to:

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# Section 1 - Health and Demographic Data

This section gives an overview of the demographics and health status of Saint Lucia.

## 1.1 Demographic and Socioeconomic Indicators

The total population of Saint Lucia in 2010 was 165,595[1] with an annual population growth rate of 0.4%[2]. The annual GDP growth rate is -3.84%[3]. The GDP per capita was US$ 5,766.

27% of the population is under 15 years of age, and 9% of the population is over 60 years of age[4]. The urban population currently stands at 28% of the total population[2]. The fertility rate in Saint Lucia is 1.81 births per woman[2]. 40.6% of the population is living below the nationally defined poverty line[3]. The adult literacy rate[i] for the population over 15 years is 90.1%[2].

## 1.2 Mortality and Causes of Death

The life expectancy at birth is 74 and 80 years for men and women respectively[2]. The infant mortality rate (i.e. children under 1 year) is 12.72/1,000 live births[2]. For children under the age of 5, the mortality rate is 15/1,000 live births[4].

[i] Literacy rate is defined as population aged 15 and over that has ever attended school.

The top 10 diseases causing mortality in Saint Lucia are described in Table 1.

***Table 1. Top 10 causes of death in Saint Lucia***

| | Disease | % of deaths | Years of life lost (%) |
|---|---|---|---|
| | All causes | 100 | 100 |
| 1 | Cerebrovascular disease | 14 | 8 |
| 2 | Diabetes mellitus | 10 | 7 |
| 3 | Ischaemic heart disease | 8 | 5 |
| 4 | Hypertensive heart disease | 5 | 3 |
| 5 | Lower respiratory infections | 3 | 3 |
| 6 | Perinatal conditions | 3 | 8 |
| 7 | Road traffic accidents | 2 | 5 |
| 8 | Prostate cancer | 2 | 1 |
| 9 | Cirrhosis of the liver | 2 | 3 |
| 10 | Stomach cancer | 2 | 1 |

Source: WHO, 2006[5]

The adult mortality rate for both sexes between 16 and 60 years is 144/1,000 population[4], while the neonatal mortality rate is 12/1,000 live births[4]. The age-standardised mortality rate by non-communicable diseases is 522/100,000[4], 205/100,000 by cardiovascular diseases[6] and 128/100,000 by cancer[5]. The mortality rate for tuberculosis is 0.9/100,000 and 0.0/100,000 for malaria.


# Section 2 - Health Services

This section provides information regarding health expenditures and human resources for health in Saint Lucia. The contribution of the public and private sector to overall health expenditure is shown and the specific information on pharmaceutical expenditure is also presented. Data on human resources for health and for the pharmaceutical sector is provided as well.

## 2.1 Health Expenditures

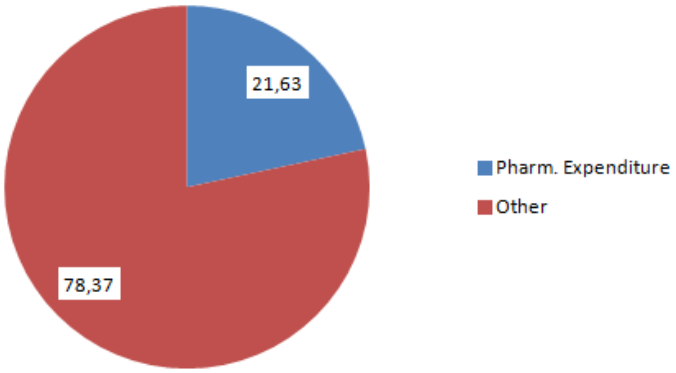
In Saint Lucia, the total annual expenditure on health (THE) in 2008 was 187.20 million East Caribbean Dollars (XCD) (USD 69.33 million)[7]. The total annual health expenditure was 7.33% of the GDP. The total annual expenditure on health per capita was EC$ 1,130.5 (USD 418.7).

The general government[ii] health expenditure (GGHE) in 2010, as reflected in the national health accounts (NHA) was ECD 129.47 million XCD (USD 47.65 million). That is, 69.2% of the total expenditure on health, with a total annual per capita public expenditure on health of XCD 781.85 (USD 287.75). The government annual expenditure on health represents 9.67% of the total government budget. Private health expenditure covers the remaining 30.8% of the total health expenditure.

[ii] According to the NHA definition, by "government expenditure" it is meant all expenditure from public sources, like central government, local government, public insurance funds and parastatal companies.

Total pharmaceutical expenditure (TPE) in Saint Lucia in 2008 was XCD 40.5 million (USD 15 million)[8], which is a per capita pharmaceutical expenditure of XCD 244.6 (USD 90.6). The total pharmaceutical expenditure accounts for 1.6% of the GDP and makes up 21.6% of the total health expenditure (Figure 1).

***Figure 1. Share of Total Pharmaceutical Expenditure as percentage of the Total Health Expenditure (2008). The THE in 2008 was XCD 187.20 million (USD 69.33 million)***




Social security expenditure makes up 2.73% of government expenditure on health[6].

Private out-of-pocket expenditure as % of private health expenditure is 94.56%. Premiums for private prepaid health plans are 5.44% of total private health expenditure[6].

## 2.2 Health Personnel and Infrastructure

There are 70 (4.2/10,000) licensed pharmacists and 108 (6.5/10,000) physicians in Saint Lucia[9]. The ratio of doctors to pharmacies is 5.4 : 1.


The health infrastructure is described in Table 2. There are 3 hospitals[7] and 28 hospital beds per 10,000 population[4] in Saint Lucia. There are 34 primary health care units and centres[7] and 20 licensed private pharmacies[8, iii].

***Table 2. Health centres and hospital statistics***

| Infrastructure | |
|---|---|
| Hospitals[7] | 3 |
| Hospital beds[4] | 28/10,000 pop. |
| Primary health care units and centres[7] | 34 |
| Licensed private pharmacies[8] | 20 |

[iii] 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.


# Section 3 - Policy Issues

This section addresses the characteristics of the pharmaceutical policy in Saint Lucia.

## 3.1 Policy Framework

In Saint Lucia, a National Health Policy (NHP) does not exist. An official National Medicines Policy (NMP) document or policies addressing pharmaceuticals do not either exist[8].

A policy relating to clinical laboratories does not exist.

Access to essential medicines/technologies as part of the fulfillment of the right to health, is not recognized in the constitution or national legislation. There are, however, official written guidelines on medicines donations.

There is no national good governance policy in Saint Lucia. A policy is not in place to manage and sanction conflict of interest issues in pharmaceutical affairs. The "Staff Orders" correspond to the formal code of conduct for the public officials.


# Section 4 – Medicines Trade and Production

This section provides information about the capacity for manufacturing medicines and the legal provisions governing patents.

## 4.1 Intellectual Property Laws and Medicines

Saint Lucia is a member of the World Trade Organization[10]. Legal provisions granting patents to manufacturers exist[11]. These cover pharmaceuticals and medical equipment.

Intellectual Property Rights are managed and enforced by the Attorney General's Chambers.

National Legislation[iv] has been modified to implement the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and contains TRIPS-specific flexibilities and safeguards[10], presented in Table 3. Saint Lucia is not eligible for the transitional period to 2016.

[iv] According to the HERA/CARICOM Report (2009)[11], the approved Patents Act (2001) is TRIPS-compliant but it is not yet in force. St. Lucia is bound by the following international agreements:

- EU-CARIFORUM EPA
- Patent Cooperation Treaty


***Table 3. TRIPS flexibilities and safeguards in the national law[12]***

| Flexibility and safeguards | Included |
|---|---|
| Compulsory licensing provisions that can be applied for reasons of public health | Yes |
| Bolar exceptions[v] | No |
| Parallel importing provisions | Yes |

The country is engaged in capacity-strengthening initiatives to manage and apply Intellectual Property Rights in order to contribute to innovation and promote public health[11].

There are no provisions for data exclusivity for pharmaceuticals, patent extension or linkage between patent status and marketing authorization[11].

[v] Many countries use this provision of the TRIPS Agreement to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.

In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval (for example from public health authorities) without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. *Article 30*

This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada - Patent Protection for Pharmaceutical Products")
*[In: WTO OMC Fact sheet: TRIPS and pharmaceutical patents, can be found on line at: http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]*


## 4.2 Manufacturing

There are no licensed pharmaceutical manufacturers in Saint Lucia and, consequently, the country has no capacity to carry out research and development activities to discover/produce new active substances, to produce formulations or to repack finished dosage forms.


# Section 5 – Medicines Regulation

This section details the pharmaceutical regulatory framework, resources, governing institutions and practices in Saint Lucia.

## 5.1 Regulatory Framework

In Saint Lucia, there is not a Medicines Regulatory Authority (MRA) as defined, nevertheless, some regulatory functions are carried out by the Ministry of Health and the Pharmacy Council (detailed in Table 4).

***Table 4. Regulatory activities carried out in Saint Lucia[8]***

| Function | |
|---|---|
| Marketing authorisation / registration | No |
| Inspection | Yes |
| Import control | No |
| Licensing | Yes |
| Market control | No |
| Quality control | No |
| Medicines advertising and promotion | No |
| Clinical trials control | No |
| Pharmacovigilance | No |

The Pharmacy Council is responsible for the registration of Pharmacists and pharmacies; and the Ministry of Health exerts control on narcotics and psychotropic substances.


Saint Lucia is involved in harmonization/collaboration initiatives such as the Caribbean Community (CARICOM)[13] and the Organisation of Eastern Caribbean States (OECS)[14]. An assessment of the medicines regulatory system has been conducted in the last five years[8]. According to the mentioned report, existing medicines legislation includes the Pharmacy Act No. 8 of 2003[15]; the Pharmacy (Forms and Fees) Regulations 2006[16] and the Pharmacy Regulations 2007[17]. The Council is responsible for regulating the pharmacy practice including registration of Pharmacists, pharmacies and sellers of poisons.

### 5.2 Marketing Authorization (Registration)

In Saint Lucia, legal provisions do not require [vi] marketing authorization (registration) for pharmaceutical products on the market[8].

### 5.3 Regulatory Inspection

In Saint Lucia, legal provisions exist allowing for appointment of government pharmaceutical inspectors[14]. There are no specific legal provisions permitting inspectors to inspect premises where pharmaceutical activities are performed, even though, such inspections are required. The inspection requirements are the same for public and private facilities.

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[vi] One of the functions of the Pharmacy Council 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 licenses for manufacture, importation, wholesale, market authorization of medicines, control of clinical trials and counterfeit products, control of product promotion and advertising or safety monitoring of products.


There are no Good Manufacturing Practices (GMP) inspections as there is no manufacturers in the country 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)[8].

### 5.4 Import Control

Legal provisions do not exist requiring authorization to import medicines[8]. Legal provisions do not either exist requiring importation of medicines through authorized ports of entry.

### 5.5 Licensing

In Saint Lucia, legal provisions do not require importers, wholesalers or distributors to be licensed[8]. Legal provisions exist requiring pharmacists to be registered as well as the private pharmacies[8].

### 5.6 Market Control and Quality Control

In Saint Lucia, legal provisions do not exist for controlling the pharmaceutical market[7]. A laboratory does not exist in Saint Lucia for Quality Control testing[7]. Samples, however, are sent to the Caribbean Regional Drug Testing Laboratory


(CRDTL)[vii] in Jamaica. Results of quality testing in the last two years are not publicly available.

Medicines are only tested for public procurement prequalification, and samples are not collected by government inspectors for undertaking post-marketing surveillance testing.

