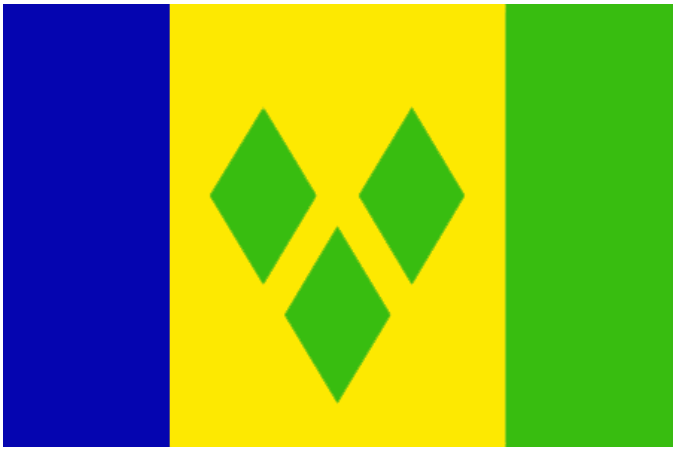
SAINT VINCENT AND THE GRENADINES



PHARMACEUTICAL COUNTRY PROFILE

SAINT VINCENT AND THE GRENADINES

Pharmaceutical Country Profile

Published by the Ministry of Health, Wellness and The Environment of St. Vincent and the Grenadines in collaboration with the Pan American Health Organization/World Health Organization (PAHO/WHO)

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Users of this Profile are encouraged to send and comments or queries to the following address:

JOANN INCE JACK
Chief Pharmacist

Email: jojo_annei@yahoo.com

Foreword

The 2012 Pharmaceutical Country Profile for St. Vincent and the Grenadines has been produced by the Ministry of Health, Wellness and The Environment, 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 St. Vincent and the Grenadines. The compiled data comes from international sources (e.g. the World Health Statistics[1,2]), 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.

For their contributions to the process of data collection and the development of this profile, on behalf of the Ministry, I would like to express my appreciation to the following persons:

Pan American Health Organization/World Health Organization

Nelly Marin Jaramillo *(Pharmaceutical Policies Regional Advisor for the Americas)*
Adriana Mitsue Ivama *(Medicines and Health Technologies Sub-regional Advisor for the Caribbean)*

Anneke Wilson *(Country Programme Specialist for St. Vincent and the Grenadines)*

Tassia Williams *(former Intern on Medicines and Health Technologies, CPC Office)*

Robinson Rojas Cortes *(HSS-MT Regional Consultant)*

Ernest Pate *(Caribbean Programme Coordinator, CPC)*

Merle J. Lewis *(PAHO/WHO Representative for Barbados and Eastern Caribbean Countries)*

Carol Harris-Coppin *(Administrative Assistant, ECC Office)*

Arlette Scantlebury *(Administrative Assistant, CPC Office)*

Ministry of Health, Wellness and The Environment

Joann Ince Jack *(Chief Pharmacist – Chairperson of the Pharmacy Council)*

Jennifer George *(Epidemiologist)*

Lucine Edwards *(Health planner)*

Tyrone Jack *(Drug Inspector)*

Ilonka O'Garro (Pharmacovigilance and Drug Information Officer)

Commercial and Intellectual Property Office

Andrea Young Lewis *(Director)*

Central Medical Stores

Levi Walker *(Manager)*

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

ST. CLAIRE THOMAS
Chief Medical Officer (CMO)
Ministry of Health, Wellness and The Environment
St. Vincent and the Grenadines