## 5.7 Medicines Advertising and Promotion

In Saint Lucia, legal provisions do not exist to control the promotion and advertising of prescription medicines[7]. Legal provisions do not prohibit direct advertising of prescription medicines to the public and pre-approval for medicines advertisements and promotional materials is not required[7].

## 5.8 Clinical Trials

In Saint Lucia, legal provisions do not exist requiring authorization for conducting Clinical Trials[8].

[vii] Quality control is carried out by the Caribbean Regional Drug Testing Laboratory (CRDTL) 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. Available online: http://www.caricom.org/jsp/secretariat/legal_instruments/agreement_crdtl.jsp?menu=secretariat


## 5.9 Controlled Medicines

Saint Lucia is a signatory to a number of international conventions, detailed in Table 5.

***Table 5. International Conventions to which Saint Lucia is a signatory[18]***

| Convention | Signatory |
|---|---|
| Single Convention on Narcotic Drugs, 1961 | Yes |
| 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961 | Yes |
| Convention on Psychotropic Substances 1971 | Yes |
| United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 | Yes |

The legal provisions and regulations for the control of narcotic and psychotropic substances and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need.

Figures regarding the annual consumption of certain controlled substances in the country are outlined in Table 6 below.


***Table 6. Annual consumption[viii] of selected controlled substances***

| Controlled Substance | Annual consumption (mg/capita) |
|---|---|
| Morphine[17] | 0.988235 |
| Fentanyl | 0.000100 |
| Pethidine | 8.700000 |
| Oxycodone | 0.000000 |
| Hydrocodone | 0.035000 |
| Phenobarbital | 5.310000 |
| Methadone | 0.210000 |

## 5.10 Pharmacovigilance

In Saint Lucia, there are no legal provisions requiring pharmacovigilance activities[8]**.** Laws regarding the monitoring of Adverse Drug Reactions (ADR) do not either exist[8]. A national pharmacovigilance centre does not exist.

Pharmacovigilance is performed in partnership with the OECS Pharmaceutical Procurement Service (PPS) and ADR reports are sent to PPS/OECS which perform it for OECS countries. An official standardized form for reporting ADRs common to OECS countries is used; and a computerized national ADR database exists at PPS/OECS (Vigiflow). These reports are sent to the WHO collaborating centre in Uppsala by PPS/OECS[19]. A clear communication strategy for routine communication and crises communication does not exist.

[viii] Data for fentanyl, pethidine, oxycodone, hydrocodone, phenobarbital and methadone were obtained from the Chief Pharmacist office.


Feedback is not provided to reporters. Medication errors are not reported. In the last two years physicians and pharmacists have reported ADRs; however, no regulatory decision has been taken based on local pharmacovigilance data.

The governmental plan to enhance the pharmacovigilance system includes promoting the submittal of ADR reports. Currently there are only two active OECS member states (St. Vincent and the Grenadines and Dominica) reporting ADR. OECS/PPS encourages the other countries to report and will upload the data to the Vigiflow database in the Uppsala Monitoring Centre (UMC). Saint Lucia will intend to communicate the findings through a pharmacovigilance bulletin.


# Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in Saint Lucia, including the medicines coverage through public and private health insurance, use of user charges for medicines and the existence of public programmes providing free medicines. Policies and regulations affecting the pricing and availability of medicines (e.g. price control and taxes) are also discussed.

## 6.1 Medicines Coverage and Exemptions

In Saint Lucia, there are provisions for certain groups to receive medicines free of charge (see Table 7). Furthermore, the public health system or social health insurance scheme provides medicines free of charge for particular conditions (see Table 8).

***Table 7. Population groups provided with medicines free of charge***

| Patient group | Covered |
|---|---|
| Patients who cannot afford them | Yes |
| Children under 5 | Yes |
| Pregnant women | No |
| Elderly persons | No |


***Table 8. Medications provided publicly, at no cost***

| Conditions | Covered |
|---|---|
| Malaria | No |
| Tuberculosis | Yes |
| Sexually transmitted diseases | Yes |
| HIV/AIDS | Yes |
| Expanded Program on Immunization (EPI) vaccines for children | Yes |

The public health services provide at least partial medicines coverage. It provides coverage for medicines that are on the Essential Medicines List (EML) for inpatients and outpatients.

Private health insurance schemes provide medicines coverage, but they are not required to provide coverage for medicines that are on the EML.

## 6.2 Patients Fees and Copayments

Co-payments or fee requirements for consultations are levied at the point of delivery. However, there are no copayments or fee requirements imposed for medicines.

Revenue from fees or from the sale of medicines is not used to pay the salaries or supplement the income of public health personnel in the same facility.


### 6.3 Pricing Regulation for the Private Sector[ix]

In Saint Lucia, there are no legal legal or regulatory provisions affecting pricing of medicines.

The government does not run an active national medicines price monitoring system for retail prices. Regulations do not exist mandating that retail medicine price information should be publicly accessible.

### 6.4 Prices, Availability and Affordability

No surveys on medicines prices, availability or affordability have been conducted in Saint Lucia in the past 5 years.

### 6.5 Price Components

No surveys on medicines price components have been conducted in Saint Lucia in the past 5 years.

### 6.6 Duties and Taxes on Pharmaceuticals (Market)

Saint Lucia does not impose duties on imported finished pharmaceutical products.

[ix] This section does not include information pertaining to the non-profit voluntary sector.


# Section 7 - Pharmaceutical procurement and distribution in the public sector

This section provides a short overview on the procurement and distribution of pharmaceuticals in the public sector of Saint Lucia.

## 7.1 Public Sector Procurement

Public sector procurement in Saint Lucia is centralized[7]. It is the responsibility of the Ministry of Health trough OECS/PPS. The Ministry procures a limited number of non-formulary medicines and health products for specific patients on demand. All medicines used in the country are imported.

Public sector request for tender documents are not publicly available but public sector tender awards are. Procurement is based on the prequalification of suppliers. Suppliers who are willing to participate in the procurement process must register with the OECS/PPS.

There is a written public sector procurement policy. This policy was approved in 1986. The key functions of the procurement unit and those of the tender committee are not clearly separated. A process exists at the OECS/PPS to ensure the quality of products that are publicly procured. The quality assurance process does not include the pre-qualification of products and suppliers.


A list of samples tested during the procurement process and the results of quality testing are not available. The tender methods employed in public sector procurement include international competitive tenders and direct purchasing.

## 7.2 Public Sector Distribution

Medicines distribution is the responsibility of the Ministry of Health. The government supply system department in Saint Lucia has a Central Medical Store (CMS) at National Level and there are no public warehouses in the secondary tier of the public sector distribution. There are no national guidelines on Good Distribution Practices (GDP) and a licensing authority that issues GDP licenses does not exist.

A number of processes are in place at the Central Medical Store as detailed in Table 9.

***Table 9. Processes employed by the Central Medical Store***

| Process | |
|---|---|
| Forecasting of order quantities | Yes |
| Requisition / Stock orders | Yes |
| Preparation of picking / packing slips | Yes |
| Reports of stock on hand | Yes |
| Reports of outstanding order lines | Yes |
| Expiry dates management | Yes |
| Batch tracking | Yes |
| Reports of products out of stock | Yes |


Routine procedure to track the expiry dates of medicines at the CMS exists. The public CMS is not ISO certified.

### 7.3 Private Sector Distribution

Legal provisions do not exist for licensing wholesalers or distributors in the private sector.


# Section 8 - Selection and rational use of medicines

This section outlines the structures and policies governing the selection of essential medicines and promotion of rational drug in Saint Lucia.

## 8.1 National Structures

A National Essential Medicines List (EML)[x] exists[7]. The EML was lastly updated in 2009 and is not publicly available.

There are currently 600 medicines on the EML. Selection of medicines for the EML is not undertaken through a written process. A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is not in place.

National Standard Treatment Guidelines (STGs) for the most common illnesses are produced/endorsed by the Ministry of Health. These were last updated in 2011. There are no specific STGs for Primary or Secondary care.

Of the public health facilities, 54.2% have a copy of the EML and 58.3% have a copy of the STGs[7].

There is no public or independently funded national medicines information. There is no national programme or committee to monitor and promote rational use of medicines.

[x] Saint Lucia has adopted the OECS Medicines Formulary (OMF) as the equivalent of its national Essential Medicines List[7].


A written National Strategy for containing antimicrobial resistance does not exist. A funded national intersectoral task force to coordinate the promotion of the appropriate use of antimicrobials and prevention of infection does not either exist. A national reference laboratory does not have responsibility for coordinating epidemiological surveillance of antimicrobial resistance.

There is a formal committee for the selection of products on the OECS Medicines Formulaty (OMF), which is adopted as national EML .

## 8.2 Prescribing

Legal provisions do not exist to govern the licensing and prescribing practices of prescribers. Prescribers in the private sector dispense medicines.

There are no regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs).

The training curriculum for doctors and nurses does not include the concept of EML or the use of STGs. Mandatory continuing education that includes pharmaceutical issues is not required for doctors or paramedical staff.

Prescribing by International Non-Proprietary (INN) name is obligatory only in the public sector. The average number of medicines prescribed per patient contact in public health facilities is 3.2. Of the medicines prescribed in the outpatient public health care facilities, 92.9% are on the national EML and 43.9% are prescribed

by INN name[8]. Of the patients treated in the outpatient public health care facilities, 21.5% receives antibiotics and 0% receives injections. Of prescribed drugs, 86.4% are dispensed to patients. Of medicines in public health facilities, 96.4% are adequately labelled.

***Table 10. Characteristics of medicines prescribing***

| Description | % |
|---|---|
| % of medicines prescribed in outpatient public health care facilities that are in the national EML (mean) | 92.9 |
| % of medicines in outpatient public health care facilities that are prescribed by INN name (mean) | 43.9 |
| % of patients in outpatient public health care facilities receiving antibiotics (mean) | 21.5 |
| % of patients in outpatient public health care facilities receiving injections (mean) | 0.0 |
| % of prescribed drugs dispensed to patients (mean) | 86.4 |
| % of medicines adequately labelled in public health facilities (mean) | 96.4 |

A professional association code of conduct which governs the professional behaviour of doctors and nurses exists (respectively).

## 8.3 Dispensing

Legal provisions in Saint Lucia exist to govern dispensing practices of pharmaceutical personnel[14]. There are no schools of Pharmacy in the country.


However, mandatory continuing education that includes rational use of medicines is required for pharmacists.

Substitution of generic equivalents at the point of dispensing is allowed in public and private sector facilities. Sometimes antibiotics are sold over-the-counter without a prescription.

In practice, Family Nurse Practitioners sometimes prescribe prescription-only medicines at the primary care level in the public sector, according to national regulations.