Table of content

List of tables

Acronyms and abbreviations

ADR	Adverse Drug Reaction
API	Active Pharmaceutical Ingredient
ARV	Antiretroviral
CAP	Caribbean Association of Pharmacists
CARICOM	Caribbean Community
CIF	Cost Insurance and Freight
CIPO	Commerce and Intellectual Property Office
CMO	Chief Medical Officer
CMS	Central Medical Stores
CPC	Caribbean Program Coordination
CRDTL	Caribbean Regional Drug Testing Laboratory
CSME	CARICOM Single Market and Economy
DTC	Drug and Therapeutics Committee
EC$	East Caribbean Dollar
ECC	Eastern Caribbean Countries
EML	Essential Medicines List
EPI	Expanded Program on Immunization
FDA	Food and Drug Administration
GDP	Gross Domestic Product
GDP	Good Distribution Practices
GGHE	General Government Health Expenditure
GMP	Good Manufacturing Practices
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
INN	International Nonproprietary Name
ME	Medication Error
MRA	Medicines Regulatory Authority
MSP	Manufacturing Selling Price
NHP	National Health Policy
NMP	National Medicines Policy
OECS/PPS	Organization of Eastern Caribbean States / Pharmaceutical Procurement Service
OTC	Over The Counter
TPE	Total Pharmaceutical Expenditure
TRIPS	Trade Related aspects of Intellectual Property Rights
US$	United States Dollar
VAT	Value Added Tax
WTO	World Trade Organization

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 St. Vincent and the Grenadines. 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 Head Quarter 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 St. Vincent and the Grenadines was Tyrone Jack 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 PAHO/WHO web site.

This profile will be regularly updated by the PAHO/WHO in partnership with the country officials.
Users of this profile are encouraged to send comments, corrections or queries to:

Tyrone Jack
Drug Inspector
Ministry of Health, Wellness and The Environment
Ministerial Building
Kingstown, St. Vincent and the Grenadines
Tel: (784) 457-2586
Fax: (784) 457-2684
tjreynold@yahoo.com

Adriana Mitsue Ivama
Medicines and Health Technologies Sub Regional Advisor
Pan-American Health Organization/World Health Organization (PAHO/WHO) – Office of Caribbean Programme Coordination (CPC)
Dayrells Rd & Navy Garden, Christ Church, Barbados
Tel: (246) 434-5200
Fax: (246) 436-9779
ivamaadr@cpc.paho.org

Section 1 - Health and Demographic Data

This section gives an overview of the demographics and health status of St. Vincent and the Grenadines.

1.1 Demographic and Socioeconomic Indicators

The total population of St. Vincent and the Grenadines (SVG) in 2010 was 109,333[3] with an annual population growth rate of 0.1%[3]. The annual Gross Domestic Product (GDP) growth rate was -1.84%[4]. The GDP per capita was US$ 5,213.

27% of the population is under 15 years of age[2], and 9% of the population is over 60 years of age[2]. The urban population currently stands at 47% of the total population[2]. The fertility rate in the country is 2.1 births per woman[2].

The indigent poverty line was set in the SVG Country Poverty Assessment[5] at EC$6.70 (US$2.32)/adult/day. 2.7% of the population fell below that line[5]. 30.2% of the population lives below the nationally defined poverty line[5]. The income share held by the lowest 20% of the population is 7% (as percentage of national income)[5]. The adult literacy rate for the population over 15 years is 88.7%[5].

1.2 Mortality and Causes of Death

The life expectancy at birth is 70 and 74 years for men and women respectively[3]. The infant mortality rate (i.e. children under 1 year) is 11/1,000 live births[3]. For

children under the age of 5, the mortality rate is 12/1,000 live births[3]. The maternal mortality rate is 58/100,000 live births[1].

The top 10 diseases causing mortality in St. Vincent and the Grenadines, according to the Epidemiology Department of the Ministry, are listed in Table 1.

Table 1. Top 10 diseases causing mortality in St. Vincent and the Grenadines in 2010[6]

	Disease (group of diseases)
1	Neoplasms (Prostate cancer - most prevalent)
2	Ischemic heart disease
3	Hypertensive heart disease
4	Communicable disease (Acute respiratory infection - most prevalent)
5	Cerebrovascular disease
6	Injuries – violence
7	Diabetes mellitus
8	Perinatal conditions
9	Other heart disease
10	Disease of the digestive system

The top 10 diseases causing morbidity in St. Vincent and the Grenadines are listed in Table 2.

Table 2. Top 10 diseases causing morbidity in St. Vincent and the Grenadines in 2010

	Disease (group of diseases)
1	Communicable disease
2	Hypertension
3	Hypertension + Diabetes mellitus
4	Diabetes mellitus
5	Musculoskeletal disease
6	Gastritis
7	Asthma
8	Endocrine / Metabolic disease
9	Injuries – violence
10	Disabilities (Mental and physical-motor)

The neonatal mortality rate is 15.1/1,000 live births[2]. The age standardised mortality rate by non-communicable diseases is 674/100,000[2], and 88.7/100,000 by cancer[1]. The mortality rate for HIV/AIDS is 10.9/100,000[1] and 1.0/100,000 for tuberculosis[2]. The mortality rate for malaria is 0.0/100,000[6].

Section 2 - Health Services

This section provides information regarding health expenditures in St. Vincent and the Grenadines. 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

The general government[i] health expenditure (GGHE) in 2009, as reflected in the SVG Estimates of Revenue and Expenditure 2011 [7], was EC$55,868,278 (US$19,545,391). That is, a total annual per capita public expenditure on health of EC$511.2 (US$178.8). The government annual expenditure on health represents 10.18% of the total government budget[7].

100% of the population is covered by the public health service[ii].

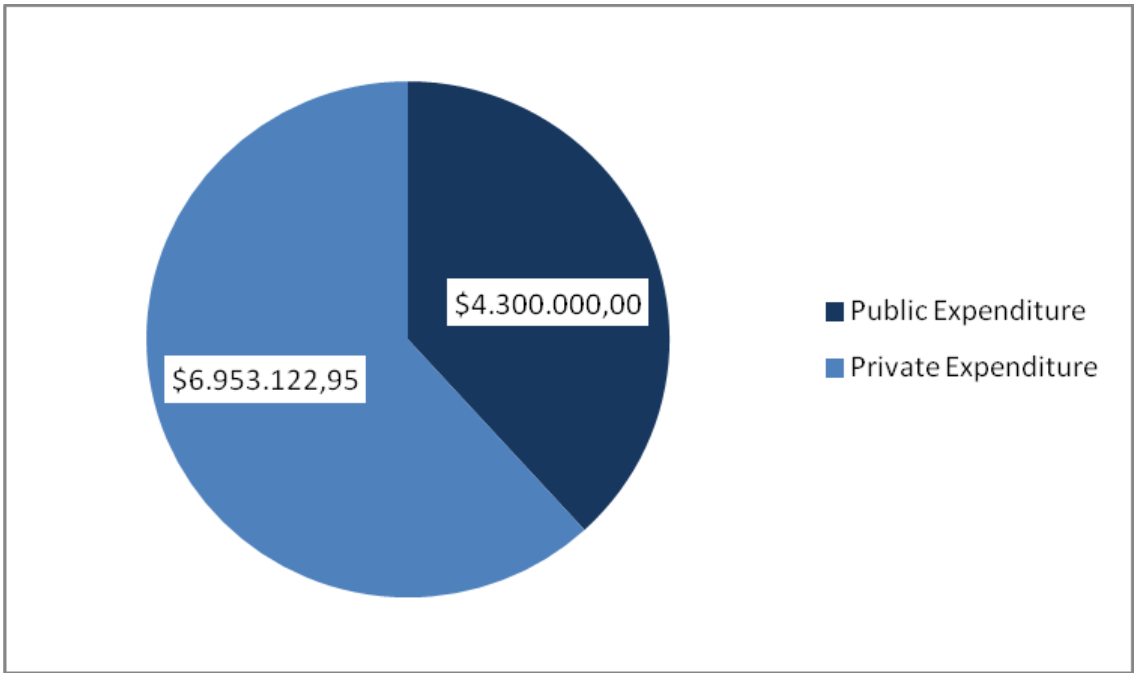
Total pharmaceutical expenditure (TPE) in St. Vincent and the Grenadines in 2009, according to the Customs Department, was EC$11,253,122 (US$4,166,429), which is a per capita pharmaceutical expenditure of EC$102 (US$38). The total pharmaceutical expenditure accounts for 0.7% of the GDP. Public expenditure on pharmaceuticals represents 38% of the total expenditure