## References


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[16] Saint Lucia, Pharmacy (Forms and Fees) Regulations, 2006. Available online: http://www.pharmacycouncilslu.org/09july/Pharmacy%20Regulations%20I%20_Forms%20and%20Fees_.pdf


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# SAINT LUCIA

# Pharmaceutical Country Profile

# ANNEX

## Survey Data

**(Fragment of the questionnaire)**

**2011**

## Section 0 General Info

### 0.01 Contact Info

| | | |
|---|---|---|
| 0.01.01 | Country (precoded) | Saint Lucia |
| 0.01.02 | Name coordinator | Donna Daniel |
| 0.01.03 | Address (Street, City) | The Waterfront, Castries |
| 0.01.04 | Phone number | 1-758-453-2668 tel/Fax @ Office/1-758-285-0125 Mobile 1/1-758-724-7411Mobile 2/1-758-453-0338 Fax |
| 0.01.05 | Email address | louised4@yahoo.com |
| 0.01.06 | Web address | |
| 0.01.07 | Institution | Chief Pharmacist, Ministry of Health |

# Section 1 Health and Demographic data

## 1.00 Respondent Information Section 1

| | | |
|---|---|---|
| 1.00.01 | Name of person responsible for filling out Survey section 1 | Dr. Alina Jaime |
| 1.00.02 | Phone number | |
| 1.00.03 | Email address | montane5@yahoo.com |
| 1.00.04 | Other respondents for filling out this section | |

## 1.01 Demographic and Socioeconomic Indicators

### Core questions (click here for help)

| | | | Year | Source |
|---|---|---|---|---|
| 1.01.01 | Population, total (,000) | 165. 595 | 2010 | St Lucia Central Statistics Office |
| 1.01.02 | Population growth rate (Annual %) | 0.4 | 2011 | CIA |
| 1.01.03 | Total Gross Domestic Product (GDP) (millions US$) | 945.83 | 2009 | World Bank data |
| 1.01.04 | GDP growth (Annual %) | -3.84 | 2009 | World Bank data |
| 1.01.05C | GDP per capita (US$ current exchange rate) | 10,163.30 | 2001 | IMF |
| 1.01.06 | Comments and References | 1.01.01. Census 2010 (Preliminary Report). It includes the non-resident population of 7,194; Available at: http://www.stats.gov.lc/StLuciaPreliminaryCensusReport2010.pdf | | |

### Supplementary questions (click here for help)

| | | | Year | Source |
|---|---|---|---|---|
| 1.01.07S | Population < 15 years (% of total population) | 7 | 2008 | WHS |
| 1.01.08S | Population > 60 years (% of total | 9 | 2008 | WHS |

| | | | | |
|---|---|---|---|---|
| | population) | | | |
| 1.01.09S | Urban population (% of total population) | 28 | 2011 | CIA |
| 1.01.10S | Fertility rate, total (Births per woman) | 1.81 | 2011 | CIA |
| 1.01.11S | Population living with less than $1.25/day (international PPP) (%) | | | |
| 1.01.12S | Population living below nationally defined poverty line (%) | 40.6 | 1995 | World Bank Data |
| 1.01.13S | Income share held by lowest 20% of the population (% of national income) | | | |
| 1.01.14S | Adult literacy rate, 15+ years (% of relevant population) | 90.1 | 2011 | CIA |
| 1.01.15S | Comments and References | 1.01.14S definition literacy rate: age 15 and over has ever attended school | | |

## 1.02 Mortality and Causes of Death

### Core questions (click here for help)

| | | | Year | Source |
|---|---|---|---|---|
| 1.02.01 | Life expectancy at birth for men (Years) | 74 | 2011 | CIA |
| 1.02.02 | Life expectancy at birth for women (Years) | 80 | 2011 | CIA |
| 1.02.03 | Infant mortality rate, between birth and age 1 (/1,000 live births) | 12.72 | 2011 | CIA |
| 1.02.04 | Under 5 mortality rate (/1,000 live births) | 15 | 2008 | WHS |
| 1.02.05 | Maternal mortality ratio (/100,000 live births) | | | |
| 1.02.06 | Please provide a list of top 10 diseases causing mortality | | 2006 | WHO Mortality Country Fact Sheet |

| | | |
|---|---|---|
| 1.02.06.01 | Disease 1 | Cerebrovascular disease |
| 1.02.06.02 | Disease 2 | Diabetes mellitus |
| 1.02.06.03 | Disease 3 | Ischaemic heart disease |
| 1.02.06.04 | Disease 4 | Hypertensive heart disease |
| 1.02.06.05 | Disease 5 | Lower respiratory infections |
| 1.02.06.06 | Disease 6 | Perinatal conditions |
| 1.02.06.07 | Disease 7 | Road traffic accidents |
| 1.02.06.08 | Disease 8 | Prostate cancer |
| 1.02.06.09 | Disease 9 | Cirrhosis of the liver |
| 1.02.06.10 | Disease 10 | Stomach cancer |
| 1.02.07 | Please provide a list of top 10 diseases causing morbidity  | |
| 1.02.07.01 | Disease 1 | |
| 1.02.07.02 | Disease 2 | |
| 1.02.07.03 | Disease 3 | |
| 1.02.07.04 | Disease 4 | |
| 1.02.07.05 | Disease 5 | |
| 1.02.07.06 | Disease 6 | |
| 1.02.07.07 | Disease 7 | |
| 1.02.07.08 | Disease 8 | |
| 1.02.07.09 | Disease 9 | |
| 1.02.07.10 | Disease 10 | |
| 1.02.08 | Comments and References | |

| Supplementary questions (click here for help) | | | | |
|---|---|---|---|---|
| | | | Year | Source |
| 1.02.09S | Adult mortality rate for both sexes between 15 and 60 years (/1,000 population) | 144 | 2008 | WHS |
| 1.02.10S | Neonatal mortality rate ( /1,000 live births) | 12 | 2008 | WHS |
| 1.02.11S | Age-standardized mortality rate by non-communicable diseases (/100,000 population) | 522 | 2004 | WHS |
| 1.02.12S | Age-standardized mortality rate by cardiovascular diseases (/100,000 population) | 205 | 2009 | WHS |
| 1.02.13S | Age-standardized mortality rate by cancer ( /100,000 population) | 128 | 2009 | WHS |
| 1.02.14S | Mortality rate for HIV/AIDS (/100,000 population) | | | |
| 1.02.15S | Mortality rate for tuberculosis (/100,000 population) | 0.9 | 2008 | WHS |
| 1.02.16S | Mortality rate for Malaria (/100,000 population) | 0.0 | 2006 | WHS |
| 1.02.17S | Comments and References | | | |

## Section 2 Health Services

### 2.00 Respondent Information Section 2

| | | |
|---|---|---|
| 2.00.01 | Name of person responsible for filling out this section of the instrument | Mr. Lincoln Auguste |
| 2.00.02 | Phone number | 1-758-468-3229 |
| 2.00.03 | Email address | lauguste@gosl.gov.lc |
| 2.00.04 | Other respondents for filling out this section | |

### 2.01 Health Expenditures

**Core questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 2.01.01.01 | Total annual expenditure on health (millions NCU) | 187.20 | 2008 | NHA data |
| 2.01.01.02 | Total annual expenditure on health (millions US$ average exchange rate) | 69.33 | 2008 | NHA data |
| 2.01.02C | Total health expenditure as % of Gross Domestic Product | 6.96 | | |
| 2.01.03.01C | Total annual expenditure on health per capita (NCU) | 1,101.18 | | |
| 2.01.03.02C | Total annual expenditure on health per capita (US$ average exchange rate) | 407.84 | | |
| 2.01.04.01 | General government annual expenditure on health (millions NCU) | 129.47 | 2010 | NHA data |
| 2.01.04.02 | General government annual expenditure on health (millions US$ average exchange rate) | 47.65 | 2010 | MOHE data |
| 2.01.05 | Government annual expenditure on health as percentage of total government budget (% of total government budget) | 9.67 | 2010 | MOHE data |

| | | | | |
|---|---|---|---|---|
| 2.01.06C | Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health) | 58.76 | 2008 | NHA data |
| 2.01.07.01C | Annual per capita government expenditure on health (NCU) | 647.06 | | |
| 2.01.07.02C | Annual per capita government expenditure on health (US$ average exchange rate) | 239.65 | | |
| 2.01.08C | Private health expenditure as % of total health expenditure (% of total expenditure on health) | 41.24 | 2008 | NHA data |
| 2.01.09 | Population covered by a public health service or public health insurance or social health insurance, or other sickness funds of total population) | | | |
| 2.01.10 | Population covered by private health insurance (% of total population) | | | |
| 2.01.11.01 | Total pharmaceutical expenditure (millions NCU) | | | |
| 2.01.11.02 | Total pharmaceutical expenditure (millions US$ current exchange rate) | 15 | 2008 | WHO Level II Survey |
| 2.01.12.01C | Total pharmaceutical expenditure per capita (NCU) | PREFILL CALC | | |
| 2.01.12.02C | Total pharmaceutical expenditure per capita (US$ current exchange rate) | PREFILL CALC | | |
| 2.01.13C | Pharmaceutical expenditure as a % of GDP (% of GDP) | PREFILL CALC | | |
| 2.01.14C | Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure) | PREFILL CALC | | |
| 2.01.15.01 | Total public expenditure on | | | |

| | | | | |
|---|---|---|---|---|
| | pharmaceuticals (millions NCU) | | | |
| 2.01.15.02 | Total public expenditure on pharmaceuticals (millions US$ current exchange rate) | | | |
| 2.01.16C | Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%) | PREFILL CALC | | |
| 2.01.17.01C | Total public expenditure on pharmaceuticals per capita (NCU) | PREFILL CALC | | |
| 2.01.17.02C | Total public expenditure on pharmaceuticals per capita (US$ current exchange rate) | PREFILL CALC | | |
| 2.01.18.01 | Total private expenditure on pharmaceuticals (millions NCU) | | | |
| 2.01.18.02 | Total private expenditure on pharmaceuticals (millions US$ current exchange rate) | | | |
| 2.01.19 | Comments and References | | | |

**Supplementary questions (click for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 2.01.20S | Social security expenditure as % of government expenditure on health (% of government expenditure on health) | 2.73 | 2008 | NHA |
| 2.01.21S | Market share of generic pharmaceuticals [branded and INN] by value (%) | | | |
| 2.01.22S | Annual growth rate of total pharmaceuticals market value (%) | | | |
| 2.01.23S | Annual growth rate of generic pharmaceuticals market value (%) | | | |

| | | | | |
|---|---|---|---|---|
| 2.01.24S | Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health) | 94.56 | 2008 | NHA |
| 2.01.25S | Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health) | 5.44 | 2008 | NHA |
| 2.01.26S | Comments and References | | | |

## 2.02 Health Personnel and Infrastructure

### Core questions (click for help)

| | | | Year | Source |
|---|---|---|---|---|
| 2.02.01 | Total number of pharmacists licensed/registered to practice in your country | 70 | 2009 | HERA |
| 2.02.02C | Pharmacists per 10,000 population | 4.3 | | |
| 2.02.03 | Total number of pharmacists working in the public sector | | | |
| 2.02.04 | Total number of pharmaceutical technicians and assistants | | | |
| 2.02.05 | A strategic plan for pharmaceutical human resource development is in place in your country? | Yes ☐ No ☐ | | |
| 2.02.06 | Total number of physicians | 108 | 2009 | HERA |
| 2.02.07C | Physicians per 10,000 pop | 6.7 | | |
| 2.02.08 | Total number of nursing and midwifery personnel | | | |
| 2.02.09C | Nurses and midwives per 10,000 pop | | | |
| 2.02.10 | Total number of hospitals | 3 | 2010 | WHO Level II Survey |

| | | | | |
|---|---|---|---|---|
| 2.02.11 | Number of hospital beds per 10,000 pop | 28 | 2009 | WHS |
| 2.02.12 | Total number of primary health care units and centers | 34 | 2010 | WHO Level II Survey |
| 2.02.13 | Total number of licensed pharmacies | 20 | 2009 | HERA |
| 2.02.14 | Comments and References | 2.02.14 The pharmaceutical delivery system is comprised of 3 government hospital pharmacies, 20 private for-profit retail pharmacies and 33 government health centre pharmacies. Only the private sector pharmacies are required to be licensed. | | |

**Supplementary questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 2.02.15S | Starting annual salary for a newly registered pharmacist in the public sector (NCU) | | | |
| 2.02.16S | Total number of pharmacists who graduated (first degree) in the past 2 years in your country | | | |
| 2.02.17S | Are there accreditation requirements for pharmacy schools? | Yes ☐ No☐ | | |
| 2.02.18S | Is the Pharmacy Curriculum regularly reviewed? | Yes ☐ No ☐ | | |
| 2.02.19S | Comments and References | | | |