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

[ii] There are no restrictions on who can access the public service health facilities for medical service. A patient may choose to use private services, and in such cases no medication will be provided in the public setting.

on pharmaceuticals[8] (Figure 1), this converts into a per capita public expenditure on pharmaceuticals of EC$39.3 (US$14.6).

Figure 1. Share of Total Pharmaceutical Expenditure (TPE) by sector (2009)



Total private expenditure on pharmaceuticals is EC$6,953,122 (US$2,586,727).

The private out-of-pocket expenditure corresponds to the 100% of the private health expenditure[9].

2.2 Health Personnel and Infrastructure

The health workforce is described in Table 3 and in Figure 2. There are 50 (4.5/10,000) licensed pharmacists[10], of which 24 (2.2/10,000) work in the public

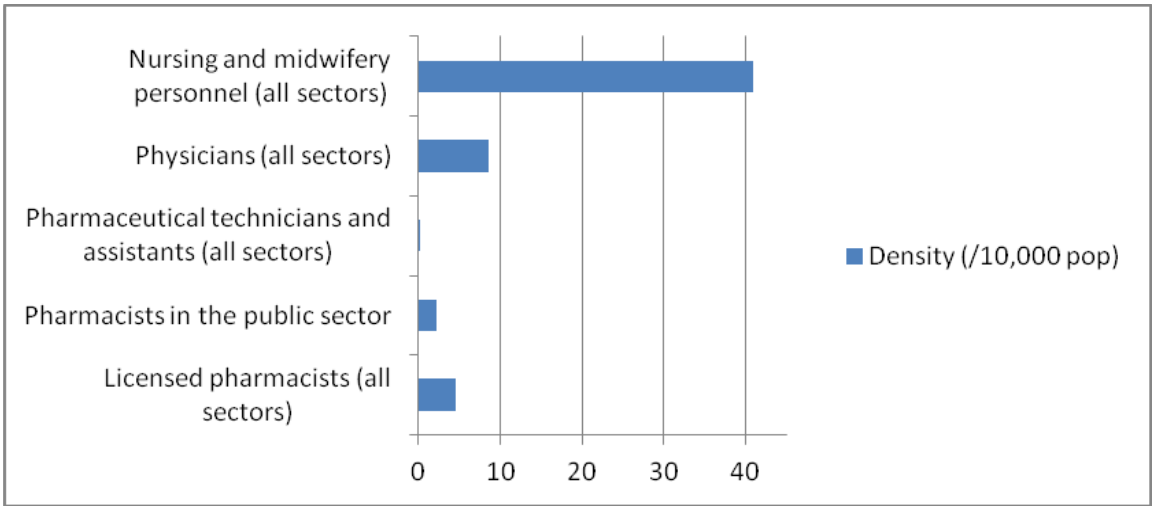
sector. There are 2 (0.2/10,000) pharmaceutical technicians and assistants (in all sectors).

There are 94 (8.6/10,000) physicians and 447 (40.9/10,000) nursing and midwifery personnel[1] in the country. The approximate ratio of doctors to pharmacies is 2:1 and the ratio of doctors to nurses and midwifery personnel is 1:5.