## Section 3 Policy issues

### 3.00 Respondent Information Section 4

| | | | | |
|---|---|---|---|---|
| 3.00.01 | Name of person responsible for filling out this section of the instrument | Donna L. Daniel | | |
| 3.00.02 | Phone number | 1-758-285-0125/724-7411 | | |
| 3.00.03 | Email address | louised4u@yahoo.com | | |
| 3.00.04 | Other respondents for filling out this section | | | |

### 3.01 Policy Framework

**Core questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 3.01.01 | National Health Policy exists. If yes, please write year of the most recent document in the "year" field. | Yes ☐ No ☒ | 2011 | MOH |
| 3.01.02 | National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the "year" | Yes ☐ No ☒ | 2011 | MOH |
| 3.01.03 | Please provide comments on the Health policy and its implementation plan | | | |
| 3.01.04 | National Medicines Policy official document exists. If yes, please write the year of the most recent document in the "year" field. | Yes ☐ No ☒ | 2009 | HERA |
| 3.01.05 | Group of policies addressing pharmaceuticals exist. | Yes ☐ No ☒ | 2011 | MOH |
| 3.01.06 | National Medicines Policy covers the following components: | — | | |

| | | | | |
|---|---|---|---|---|
| 3.01.06.01 | Selection of Essential Medicines | ☐Yes | | |
| 3.01.06.02 | Medicines Financing | ☐Yes | | |
| 3.01.06.03 | Medicines Pricing | ☐Yes | | |
| 3.01.06.04 | Medicines Procurement | ☐Yes | | |
| 3.01.06.05 | Medicines Distribution | ☐Yes | | |
| 3.01.06.06 | Medicines Regulation | ☐Yes | | |
| 3.01.06.07 | Pharmacovigilance | ☐Yes | | |
| 3.01.06.08 | Rational Use of Medicines | ☐Yes | | |
| 3.01.06.09 | Human Resource Development | ☐Yes | | |
| 3.01.06.10 | Research | ☐Yes | | |
| 3.01.06.11 | Monitoring and Evaluation | ☐Yes | | |
| 3.01.06.12 | Traditional Medicine | ☐Yes | | |
| 3.01.07 | National medicines policy implementation plan exists. If yes, please write year of the most recent document. | Yes ☐ No ☒ | 2011 | MOH |
| 3.01.08 | Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in the "year" field | Yes ☐ No ☒ | 2011 | MOH |
| 3.01.09 | National clinical laboratory policy implementation plan exists. If yes, please write year of the most recent document in the "year" field | Yes ☐ No ☒ | 2011 | MOH |
| 3.01.10 | Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation? | Yes ☐ No ☒ | 2011 | MOH |

| | | | | |
|---|---|---|---|---|
| 3.01.11 | There are official written guidelines on medicines donations. | Yes ☒ No ☐ | 2011 | MOH |
| 3.01.12 | Is pharmaceutical policy implementation being regularly monitored/assessed? | Yes ☐ No ☒ | 2011 | MOH |
| 3.01.12.01 | Who is responsible for pharmaceutical policy monitoring? | Ministry of Health | | |
| 3.01.13 | Is there a national good governance policy? | Yes ☐ No ☒ | 2011 | MOH |
| 3.01.13.01 | Multisectoral | ☐Yes | | |
| 3.01.13.02 | For the pharmaceutical sector | ☐Yes | | |
| 3.01.13.03 | Which agencies are responsible? | | | |
| 3.01.14 | A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs. | Yes ☐ No ☒ | 2011 | MOH |
| 3.01.15 | There is a formal code of conduct for public officials. | Yes ☒ No ☐ | 2011 | MOH |
| 3.01.16 | Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)? | Yes ☐ No ☐ | | |
| 3.01.16.01 | Please describe: | | | |
| 3.01.17 | Comments and References | 3.01.15. The "Staff Orders" correspond to the code of conduct for the public officials. | | |

## Section 4 Medicines Trade and Production

### 4.00 Respondent Information Section 4

| | | |
|---|---|---|
| 4.00.01 | Name of person responsible for filling out this section of the instrument | Donna L. Daniel |
| 4.00.02 | Phone number | 1-758-285-0125/724-7411 |
| 4.00.03 | Email address | louised4u@yahoo.com |
| 4.00.04 | Other respondents for filling out this section | |

### 4.01 Intellectual Property Laws and Medicines

**Core questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 4.01.01 | Country is a member of the World Trade Organization | Yes ☒ No☐ | 1995 | WTO 2011 |
| 4.01.02 | Legal provisions provide for granting of Patents on: | | 2010 | Patents Act |
| 4.01.02.01 | Pharmaceuticals | Yes ☒ No☐ | | |
| 4.01.02.02 | Laboratory supplies | Yes ☐ No ☐ | | |
| 4.01.02.03 | Medical supplies | Yes ☐ No ☐ | | |
| 4.01.02.04 | Medical equipment | Yes ☒ No ☐ | | |
| 4.01.03.01 | Please provide name and address of the institution responsible for managing and enforcing intellectual property rights | Registry of Companies and intellectual property (Attorney Generals Chambers) | | |
| 4.01.03.02 | Please provide URL | | | |
| 4.01.04 | National Legislation has been modified to implement the TRIPS Agreement | Yes ☒ No ☐ | 2001 | Patent Act |
| 4.01.05 | Current laws contain (TRIPS) flexibilities and safeguards | Yes ☒ No☐ | 2001 | Patent Act |

| | | | | |
|---|---|---|---|---|
| 4.01.06 | Country is eligible for the transitional period to 2016 | Yes ☐ No☒ | 2011 | MOH |
| 4.01.07 | Which of the following (TRIPS) flexibilities and safeguards are present in the national law? | | 2009 | HERA/CARICOM |
| 4.01.07.01 | Compulsory licensing provisions that can be applied for reasons of public health | Yes ☒ No ☐ | | |
| 4.01.07.02 | Bolar exception | Yes ☐ No ☒ | | |
| 4.01.08 | Are parallel importing provisions present in the national law? | Yes ☒ No ☐ | 2009 | HERA/CARICOM |
| 4.01.09 | The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health | Yes ☒ No ☐ | 2009 | HERA/CARICOM |
| 4.01.10 | Are there legal provisions for data exclusivity for pharmaceuticals | Yes ☐ No ☒ | 2009 | HERA/CARICOM |
| 4.01.11 | Legal provisions exist for patent extension | Yes ☐ No ☒ | 2009 | HERA/CARICOM |
| 4.01.12 | Legal provisions exist for linkage between patent status and Marketing Authorization | Yes ☐ No ☒ | 2009 | HERA/CARICOM |
| 4.01.13 | Comments and References | According to the HERA/CARICOM Report (2009), The approved Patents Act 2001 is TRIPS-compliant but it is not yet in force. St. Lucia is bound by the following international agreements:<br>• EU-CARIFORUM EPA<br>• Patent Cooperation Treaty | | |

## 4.02 Manufacturing

**Core questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 4.02.01 | Number of licensed | 0 | 2010 | WHO Level |

| | | | | |
|---|---|---|---|---|
| | pharmaceutical manufacturers in the country | | | II Survey |
| 4.02.02 | Country has manufacturing capacity | | 2011 | MOH |
| 4.02.02.01 | R&D to discover new active substances | Yes ☐ No ☒ Unknown ☐ | | |
| 4.02.02.02 | Production of pharmaceutical starting materials (APIs) | Yes ☐ No ☒ Unknown ☐ | | |
| 4.02.02.03 | Production of formulations from pharmaceutical starting material | Yes ☐ No ☒ Unknown ☐ | | |
| 4.02.02.04 | Repackaging of finished dosage forms | Yes ☐ No ☒ Unknown ☐ | | |
| 4.02.03 | Percentage of market share by value produced by domestic manufacturers (%) | 0 | 2009 | HERA |
| 4.02.04 | Comments and References | | | |

**Supplementary questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 4.02.05S | Percentage of market share by volume produced by domestic manufacturers (%) | | | |
| 4.02.06S | Number of multinational pharmaceutical companies manufacturing medicines locally | | | |
| 4.02.07S | Number of manufacturers that are Good Manufacturing Practice (GMP) certified | | | |
| 4.02.08S | Comments and References | | | |

## Section 5 Medicines Regulation

### 5.00 Respondent Information Section 4

| | | |
|---|---|---|
| 5.00.01 | Name of person responsible for filling out this section of the instrument | Donna L. Daniel |
| 5.00.02 | Phone number | 1-758-285-0125/724-7411 |
| 5.00.03 | Email address | louised4u@yahoo.com |
| 5.00.04 | Other respondents for filling out this section | Roseann St. Rose OECS/PPS |

### 5.01 Regulatory Framework

**Core questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 5.01.01 | Are there legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA)? | Yes ☐ No ☒ | 2009 | HERA/CARICOM |
| 5.01.02 | There is a Medicines Regulatory Authority | Yes ☐ No ☒ | 2009 | HERA/CARICOM |
| 5.01.03 | If yes, please provide name and address of the Medicines regulatory authority | There is not an regulatory authority as defined, nevertheless, some regulatory functions are carried out by the MOH or Pharmacy Council. | | |
| 5.01.04 | The Medicines Regulatory Authority is: | | | |
| 5.01.04.01 | Part of MoH | ☐Yes | | |
| 5.01.04.02 | Semi autonomous agency | ☐Yes | | |
| 5.01.04.03 | Other (please specify) | | | |
| 5.01.05 | What are the functions of the National Medicines Regulatory Authority? | | 2009 | HERA/CARICOM |

| | | | | |
|---|---|---|---|---|
| 5.01.05.01 | Marketing authorization / registration | Yes ☐ No ☐ | | |
| 5.01.05.02 | Inspection | Yes ☒ No ☐ | | |
| 5.01.05.03 | Import control | Yes ☐ No ☐ | | |
| 5.01.05.04 | Licensing | Yes ☒ No ☐ | | |
| 5.01.05.05 | Market control | Yes ☐ No ☐ | | |
| 5.01.05.06 | Quality control | Yes ☐ No ☐ | | |
| 5.01.05.07 | Medicines advertising and promotion | Yes ☐ No ☐ | | |
| 5.01.05.08 | Clinical trials control | Yes ☐ No ☐ | | |
| 5.01.05.09 | Pharmacovigilance | Yes ☐ No ☐ | | |
| 5.01.05.10 | Other: (please explain) | Pharmacy Council is responsible for registration of Pharmacists and pharmacies; MOH does control of narcotics and psychotropic substances . | | |
| 5.01.06 | Number of the MRA permanent staff | | | |
| 5.01.06.01 | Date of response | | | |
| 5.01.07 | The MRA has its own website | Yes ☐ No ☐ | | |
| 5.01.07.01 | - If yes, please provide MRA Web site address (URL) | | | |
| 5.01.08 | The MRA receives external technical assistance | Yes ☐ No ☐ | | |
| 5.01.08.01 | If yes, please describe: | | | |
| 5.01.09 | The MRA is involved in harmonization/ collaboration initiatives | Yes ☒ No ☐ | 2011 | MOH |
| 5.01.09.01 | - If yes, please specify | St Lucia is member of CARICOM and OECS. | | |
| 5.01.10 | An assessment of the medicines regulatory system has been conducted in the last five years. | Yes ☒ No ☐ | 2009 | HERA/CARICOM |

| | | | | |
|---|---|---|---|---|
| 5.01.11 | Medicines Regulatory Authority gets funds from regular budget of the government. | Yes ☐ No ☐ | | |
| 5.01.12 | Medicines Regulatory Authority is funded from fees for services provided. | Yes ☐ No ☐ | | |
| 5.01.13 | Medicines Regulatory Authority receives funds/support from other sources | Yes ☐ No ☐ | | |
| 5.01.13.01 | - If yes, please specify | | | |
| 5.01.14 | Revenues derived from regulatory activities are kept with the Regulatory Authority | Yes ☐ No ☒ | 2011 | MOH |
| 5.01.15 | The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc. | Yes ☐ No ☐ | | |
| 5.01.16 | Comments and References | According to HERA/CARICOM (2009): Existing medicines legislation includes the Pharmacy Act No. 8 of 2003; the Pharmacy (Forms and fess) Regulations 2006 and the Pharmacy Regulations 2007. The Council is responsible for regulating the pharmacy practice including registration of pharmacists, pharmacies and sellers of poisons. | | |