Table 3. Human resources for health in St. Vincent and the Grenadines

Human Resource	
Licensed pharmacists (all sectors)	50 (4.5/10,000)
Pharmacists in the public sector	24 (2.2/10,000)
Pharmaceutical technicians and assistants (all sectors)	2 (0.2/10,000)
Physicians (all sectors)	94 (8.6/10,000)
Nursing and midwifery personnel (all sectors)	447 (40.9/10,000)

Figure 2. Density of the health workforce



In St. Vincent and the Grenadines, there is no strategic plan for pharmaceutical human resource development in place; nevertheless, the 2011 Corporate Plan of the Ministry Pharmaceutical Services proposes the expansion on the number of professionals and assistants, the review of a carrier grade, post description and organogram.

The health infrastructure is described in Table 4. There are 7 hospitals in total[11] and 45 hospital beds per 10,000 population. There are 40 primary health care units and centres and 49 licensed pharmacies[10].

Table 4. Health centres and hospital statistics

Infrastructure	
Hospitals	7[iii]
Hospital beds	45/10,000 population
Primary health care units and centres	40
Licensed pharmacies	49

The annual starting salary for a newly registered pharmacist in the public sector is EC$ 41,880[7]. The total number of pharmacists who graduated (as a first degree) in the past 2 years is 6[10,iv].

[iii] Secondary care is offered at Kingstown General Hospital, a 209-bed referral hospital offering various categories of specialist care. Acute care, not requiring specialist intervention, is also provided by 5 rural hospitals with a combined capacity of 58 beds. Acute and chronic psychiatric care is provided through the Mental Health Centre, which has 138 beds. There is also a geriatric institution with 100 beds.

[iv] There are no Pharmacy schools in SVG. 3 of the 6 new registrants graduated with associated degrees and the other 3 with Bs. in Pharmacy. The Pharmacy degree was completed overseas.

Section 3 - Policy Issues

This section addresses the main characteristics of the pharmaceutical policy in St. Vincent and the Grenadines. The many components of a national pharmaceutical policy are taken from the WHO publication "How to develop and implement a national drug policy" (http://apps.who.int/medicinedocs/en/d/Js2283e/).

3.1 Policy Framework

In St. Vincent and the Grenadines, a National Health Policy (NHP) does not exist[12]. However, the Ministry of Health, Wellness and The Environment led the process to develop the National Strategic Plan 2007-2012.

An official National Medicines Policy (NMP) document does not exist[12], and policies addressing pharmaceuticals[v] do not either exist at present[12].

A policy relating to clinical laboratories does not exist[12]. Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in the national legislation. There are official written guidelines on medicines donations.

There is no national good governance policy in St. Vincent and the Grenadines.

[v] There is no policy framework for selection of essential medicines, financing, pricing, procurement, distribution, pharmacovigilance, rational use, human resources, research, monitoring and evaluation, or traditional medicine.

A policy is not in place to manage and sanction conflict of interest issues in pharmaceutical affairs and there is no associated formal code of conduct for public officials. A whistle-blowing mechanism that allows individuals to raise concerns about wrongdoing occurring in the pharmaceutical sector of St. Vincent and the Grenadines, does not either exist.

Section 4 – Medicines Trade and Production

In this section, information about the capacity for manufacturing medicines and the legal provisions governing patents is provided.

4.1 Intellectual Property Laws and Medicines

St. Vincent and the Grenadines is a member of the World Trade Organization (WTO)[13]. Legal provisions granting patents to manufacturers exist[14]. These cover pharmaceuticals, laboratory supplies, medical supplies and medical equipment.

Intellectual Property Rights are managed and enforced by the Commerce and Intellectual Property Office (CIPO)[15].

National Legislation has been modified to implement the Trade-Related aspects of Intellectual Property Rights (TRIPS) Agreement[14] and contains TRIPS-specific flexibilities and safeguards[14], presented in Table 5. St. Vincent and the Grenadines is not eligible for the transitional period to 2016.

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.

Table 5. TRIPS flexibilities and safeguards present in the national law[14,16]

Flexibilities and safeguards	Included
Compulsory licensing provisions that can be applied for reasons of public health	Yes
Bolar exceptions[vi]	No
Parallel importing provisions	Yes

There are legal provisions for data exclusivity for pharmaceuticals[14], but not for patent extension or linkage between patent status and marketing authorization.

4.2 Manufacturing

There are no licensed domestic or multinational pharmaceutical manufacturers in St. Vincent and the Grenadines. Consequently the country has no capacity to discover new active substances, to produce active pharmaceutical ingredients (APIs), to produce formulations from starting material or to repackage finished dosage forms.

[vi] 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]

Section 5 – Medicines Regulation

This section details the pharmaceutical regulatory framework, resources, governing institutions and practices in St. Vincent and the Grenadines.

5.1 Regulatory Framework

In St. Vincent and the Grenadines, there are legal provisions[17] establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA)[vii] – the regulatory functions (see Table 6) are performed by the Pharmacy Council[10] and the Drug Inspector (part of the Ministry). The Pharmacy Council does not have its own website.

Table 6. Regulatory functions of the Pharmacy Council / Drug Inspector[10]

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

[vii] St. Vincent and the Grenadines Pharmacy Council, Environmental Health Department Complex, Ministry of Health, Wellness and The Environment, Kingstown VC0100, St. Vincent and the Grenadines.

The registration of pharmacists, pharmacies, pharmacy students, pharmacy assistants and pharmacy owners is also conducted by the Pharmacy Council. The quality control testing is performed by the Caribbean Regional Drug Testing Laboratory (CRDTL)[18].

The MRA does not receive external technical assistance to support its activities. It is, however, involved in collaboration initiatives such as the Caribbean Association of Pharmacists (CAP) and the Caribbean Community (CARICOM) towards the harmonization of laws and practice under the CARICOM Single Market and Economy (CSME).

An assessment of the medicines regulatory system has not been conducted in the last five years. Funding for the MRA is not provided through the regular government budget, but from fees for services provided. The Regulatory Authority retains revenues derived from regulatory activities. This body does not utilize a computerized information management system to store and retrieve information on processes.

The Drug Inspector

The Drug Inspector preceded the Pharmacy Council as a semiautonomous member of the staff with responsibility to monitor the standards of products and services rendered to the public and to enforce the legislation relating to pharmaceutical use in the country. The Drug Inspector is a co-opted member of the Council, howbeit, a non-voting member.

5.2 Marketing Authorization (Registration)

In St. Vincent and the Grenadines, legal provisions require marketing authorization (registration) for pharmaceutical products on the market[viii]. The SVG Pharmacy Act gives the Pharmacy Council the mandate to decide on matters relating to the registration of drugs[ix].

Nevertheless, the Pharmacy Council has forwarded to the Attorney General, recommendations for specific regulations on this matter. At the moment, the country does not have the capacity or competencies to establish and enforce drug registration. The Council recommends a regional approach to marketing authorization.

5.3 Regulatory Inspection

In St. Vincent and the Grenadines, legal provisions exist allowing for appointment of government pharmaceutical inspectors[17]. Legal provisions also exist permitting inspectors to inspect premises where pharmaceutical activities are performed[17]. Such inspections are required by law and are a pre-requisite for the licensing of public and private facilities. The inspection requirements are the same for public and private facilities[10]. Inspections are carried out on a number of entities, outlined in Table 7.

[viii] Although the legal previsions require the registration of all drugs in the market, the Pharmacy Council has been unable to fulfill this function so far mainly due to insufficient resources.

[ix] Section 27: “registration of drug ought to be a requirement for import”, and Section 28: “the Council has the authority to publish a list which can only be imported in to the country under a license issued by the Council”.

Table 7. Local entities inspected by the government

Entity	Inspection	Frequency
Local manufacturers	N/A	
Private wholesalers	Yes	Annual
Retail distributors	Yes	Biannual
Public pharmacies and stores	Yes	-
Pharmacies and dispensing points of health facilities	Yes	-

5.4 Import Control

Legal provisions exist requiring authorization to import medicines[17]. Laws exist that allow the sampling of imported products for testing[17]. Legal provisions also exist requiring importation of medicines through authorized ports of entry, but regulations do not exist to allow for inspection of imported pharmaceutical products at the mentioned ports.