## 5.02 Marketing Authorization (Registration)

**Core questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 5.02.01 | Legal provisions require a Marketing Authorization (registration) for all pharmaceutical products on the market | Yes ☐ No ☒ | 2009 | HERA/CARICO |
| 5.02.02 | Are there any mechanism for exception/waiver of registration? | Yes ☐ No ☐ | | |

| | | | | |
|---|---|---|---|---|
| 5.02.03 | Are there mechanisms for recognition of registration done by other countries | Yes ☐ No ☐ | | |
| 5.02.03.01 | If yes, please explain: | | | |
| 5.02.04 | Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products | Yes ☐ No ☐ | | |
| 5.02.05 | Information from the prequalification programme managed by WHO is used for product registration | Yes ☐ No ☐ | | |
| 5.02.06 | Number of pharmaceutical products registered in your country | | | |
| 5.02.07 | Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available | Yes ☐ No ☒ | 2011 | MOH |
| 5.02.07.01 | If yes, how frequently updated | | | |
| 5.02.07.02 | If yes, please provide updated list or URL * | | | |
| 5.02.08 | Medicines registration always includes the INN (International Non-proprietary Names) | Yes ☐ No ☒ | 2011 | MOH |
| 5.02.09 | Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications | Yes ☐ No ☐ | | |
| 5.02.10 | Comments and References | Marketing authorization is not performed.<br><br>According HERA/CARICOM (2009) 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.<br><br>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. | | |
| **Supplementary questions (click here for help)** | | | | |
| | | | Year | Source |
| 5.02.11S | Legal provisions require Marketing Authorization holders to provide information about variations to the existing Marketing Authorization | Yes ☐ No ☐ | | |
| 5.02.12S | Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered | Yes ☐ No ☐ | | |
| 5.02.13S | Legal provisions require the establishment of an expert committee involved in the marketing authorization process | Yes ☐ No ☒ | 2011 | MOH |
| 5.02.14S | Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application | Yes ☐ No ☒ | 2011 | MOH |
| 5.02.15S | Legal provisions require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration | Yes ☐ No ☐ | | |
| 5.02.16S | Legal provisions allow applicants to appeal against MRAs decisions | Yes ☐ No ☐ | | |
| 5.02.17S | Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US$) | | | |
| 5.02.18S | Registration fee - the Amount per application for a generic pharmaceutical product (US$) | | | |

| | | | | |
|---|---|---|---|---|
| 5.02.19S | Time limit for the assessment of a Marketing Authorization application (months) | | | |
| 5.02.20S | Comments & References | | | |

## 5.03 Regulatory Inspection

**Core Questions(click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 5.03.01 | Legal provisions exist allowing for appointment of government pharmaceutical inspectors | Yes ☒ No ☐ | 2001 | Pharmacy Act |
| 5.03.02 | Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed | Yes ☐ No ☒ | 2011 | MOH |
| 5.03.02.01 | If yes, legal provisions exist requiring inspections to be performed | Yes ☒ No ☐ | | |
| 5.03.03 | Inspection is a pre-requisite for licensing of: | | | |
| 5.03.03.01 | Public facilities | Yes ☐ No ☐ | | |
| 5.03.03.02 | Private facilities | Yes ☐ No ☐ | | |
| 5.03.04 | Inspection requirements are the same for public and private facilities | Yes ☒ No ☐ | | |
| 5.03.05.01 | Local manufactures are inspected for GMP compliance | Yes ☐ No ☒ | 2009 | HERA |
| 5.03.05.02 | Private wholesalers are inspected | Yes ☐ No ☒ | | |
| 5.03.05.03 | Retail distributors are inspected | Yes ☐ No ☒ | | |
| 5.03.05.04 | Public pharmacies and stores are inspected | Yes ☐ No ☐ | | |
| 5.03.05.05 | Pharmacies and dispensing points of | Yes ☐ No ☐ | | |

| | | | | |
|---|---|---|---|---|
| | health facilities are inspected | | | |
| 5.03.05.06 | Please provide details on frequency of inspections for the different categories of facilities | | | |
| 5.03.06 | Comments and References | According to HERA/CARICOM (2009): 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). | | |
| | | | | |
| **5.04 Import Control**<br><br>**Core Questions (click here for help)** | | | | |
| | | | Year | Source |
| 5.04.01 | Legal provisions exist requiring authorization to import medicines | Yes ☐ No ☒ | 2009 | HERA |
| 5.04.02 | Legal provisions exist allowing the sampling of imported products for testing | Yes ☐ No ☐ | | |
| 5.04.03 | Legal provisions exist requiring importation of medicines through authorized ports of entry | Yes ☐ No ☒ | 2009 | HERA |
| 5.04.04 | Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry | Yes ☐ No ☐ | | |
| 5.04.05 | Comments and References | | | |
| | | | | |
| **5.05 Licensing** | | | | |
| | | | Year | Source |
| 5.05.01 | Legal provisions exist requiring manufacturers to be licensed | Yes ☐ No ☒ | 2009 | HERA |
| 5.05.02 | Legal provisions exist requiring both domestic and international manufacturers to comply with Good | Yes ☐ No ☒ | 2009 | HERA |

| | | | | |
|---|---|---|---|---|
| | manufacturing Practices (GMP) | | | |
| 5.05.02.01 | If no, please explain | | | |
| 5.05.03 | GMP requirements are published by the government. | Yes ☐ No ☐ | | |
| 5.05.04 | Legal provisions exist requiring importers to be licensed | Yes ☐ No ☒ | 2009 | HERA |
| 5.05.05 | Legal provisions exist requiring wholesalers and distributors to be licensed | Yes ☐ No ☒ | 2009 | HERA |
| 5.05.06 | Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices<br><br>**When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)** | Yes ☐ No ☐ | | |
| 5.05.07 | National Good Distribution Practice requirements are published by the government | Yes ☐ No ☐ | | |
| 5.05.08 | Legal provisions exist requiring pharmacists to be registered | Yes ☒ No ☐ | 2009 | HERA |
| 5.05.09 | Legal provisions exists requiring private pharmacies to be licensed | Yes ☒ No ☐ | 2009 | HERA |
| 5.05.10 | Legal provision exist requiring public pharmacies to be licensed | Yes ☐ No ☒ | 2009 | HERA |
| 5.05.11 | National Good Pharmacy Practice Guidelines are published by the government | Yes ☐ No ☐ | | |
| 5.05.12 | Legal provisions require the publication of a list of all licensed pharmaceutical facilities | Yes ☐ No ☐ | | |
| 5.05.13 | Comments and References | | | |

## 5.06 Market Control and Quality Control

**Core Questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 5.06.01 | Legal Provisions for regulating the pharmaceutical market exist | Yes ☐ No ☒ | 2010 | WHO Level II Survey |
| 5.06.02 | Does a laboratory exist in the country for Quality Control testing? | Yes ☐ No ☒ | 2010 | WHO Level II Survey |
| 5.06.02.01 | If yes, is the laboratory part of the MRA? | Yes ☐ No ☐ | | |
| 5.06.02.02 | Does the regulatory authority contract services elsewhere? | Yes ☒ No ☐ | | |
| 5.06.02.03 | If yes, please describe | Samples are sent to the Caribbean Drug Test Laboratory (CRDTL) in Jamaica | | |
| 5.06.03 | Is there any national laboratory accepted for collaboration with WHO prequalification Programme? Please describe. | | | |
| 5.06.04 | Medicines are tested: | | 2001 | MOH |
| 5.06.04.01 | For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities) | Yes ☐ No ☐ | | |
| 5.06.04.02 | For quality monitoring in private sector (routine sampling in retail outlets) | Yes ☐ No ☐ | | |
| 5.06.04.03 | When there are complaints or problem reports | Yes ☐ No ☐ | | |
| 5.06.04.04 | For product registration | Yes ☐ No ☐ | | |
| 5.06.04.05 | For public procurement prequalification | Yes ☒ No ☐ | | |

| | | | | |
|---|---|---|---|---|
| 5.06.04.06 | For public program products prior to acceptance and/or distribution | Yes ☐ No ☐ | | |
| 5.06.05 | Samples are collected by government inspectors for undertaking post-marketing surveillance testing | Yes ☐ No ☒ | 2011 | MOH |
| 5.06.06 | How many Quality Control samples were taken for testing in the last two years? | | | |
| 5.06.07 | Total number of samples tested in the last two years that failed to meet quality standards | | | |
| 5.06.08 | Results of quality testing in past two years are publicly available | Yes ☐ No ☒ | | |
| 5.06.09 | Comments and References | 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. | | |

## 5.07 Medicines Advertising and Promotion

**Core Questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 5.07.01 | Legal provisions exist to control the promotion and/or advertising of prescription medicines | Yes ☐ No ☒ | 2010 | WHO Level II Survey |
| 5.07.02 | Who is responsible for regulating, promotion and/or advertising of medicines? Please describe: | | | |
| 5.07.03 | Legal provisions prohibit direct advertising of prescription medicines to the public | Yes ☐ No ☒ | 2010 | WHO Level II Survey |
| 5.07.04 | Legal provisions require a pre-approval for medicines advertisements and promotional | Yes ☐ No ☒ | 2010 | WHO Level II Survey |

| | | | | |
|---|---|---|---|---|
| | materials  | | | |
| 5.07.05 | Guidelines/Regulations exist for advertising and promotion of non-prescription medicines | Yes ☐ No ☐ | | |
| 5.07.06 | A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available | Yes ☐ No ☐ | | |
| 5.07.06.01 | If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both | | | |
| | Domestic only | ☐Yes | | |
| | Multinational only | ☐Yes | | |
| | Both | ☐Yes | | |
| 5.07.06.02 | If yes, adherence to the code is voluntary | Yes ☐ No ☐ | | |
| 5.07.06.03 | If yes, the code contains a formal process for complaints and sanctions | Yes ☐ No ☐ | | |
| 5.07.06.04 | If yes, list of complaints and sanctions for the last two years is publicly available | Yes ☐ No ☐ | | |
| 5.07.07 | Comments and References | | | |

## 5.08 Clinical trials

**Core Questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 5.08.01 | Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA | Yes ☐ No ☒ | 2009 | HERA/CARICOM |

| | | | | |
|---|---|---|---|---|
| 5.08.02 | Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed | Yes ☐ No ☐ | | |
| 5.08.03 | Legal provisions exist requiring registration of the clinical trials into international/national/regional registry | Yes ☐ No ☐ | | |
| 5.08.04 | Comments and References | | | |
| **Supplementary questions (click here for help)** | | | | |
| | | | Year | Source |
| 5.08.05S | Legal provisions exist for GMP compliance of investigational products | Yes ☐ No ☒ | 2011 | MOH |
| 5.08.06S | Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP) | Yes ☐ No ☐ | | |
| 5.08.07S | National GCP regulations are published by the Government. | Yes ☐ No ☐ | | |
| 5.08.08S | Legal provisions permit inspection of facilities where clinical trials are performed | Yes ☐ No ☐ | | |
| 5.08.09S | Comments and References | | | |