5.5 Licensing

The Pharmacy Council has recommended the Legal Affairs Department to include mandatory Good Manufacturing Practices (GMP) compliance for potential manufacturers.

Legal provisions exist requiring importers, wholesalers and distributors to be licensed[17]. Legal provisions do not exist requiring Good Distributing Practices

(GDP) compliance, and no official document has been published by the government on this matter.

Table 8. Legal provisions pertaining to licensing

Entity requiring licensing	
Importers	Yes
Wholesalers	Yes
Distributors	Yes

Legal provisions exist requiring pharmacists to be registered[17]. Legal provisions also exist requiring public and private pharmacies to be licensed[17]. National Good Pharmacy Practice (GPP) Guidelines are not published by the government. By law, a list of all licensed pharmaceutical facilities is not required to be published.

5.6 Market Control and Quality Control

In St. Vincent and the Grenadines, legal provisions do not exist for controlling the pharmaceutical market. A local laboratory does not exist in the country for Quality Control testing. Samples collected by government inspectors the procurement officer for undertaking post-marketing surveillance are sent to the Caribbean Regional Drug Testing Laboratory (CRDTL)[x] in Jamaica[18].

[x] The CRDTL was established in Jamaica under an agreement signed by 14 member states of the Caribbean Community (CARICOM).

Samples are collected by the Pharmaceutical Procurement Service/Organisation of Eastern Caribbean States (PPS/OECS)[19]. Medicines are tested for a number of reasons, summarised in Table 9.

Table 9. Reasons for medicines testing

Medicines tested:	
For quality monitoring in the public sector[xi]	Yes
For quality monitoring in the private sector[xii]	No
When there are complaints or problem reports	Yes
For product registration	No
For public procurement prequalification	Yes
For public program products prior to acceptance and/or distribution	Yes

The results of quality testing in the past 2 years are not publicly available.

5.7 Medicines Advertising and Promotion

In St. Vincent and the Grenadines, legal provisions do not exist to control the promotion and/or advertising of prescription medicines. The SVG Bureau of Standards[20] has a regulatory mandate to develop advertising standards, and guidelines developed by other autonomous regulatory agencies will be incorporated soon.

[xi] Routine sampling in pharmacy stores and health facilities.

[xii] Routine sampling in retail outlets.

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[17]. Guidelines or regulations do not either exist for advertising and promotion of non-prescription medicines.

5.8 Clinical Trials

In St. Vincent and the Grenadines, legal provisions do not exist requiring authorization for conducting Clinical Trials by the MRA[11]. There are no additional laws requiring the agreement by an ethics committee or institutional review board of the Clinical Trials to be performed. Clinical trials are not required to be entered into an international, national or regional registry, by law.

5.9 Controlled Medicines

St. Vincent and the Grenadines is a signatory to a number of international conventions, detailed in Table 10.

Table 10. International Conventions to which the country is a signatory[21]

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

Laws exist for the control of narcotic and psychotropic substances, and precursors [Drugs (prevention of misuse) Act - 1998[22]]. The legal provisions and regulations for the control of narcotic and psychotropic substances and precursors however, have not been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need.

The annual consumption in milligrams per capita of some controlled substances is presented in Table 11.

Table 11. Annual consumption of selected controlled substances in 2010[21]

Controlled substance	Annual consumption (mg/capita)
Morphine	1.220183
Fentanyl	0.002000
Pethidine	7.000000
Oxycodone	0.000000
Hydrocodone	0.000000
Phenobarbital	3.200000
Methadone	0.000000

5.10 Pharmacovigilance

In St. Vincent and the Grenadines, there no legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate**.** Laws regarding the monitoring of Adverse Drug Reactions (ADR) do not exist.