## 5.09 Controlled Medicines

**Core Questions (click here for help)**

| | | | Date | Source |
|---|---|---|---|---|
| 5.09.01 | The country has adopted the following conventions: | | | |
| 5.09.01.01 | Single Convention on Narcotic Drugs, 1961 | Yes ☒ No ☐ | 1991 | International Narcotics Control Board, 2010 |

| | | | | |
|---|---|---|---|---|
| 5.09.01.02 | The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961 | Yes ☒ No ☐ | 1991 | International Narcotics Control Board, 2010 |
| 5.09.01.03 | Convention on Psychotropic Substances 1971 | Yes ☒ No ☐ | 2003 | International Narcotics Control Board, 2010 |
| 5.09.01.04 | United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988 | Yes ☒ No ☐ | 1995 | International Narcotics Control Board, 2010 |
| 5.09.02 | Laws for the control of narcotic and psychotropic substances, and precursors exist | Yes ☐ No ☐ | | |
| 5.09.03 | Annual consumption of Morphine (mg/capita) | 0.988235 | 2009 | International Narcotics Control Board, 2010 |
| 5.09.04 | Comments and References | | | |

**Supplementary questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 5.09.05S | The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need | Yes ☒ No ☐ Unknown ☐ | 2011 | MOH |
| 5.09.05.01S | If yes, year of review | | | |
| 5.09.06S | Annual consumption of Fentanyl (mg/capita) | 0.0001 | 2010 | Chief Pharmacist |

| | | | | |
|---|---|---|---|---|
| 5.09.07S | Annual consumption of Pethidine (mg/capita) | 8.7 | 2010 | Chief Pharmacist |
| 5.09.08S | Annual consumption of Oxycodone (mg/capita) | 0 | 2010 | Chief Pharmacist |
| 5.09.09S | Annual consumption of Hydrocodone (mg/capita) | 0.035 | 2010 | Chief Pharmacist |
| 5.09.10S | Annual consumption of Phenobarbital (mg/capita) | 5.31 | 2010 | Chief Pharmacist |
| 5.09.11S | Annual consumption of Methadone (mg/capita) | 0.21 | 2010 | Chief Pharmacist |
| 5.09.12S | Comments and References | | | |

## 5.10 Pharmacovigilance

### Core Questions (click here for help)

| | | | Year | Source |
|---|---|---|---|---|
| 5.10.01 | There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate | Yes ☐ No ☒ | 2009 | HERA/CARICOM |
| 5.10.02 | Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA | Yes ☐ No ☒ | 2009 | HERA/CARICOM |
| 5.10.03 | Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country | Yes ☐ No ☒ | 2009 | HERA/CARICOM |
| 5.10.04 | A national pharmacovigilance centre linked to the MRA exists in your country | Yes ☐ No ☒ | 2011 | MOH |
| 5.10.04.01 | If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time | | | |

| | | | | |
|---|---|---|---|---|
| 5.10.04.02 | If a national pharmacovigilance center exists in your country, an analysis report has been published in the last two years. | Yes ☐ No ☐ | | |
| 5.10.04.03 | If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin | Yes ☐ No ☐ | | |
| 5.10.05 | An official standardized form for reporting ADRs is used in your country | Yes ☒ No ☐ | 2011 | MOH |
| 5.10.06 | A national Adverse Drug Reactions database exists in your country | Yes ☒ No ☐ | 2011 | MOH |
| 5.10.07 | How many ADR reports are in the database? | | | |
| 5.10.08 | How many reports have been submitted in the last two years? | | | |
| 5.10.09 | Are ADR reports sent to the WHO database in Uppsala? | Yes ☒ No ☐ | 2011 | MOH |
| 5.10.09.01 | If yes, number of reports sent in the last two years | | | |
| 5.10.10 | Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication? | Yes ☐ No ☐ | | |
| 5.10.11 | Is there a clear communication strategy for routine communication and crises communication? | Yes ☐ No ☒ | | |
| 5.10.12 | In the absence of a national pharmacovigilance system, ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)? | Yes ☒ No ☐ | | |

| | | | | |
|---|---|---|---|---|
| 5.10.13 | Please describe how you intend to enhance the Pharmacovigilance system | The first step is to enhance the PV system in member states actively submittinf ADR reports. Without the reports there is no system. Currently there are only two active member states St. Vincent and the Grenadines and Dominica. OECS/PPS encourages the others to report and will upload the data to the Upsala Drud monitoring centre Vigiflow database. We intent to communicate our findings in the form of a bulletin. | | |
| 5.10.14 | Comments and References | Pharmacovigilance is performed in partnership with PPS/OECS and ADR Reports are sent to PPS/OECS which perform it for OECS countries. | | |
| **Supplementary questions (click here for help)** | | | | |
| | | | Year | Source |
| 5.10.15S | Feedback is provided to reporters | Yes ☐ No ☒ | 2011 | MOH |
| 5.10.16S | The ADR database is computerized | Yes ☒ No ☐ | 2011 | MOH |
| 5.10.17S | Medication errors (MEs) are reported | Yes ☐ No ☒ | 2011 | MOH |
| 5.10.18S | How many MEs are there in the ADRs database? | | | |
| 5.10.19S | There is a risk management plan presented as part of product dossier submitted for Marketing Authorization? | Yes ☐ No ☒ | 2011 | MOH |
| 5.10.20S | In the past two years, who has reported ADRs? | | 2011 | MOH |
| 5.10.20.01S | Doctors | ☒ Yes | | |
| 5.10.20.02S | Nurses | ☐ Yes | | |
| 5.10.20.03S | Pharmacists | ☒ Yes | | |
| 5.10.20.04S | Consumers | ☐ Yes | | |
| 5.10.20.05S | Pharmaceutical Companies | ☐ Yes | | |
| 5.10.20.06S | Others, please specify whom | None | | |

| | | | | |
|---|---|---|---|---|
| 5.10.21S | Was there any regulatory decision based on local pharmacovigilance data in the last 2 years? | Yes ☐ No☒ | 2011 | MOH |
| 5.10.22S | Are there training courses in pharmacovigilance? | Yes ☒ No☐ | 2011 | MOH |
| 5.10.22.01S | If yes, how many people have been trained in the last two years? | 0 | | |
| 5.10.23S | Comments and References | | | |

# Section 6 Medicines Financing

## 6.00 Respondent Information Section 5

| | | |
|---|---|---|
| 6.00.01 | Name of person responsible for filling out this section of the instrument | Donna L. Daniel |
| 6.00.02 | Phone number | 1-758-285-0125/724-7411 |
| 6.00.03 | Email address | louised4u@yahoo.com |
| 6.00.04 | Other respondents for this sections | |

## 6.01 Medicines Coverage and Exemptions

### Core Questions (click here for help)

| | | | Year | Source |
|---|---|---|---|---|
| 6.01.01 | Do the followings receive medicines free of charge: | | 2011 | MOH |
| 6.01.01.01 | Patients who cannot afford them | Yes ☒ No ☐ | | |
| 6.01.01.02 | Children under 5 | Yes ☒ No ☐ | | |
| 6.01.01.03 | Pregnant women | Yes ☐ No ☒ | | |
| 6.01.01.04 | Elderly persons | Yes ☐ No ☒ | | |
| 6.01.01.05 | Please describe/explain your yes answers for questions above | | | |
| 6.01.02 | Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for : | | 2011 | MOH |
| 6.01.02.01 | All medicines included in the EML | Yes ☐ No ☐ | | |
| 6.01.02.02 | Any non-communicable diseases | Yes ☐ No ☐ | | |
| 6.01.02.03 | Malaria medicines | Yes ☐ No ☒ | | |
| 6.01.02.04 | Tuberculosis medicines | Yes ☒ No ☐ | | |
| 6.01.02.05 | Sexually transmitted diseases | Yes ☒ No ☐ | | |

| | | | | |
|---|---|---|---|---|
| | medicines | | | |
| 6.01.02.06 | HIV/AIDS medicines | Yes ☒ No ☐ | | |
| 6.01.02.07 | Expanded Program on Immunization (EPI) vaccines | Yes ☒ No ☐ | | |
| 6.01.02.08 | If others, please specify | | | |
| 6.01.02.09 | Please describe/explain your yes answers for questions above | | | |
| 6.01.03 | Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage? | Yes ☒ No ☐ | 2011 | MOH |
| 6.01.03.01 | Does it provide coverage for medicines that are on the EML for inpatients | Yes ☒ No ☐ | | |
| 6.01.03.02 | Does it provide coverage for medicines that are on the EML for outpatients | Yes ☒ No ☐ | | |
| 6.01.03.03 | Please describe the medicines benefit of public/social insurance schemes | | | |
| 6.01.04 | Do private health insurance schemes provide any medicines coverage? | Yes ☒ No ☐ | 2011 | MOH |
| 6.01.04.01 | If yes, is it required to provide coverage for medicines that are on the EML? | Yes ☐ No ☒ | | |
| 6.01.05 | Comments and References | | | |

## 6.02 Patients Fees and Copayments

### Core Questions (click here for help)

| | | | Year | Source |
|---|---|---|---|---|
| 6.02.01 | In your health system, at the point of delivery, are there any co-payment/fee requirements for | Yes ☒ No ☐ | 2011 | MOH |

| | | | | |
|---|---|---|---|---|
| | consultations | | | |
| 6.02.02 | In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines | Yes ☐ No ☒ | 2011 | MOH |
| 6.02.03 | In practice, (even though this may be contrary to regulations) is revenue from fees or sales of medicines sometimes used to pay the salaries or supplement the income of public health personnel in the same facility? | Yes ☐ No ☒ | 2011 | MOH |
| 6.02.03.01 | Please describe the patient fees and copayments system | | | |
| 6.02.04 | Comments and References | | | |
| | | | | |
| **6.03 Pricing Regulation for the Private Sector**<br><br>**Core Questions (click here for help)** | | | | |
| | | | Year | Source |
| 6.03.01 | Are there legal or regulatory provisions affecting pricing of medicines | Yes ☐ No ☒ | 2011 | MOH |
| 6.03.01.01 | If yes, are the provisions aimed at Manufacturers | Yes ☐ No ☐ | | |
| 6.03.01.02 | If yes, are the provisions aimed at Wholesalers | Yes ☒ No ☐ | | |
| 6.03.01.03 | If yes, are the provisions aimed at Retailers | Yes ☒ No ☐ | | |
| 6.03.01.04 | Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.) | | | |
| 6.03.02 | Government runs an active national medicines price monitoring system for retail prices | Yes ☐ No ☒ | 2011 | MOH |

| | | | | |
|---|---|---|---|---|
| 6.03.03 | Regulations exists mandating that retail medicine price information should be publicly accessible | Yes ☐ No ☒ | 2011 | MOH |
| 6.03.03.01 | -if yes, please explain how the information is made publically available | | | |
| 6.03.04 | Comments and References | | | |

## 6.04 Prices, Availability and Affordability

### Core Questions (click here for help)

| | | | Year | Source |
|---|---|---|---|---|
| 6.04.01-04 | Please state if a medicines price survey using the WHO/HAI methodology has been conducted in the past 5 years in your country.<br><br>**If yes**, please indicate the year of the survey and use the results to fill in this table<br><br>***If no***, but other surveys on medicines prices and availability have been conducted, please do not use them to fill in this section, but rather use the comment box to write some of the results and attach the report to the questionnaire | Yes ☐ No ☒ Unknown ☐ | 2011 | MOH |

| | **Basket Of key medicines** | | | Public procurement | Public patient | Private patient | | |
|---|---|---|---|---|---|---|---|---|
| | **Availability** (one or both of) | **Mean (%)** | **Orig** | | 6.04.01.01 | 6.04.01.03 | | |
| | | | **LPG** | | 6.04.01.02 | 6.04.01.04 | | |
| | | **Median (%)** | **Orig** | | 6.04.02.01 | 6.04.02.03 | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | **LPG** | | 6.04.02.02 | 6.04.02.04 | |
| | **Price** | **Median Price Ratio** | **Orig** | 6.04.03.01 | 6.04.03.03 | 6.04.03.05 | |
| | | | **LPG** | 6.04.03.02 | 6.04.03.04 | 6.04.03.06 | |
| | **Affordability** Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection | **Number of days' wages** | **Orig** | | 6.04.04.01 | 6.04.04.03 | |
| | | | **LPG** | | 6.04.04.02 | 6.04.04.04 | |
| 6.04.05 | Comments and References | | | | | | |

## 6.05 Price Components and Affordability

### Core Questions (click here for help)

| | | | Year | Source |
|---|---|---|---|---|
| 6.05.01 | Please state if a survey of medicines price components has been conducted in the past 5 years in your country | Yes ☐ No ☒ Unknown ☐ | 2011 | MOH |
| 6.05.02 | Median cumulative percentage mark-up between Manufacturer Selling Price (MSP)/ Cost Insurance and Freight (CIF) price and final medicine price for a basket of key medicines in the public sector (Median % contribution) | | | |
| 6.05.03 | Median cumulative percentage mark-up between MSP/CIF price and final medicine price for a basket of key medicines in the private sector (Median % contribution) | | | |

| | | |
|---|---|---|
| 6.05.04 | Comment and References | |
| **Supplementary questions (click here for help)** | | |
| 6.05.05S | Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution) | |
| 6.05.06S | Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution) | |
| 6.05.07S | Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%) | |
| 6.05.08S | Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%) | |
| 6.05.09S | Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%) | |
| 6.05.10S | Median percentage contribution of the wholesale mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%) | |
| 6.05.11S | Median percentage contribution of the retail mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%) | |
| 6.05.12S | Comment and References | |

| | | |
|---|---|---|
| **6.06 Duties and Taxes on Pharmaceuticals (Market)** | | |
| **Core Questions (click here for help)** | | |
| | Year | Source |

| | | | | |
|---|---|---|---|---|
| 6.06.01 | There are duties on imported active pharmaceutical ingredients (APIs) | Yes ☐ No ☒ | 2011 | MOH |
| 6.06.02 | There are duties on imported finished products | Yes ☐ No ☒ | 2011 | MOH |
| 6.06.03 | VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products | Yes ☐ No ☐ | | |
| 6.06.04 | There are provisions for tax exceptions or waivers for pharmaceuticals and health products | Yes ☐ No ☐ | | |
| 6.06.05 | Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist | | | |
| 6.06.06 | Comments and References | | | |
| **Supplementary questions (click here for help)** | | | | |
| | | | Year | Source |
| 6.06.07S | Duty on imported active pharmaceutical ingredients, APIs (%) | | | |
| 6.06.08S | Duty on imported finished products (%) | | | |
| 6.06.09S | VAT on pharmaceutical products (%) | | | |
| 6.06.10S | Comments and References | | | |

# Section 7 Pharmaceutical procurement and distribution

## 7.00 Respondent Information Section 6

| | | |
|---|---|---|
| 7.00.01 | Name of person responsible for filling out this section of the instrument | Allison Jean |
| 7.00.02 | Phone number | 1-758-452-3228 |
| 7.00.03 | Email address | alliectl@hotmail.com |
| 7.00.04 | Other respondents for filling out this section | |

## 7.01 Public Sector Procurement

### Core Questions (click here for help)

| | | | Date | Source |
|---|---|---|---|---|
| 7.01.01 | Public sector procurement is: | | 2010 | WHO Level II Survey |
| 7.01.01.01 | Decentralized | ☐ Yes | | |
| 7.01.01.02 | Centralized and decentralized | ☐ Yes | | |
| 7.01.01.03 | Please describe | Centralized at country level.<br><br>Public sector medicines procurement is the responsibility of the Ministry of Health trough PPS/OECS on behalf of the Ministry of Health. The MOH procures a limited number of non-formulary medicines and health products for specific patients on demand. At public sector medicines distribution is the responsibility of the Ministry of Health. All medicines used in the country are imported. | | |
| 7.01.02 | If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is: | | 2011 | MOH |

| | | | | |
|---|---|---|---|---|
| 7.01.02.01 | Part of MoH | Yes ☒ No ☐ | | |
| 7.01.02.02 | Semi-Autonomous | Yes ☐ No ☐ | | |
| 7.01.02.03 | Autonomous | Yes ☐ No ☐ | | |
| 7.01.02.04 | A government procurement agency which procures all public goods | Yes ☐ No ☐ | | |
| 7.01.03 | Public sector requests for tender documents are publicly available | Yes ☐ No ☒ | 2011 | MOH |
| 7.01.04 | Public sector tender awards are publicly available | Yes ☒ No ☐ | 2011 | MOH |
| 7.01.05 | Procurement is based on prequalification of suppliers | Yes ☒ No ☐ | 2011 | MOH |
| 7.01.05.01 | If yes, please describe how it works | Suppliers who are willing to participate in the procurement process must register with the OECS/PPS. Suppliers who satisfy all registration requirements are prequalified. | | |
| 7.01.06 | Comments and References | | | |

**Supplementary questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 7.01.07S | Is there a written public sector procurement policy?. If yes, please write the year of approval in the "year" field | Yes ☒ No ☐ | 1986 | MOH |
| 7.01.08S | Are there legal provisions giving priority in public procurement to goods produced by local manufacturers? | Yes ☐ No ☒ | | |
| 7.01.09S | The key functions of the procurement unit and those of the tender committee are clearly separated | Yes ☐ No ☒ | 2011 | MOH |
| 7.01.10S | A process exists to ensure the quality of products procured | Yes ☒ No ☐ | 2011 | MOH |
| 7.01.10.01S | If yes, the quality assurance process includes pre-qualification | Yes ☐ No ☒ | | |

| | | | | |
|---|---|---|---|---|
| | of products and suppliers | | | |
| 7.01.10.02S | If yes, explicit criteria and procedures exist for pre-qualification of suppliers | Yes ☒ No ☐ | | |
| 7.01.10.03S | If yes, a list of pre-qualified suppliers and products is publicly available | Yes ☐ No ☒ | | |
| 7.01.11S | List of samples tested during the procurement process and results of quality testing are available | Yes ☐ No ☒ | 2011 | MOH |
| 7.01.12S | Which of the following tender methods are used in public sector procurement: | | 2011 | MOH |
| 7.01.12.01S | National competitive tenders | Yes ☐ No ☒ | | |
| 7.01.12.02S | International competitive tenders | Yes ☒ No ☐ | | |
| 7.01.12.03S | Direct purchasing | Yes ☒ No ☐ | | |
| 7.01.13S | Comments and References | Quality control of procured medicines is conduct through PPS/OECS. | | |

## 7.02 Public Sector Distribution

### Core Questions (click here for help)

| | | | Year | Source |
|---|---|---|---|---|
| 7.02.01 | The government supply system department has a Central Medical Store at National Level | Yes ☒ No ☐ | 2011 | MOH |
| 7.02.02 | Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial) | 0 | 2011 | MOH |
| 7.02.03 | There are national guidelines on Good Distribution Practices (GDP) | Yes ☐ No ☒ | 2011 | MOH |

| | | | | |
|---|---|---|---|---|
| 7.02.04 | There is a licensing authority that issues GDP licenses | Yes ☐ No ☒ | 2011 | MOH |
| 7.02.04.01 | If a licensing authority exists, does it accredit public distribution facilities? | Yes ☐ No ☐ | | |
| 7.02.05 | List of GDP certified warehouses in the public sector exists | Yes ☐ No ☒ | 2011 | MOH |
| 7.02.06 | List of GDP certified distributors in the public sector exists | Yes ☐ No ☒ | 2011 | MOH |
| 7.02.07 | Comments and References | | | |
| **Supplementary questions (click here for help)** | | | | |
| | | | Year | Source |
| 7.02.08S | Which of the following processes is in place at the Central Medical Store: | | 2011 | MOH |
| 7.02.08.01S | Forecasting of order quantities | Yes ☒ No ☐ | | |
| 7.02.08.02S | Requisition/Stock orders | Yes ☒ No ☐ | | |
| 7.02.08.03S | Preparation of picking/packing slips | Yes ☒ No ☐ | | |
| 7.02.08.04S | Reports of stock on hand | Yes ☒ No ☐ | | |
| 7.02.08.05S | Reports of outstanding order lines | Yes ☒ No ☐ | | |
| 7.02.08.06S | Expiry dates management | Yes ☒ No ☐ | | |
| 7.02.08.07S | Batch tracking | Yes ☒ No ☐ | | |
| 7.02.08.08S | Reports of products out of stock | Yes ☒ No ☐ | | |
| 7.02.09S | Percentage % availability of key medicines at the Central Medical Store | | | |
| 7.02.10S | Average stock-out duration for a basket of medicines at the Central Medical Store, in days | | | |

| | | | | |
|---|---|---|---|---|
| 7.02.11S | Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store | Yes ☒ No ☐ | 2011 | MOH |
| 7.02.12S | The Public Central Medical Store is GDP certified by a licensing authority | Yes ☐ No ☒ | 2011 | MOH |
| 7.02.13S | The Public Central Medical Store is ISO certified | Yes ☐ No ☒ | 2011 | MOH |
| 7.02.14S | The second tier public warehouses are GDP certified by a licensing authority | Yes ☐ No ☒ | 2011 | MOH |
| 7.02.15S | The second tier public warehouses are ISO certified | Yes ☐ No ☒ | 2011 | MOH |
| 7.02.16S | Comments and References | | | |

## 7.03 Private Sector Distribution

**Core Questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 7.03.01 | Legal provisions exist for licensing wholesalers in the private sector | Yes ☐ No ☒ | 2011 | MOH |
| 7.03.02 | Legal provisions exist for licensing distributors in the private sector | Yes ☐ No ☒ | 2011 | MOH |
| 7.03.03 | List of GDP certified wholesalers in the private sector exists | Yes ☐ No ☐ | | |
| 7.03.04 | List of GDP certified distributors in the private sector exists | Yes ☐ No ☐ | | |
| 7.03.05 | Comments and References | | | |

## Section 8 Selection and rational use

### 8.00 Respondent Information Section 7

| | | |
|---|---|---|
| 8.00.01 | Name of person responsible for filling out this section of the instrument | Donna L. Daniel |
| 8.00.02 | Phone number | 1-758-285-0125/724-7411 |
| 8.00.03 | Email address | louised4u@yahoo.com |
| 8.00.04 | Other respondents for filling out this section | |

### 8.01 National Structures

**Core Questions (click here for help)**

| | | | Year | Source |
|---|---|---|---|---|
| 8.01.01 | National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field | Yes ☒ No ☐ | 2009 | WHO Level II Survey |
| 8.01.01.01 | If yes, number of medicines on the EML (no. of INN) | 600 | | |
| 8.01.01.02 | If yes, there is a written process for selecting medicines on the EML | Yes ☐ No ☒ | | |
| 8.01.01.03 | If yes, the EML is publicly available | Yes ☐ No ☒ | | |
| 8.01.01.04 | If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG) | Yes ☐ No ☒ | | |
| 8.01.02 | National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field | Yes ☒ No ☐ | 2011 | MOH |
| 8.01.03 | STGs specific to Primary care exist. Please use the "year" field to | Yes ☐ No ☒ | 2011 | MOH |

| | | | | |
|---|---|---|---|---|
| | write the year of last update of primary care guidelines | | | |
| 8.01.04 | STGs specific to Secondary care (hospitals) exists. Please use the "year" field to write the year of last update of secondary care STGs. | Yes ☐ No ☒ | 2011 | MOH |
| 8.01.05 | STGs specific to Paediatric conditions exist. Please use the "year" field to write the year of last update of paediatric condition STGs | Yes ☐ No ☐ | | |
| 8.01.06 | % of public health facilities with copy of EML (mean)- Survey data | 54.2 | 2008 | WHO Level II Survey |
| 8.01.07 | % of public health facilities with copy of STGs (mean)- Survey data | 58.3 | 2008 | WHO Level II Survey |
| 8.01.08 | A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers | Yes ☐ No ☒ | 2011 | MOH |
| 8.01.09 | Public education campaigns on rational medicine use topics have been conducted in the previous two years | Yes ☐ No ☐ | | |
| 8.01.10 | A survey on rational medicine use has been conducted in the previous two years | Yes ☐ No ☐ | | |
| 8.01.11 | A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines | Yes ☐ No ☒ | 2011 | MOH |
| 8.01.12 | A written National strategy exists to contain antimicrobial resistance. If yes, please write year of last update of the strategy in the "year" field | Yes ☐ No ☒ | 2011 | MOH |

| | | | | |
|---|---|---|---|---|
| 8.01.13 | Comments and References | | | |
| **Supplementary questions (click here for help)** | | | | |
| | | | Year | Source |
| 8.01.14S | The Essential Medicines List (EML) includes formulations specific for children | Yes ☐ No ☐ | | |
| 8.01.15S | There are explicitly documented criteria for the selection of medicines in the EML | Yes ☐ No ☐ | | |
| 8.01.16S | There is a formal committee or other equivalent structure for the selection of products on the National EML | Yes ☒ No ☐ | 2011 | MOH |
| 8.01.16.01S | If yes, conflict of interest declarations are required from members of national EML committee | Yes ☐ No ☐ | | |
| 8.01.17S | National medicines formulary exists | Yes ☐ No ☒ | 2011 | MOH |
| 8.01.18S | Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection? | Yes ☐ No ☒ | 2007 | WHO level I |
| 8.01.19S | A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance | Yes ☐ No ☒ | 2007 | WHO level I |
| 8.01.20S | Comments and References | St Lucia adopts the PPS/OECS Formulary. The committee is related to the PPS/OECS Formulary. | | |
| | | | | |
| **8.02 Prescribing** | | | | |
| **Core Questions (click here for help)** | | | | |
| | | | Year | Source |

| | | | | |
|---|---|---|---|---|
| 8.02.01 | Legal provisions exist to govern the licensing and prescribing practices of prescriber | Yes ☐ No ☒ | 2011 | MOH |
| 8.02.02 | Legal provisions exist to restrict dispensing by prescribers | Yes ☐ No ☐ | | |
| 8.02.03 | Do prescribers in the private sector dispense medicines? | Yes ☒ No ☐ | 2011 | MOH |
| 8.02.04 | Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs) | Yes ☐ No ☒ | 2011 | MOH |
| 8.02.05 | Do more than half of referral hospitals have a DTC? | Yes ☐ No ☒ Unknown ☐ | 2011 | MOH |
| 8.02.06 | Do more than half of general hospitals have a DTC? | Yes ☐ No ☒ Unknown ☐ | 2011 | MOH |
| 8.02.07 | Do more than half of regions/provinces have a DTC? | Yes ☐ No ☒ Unknown ☐ | 2011 | MOH |
| 8.02.08 | The core medical training curriculum includes components on: | | 2011 | MOH |
| 8.02.08.01 | Concept of EML | Yes ☐ No ☒ | | |
| 8.02.08.02 | Use of STGs | Yes ☐ No ☒ | | |
| 8.02.08.03 | Pharmacovigilance | Yes ☐ No ☐ | | |
| 8.02.08.04 | Problem based pharmacotherapy | Yes ☐ No ☐ | | |
| 8.02.09 | Mandatory continuing education that includes pharmaceutical issues is required for doctors (see physician) | Yes ☐ No ☒ | 2011 | MOH |
| 8.02.10 | Mandatory continuing education that includes pharmaceutical issues is required for nurses | Yes ☐ No ☐ | | |
| 8.02.11 | Mandatory continuing education that includes pharmaceutical issues | Yes ☐ No ☒ | 2011 | MOH |

| | | | | |
|---|---|---|---|---|
| | is required for paramedical staff | | | |
| 8.02.12 | Prescribing by INN name is obligatory in: | | 2011 | MOH |
| 8.02.12.01 | Public sector | Yes ☒ No ☐ | | |
| 8.02.12.02 | Private sector | Yes ☐ No ☒ | | |
| 8.02.13 | Average number of medicines prescribed per patient contact in public health facilities (mean) | 3.2 | 2008 | WHO Level II Survey |
| 8.02.14 | % of medicines prescribed in outpatient public health care facilities that are in the national EML (mean) | 92.9 | 2008 | WHO Level II Survey |
| 8.02.15 | % of medicines in outpatient public health care facilities that are prescribed by INN name (mean) | 43.9 | 2008 | WHO Level II Survey |
| 8.02.16 | % of patients in outpatient public health care facilities receiving antibiotics (mean) | 21.5 | 2008 | WHO Level II Survey |
| 8.02.17 | % of patients in outpatient public health care facilities receiving injections (mean) | 0 | 2008 | WHO Level II Survey |
| 8.02.18 | % of prescribed drugs dispensed to patients (mean) | 86.4 | 2008 | WHO |
| 8.02.19 | % of medicines adequately labelled in public health facilities (mean) | 96.4 | 2008 | WHO Level II Survey |
| 8.02.20 | Comments and References | | | |
| **Supplementary questions (click here for help)** | | | | |
| | | | Year | Source |
| 8.02.21S | A professional association code of conduct exists governing professional behaviour of doctors | Yes ☒ No ☐ | 2011 | MOH |
| 8.02.22S | A professional association code of conduct exists governing | Yes ☒ No ☐ | | |

| | | | | |
|---|---|---|---|---|
| | professional behaviour of nurses | | | |
| 8.02.23S | Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%) | | | |
| 8.02.24S | Comments and References | | | |
| | | | | |
| **8.03 Dispensing**<br><br>**Core Questions (click here for help)** | | | | |
| | | | Year | Source |
| 8.03.01 | Legal provisions exist to govern dispensing practices of pharmaceutical personnel | Yes ☒ No ☐ | 2001 | Pharmacy Act |
| 8.03.02 | The basic pharmacist training curriculum includes components on: | | 2011 | MOH |
| 8.03.02.01 | Concept of EML | Yes ☐ No ☒ | | |
| 8.03.02.02 | Use of STGs | Yes ☐ No ☒ | | |
| 8.03.02.03 | Drug Information | Yes ☐ No ☐ | | |
| 8.03.02.04 | Clinical pharmacology | Yes ☐ No ☐ | | |
| 8.03.02.05 | Medicines supply management | Yes ☐ No ☐ | | |
| 8.03.03 | Mandatory continuing education that includes rational use of medicines is required for pharmacists | Yes ☒ No ☐ | 2011 | MOH |
| 8.03.04 | Generic substitution at the point of dispensing in public sector facilities is allowed | Yes ☒ No ☐ | 2011 | MOH |
| 8.03.05 | Generic substitution at the point of dispensing in private sector facilities is allowed | Yes ☒ No ☐ | 2011 | MOH |
| 8.03.06 | In practice, (even though this may be contrary to regulations) are | Yes ☒ No ☐ Unknown ☐ | 2011 | MOH |

| | | | | |
|---|---|---|---|---|
| | antibiotics sometimes sold over-the-counter without any prescription? | | | |
| 8.03.07 | In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription? | Yes ☐ No ☐ Unknown ☐ | | |
| 8.03.08 | Comments and References | 80.03.04/05 There are provisions under the law promoting the use of generic medicines. Generic prescribing is mandatory in both the public and private sectors.<br><br>there is no pharmacy school in St. Lucia. | | |
| **Supplementary questions (click here for help)** | | | | |
| | | | Year | Source |
| 8.03.09S | A professional association code of conduct exists governing professional behaviour of pharmacists | Yes ☐ No ☐ | | |
| 8.03.10S | In practice, (even though this may be contrary to regulations) do the following groups of staff *sometimes* prescribe prescription-only medicines at the primary care level in the public sector? | | 2011 | MOH |
| 8.03.10.01S | Nurses | Yes ☒ No ☐ Unknown ☐ | | |
| 8.03.10.02S | Pharmacists | Yes ☐ No ☒ Unknown ☐ | | |
| 8.03.10.03S | Paramedics | Yes ☐ No ☒ Unknown ☐ | | |
| 8.03.10.04S | Personnel with less than one month training | Yes ☐ No ☒ Unknown ☐ | | |
| 8.03.11S | Comments and References | There are legal provisions for Family Nurse Practitioners nurses to prescribe prescribe prescription-only medicines at the primary care level in the public sector. | | |

## Section 9 Household data/access

### 9.00 Respondent Information section 8

| | | |
|---|---|---|
| 9.00.01 | Name of person responsible for filling out this section of the instrument | |
| 9.00.02 | Phone number | |
| 9.00.03 | Email address | |
| 9.00.04 | Other respondents for filling out this section | |

### 9.01 Data from Household Surveys

### Core Questions (click here for help)

| | | | Year | Source |
|---|---|---|---|---|
| 9.01.01 | What household surveys have been undertaken in the past 5 years to assess access to medicines? | | | |
| 9.01.02 | Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%) | | | |
| 9.01.03 | Adults with acute conditions not taking all medicines because they cannot afford them (%) | | | |
| 9.01.04 | Adults (from poor households) with an acute health condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%) | | | |
| 9.01.05 | Adults (from poor households) with an acute condition in two-week recall period who did not take all medicines because they cannot afford them (%) | | | |

| | | | | |
|---|---|---|---|---|
| 9.01.06 | Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%) | | | |
| 9.01.07 | Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%) | | | |
| 9.01.08 | Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%) | | | |
| 9.01.09 | Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%) | | | |
| 9.01.10 | Percentage of people who obtained the medicines prescribed in the 15 days before the interview (%) | | | |
| 9.01.11 | People who obtained prescribed medicines for free in the 15 days before the interview (%) | | | |
| 9.01.12 | Comments and References | | | |
| **Supplementary questions (click here for help)** | | | | |
| | | | Year | Source |
| 9.01.13S | Adults with acute conditions not taking all medicines because the medicines were not available (%) | | | |
| 9.01.14S | Adults with chronic conditions not taking all medicines because they cannot afford them (%) | | | |
| 9.01.15S | Adults with chronic conditions not taking all medicines because the medicines were not available (%) | | | |
| 9.01.16S | Children with acute conditions taking all medicines prescribed by | | | |

| | | | | |
|---|---|---|---|---|
| | an authorized prescriber (%) | | | |
| 9.01.17S | Children with acute conditions not taking all medicines because they cannot afford them (%) | | | |
| 9.01.18S | Children with acute conditions not taking all medicines because the medicines were not available (%) | | | |
| 9.01.19S | Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%) | | | |
| 9.01.20S | Comments and References | | | |