A national pharmacovigilance centre, however, exists[xiii], and has 1 full-time professional in charge. The centre has not published an analysis report in the previous two years and it does not regularly publish an ADR bulletin. An official standardized form for reporting ADRs (designed by the OECS/PPS) is used in the country[19], and information pertaining to ADRs is stored in a national ADR computerized database. The ADR database currently comprises 46 ADR reports, of which 30 of them were submitted between 2009 and 2010. These reports are also sent to the WHO collaborating centre in Uppsala[23].

There is no national ADR or pharmacovigilance advisory committee able to provide technical assistance or causality assessment, risk assessment, risk management, case investigation, or crisis management. A clear communication strategy for routine communication and crises communication does not exist.

Feedback is provided to reporters. Medication Errors (MEs) are not reported. No regulatory decision has been taken based on local pharmacovigilance data in the last 2 years.

In the past 2 years, doctors, nurses and pharmacists have reported ADRs. There are no ongoing courses in pharmacovigilance, but public presentations have been held to sensitize health personnel and 154 people have been trained.

In order to enhance the pharmacovigilance system it is being considered establishing a website, where reporters can download the ADR form or submit it online. Reporting via telephone will also be considered. A mailing list of physicians, nurses and pharmacists has been established (200 addresses), and regularly FDA alerts and WHO newsletters are circulated.

[xiii] The OECS/PPS is the regional pharmacovigilance centre for all OECS territories.

Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in St. Vincent and the Grenadines, 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 St. Vincent and the Grenadines, concessions are made for certain groups to receive medicines free of charge (see Table 12)[24]. Furthermore, the public health system provides medicines free of charge for particular conditions (see Table 13).

Table 12. 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	Yes

Children under 17 and persons over 60 years of age are exempted from paying the EC$5 user fee required to receive the medication. The general public registered on public assistance (poor relief) are also exempted. There are

provisions, through the Social Welfare Officer, for patients who claim they cannot afford the fee to receive an exemption stamp[xiv].

Table 13. Medications provided publicly, at no cost

Conditions	Covered
All diseases in the EML	No
Any non-communicable diseases	No
Malaria	Yes
Tuberculosis	Yes
Sexually transmitted diseases	Yes
HIV/AIDS	Yes
Expanded Program on Immunization (EPI) vaccines for children	Yes
Other – Contraceptives	Yes

Antiretrovirals (ARVs) are supplied at no cost through international donor agencies (Clinton Foundation; Global Fund to Fight AIDS, Tuberculosis and Malaria; and the Brazilian Government). Under the national laws, all children must be vaccinated under the Expanded Program on Immunization (EPI).

According to the National Insurance Services there is partial coverage for medicines that are on the Essential Medicines List (EML) for inpatients but not for outpatients. The National Services provide up to 80% coverage only in cases of labour accident.

[xiv] Exemptions are provided in the public service for indigents, unemployed pensioners, handicapped persons, children under 17, doctors and nurses, antenatal and postnatal care, family planning and psychiatric treatment.

Private health insurance schemes provide medicines coverage[25]; however, providing at least partial coverage for those on the EML is not required[xv].

6.2 Patients Fees and Copayments

Co-payments or fee requirements for consultations are not levied at the point of delivery. However, there are copayments or fee requirements imposed for medicines[26]. 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.

Hospital Fees

- ✓ Maintenance and nursing per day: EC$25 (private) and EC$10 (public).
- ✓ Surgical operations / anesthesia / gases: EC$50 (major), EC$35 (intermediate) and EC$20 (minor).
- ✓ Outpatient prescription: EC$5.

6.3 Pricing Regulation for the Private Sector[xvi]

In St. Vincent and the Grenadines, there are legal or regulatory provisions affecting pricing of medicines[27,28]. These provisions are aimed at the level of wholesalers and retailers. Medicines are price controlled in the private sector with a 12% rate at the wholesale level and a 13% rate at the retail level.

[xv] 80% coverage is provided for behind the counter and prescription medicines only.

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

The government runs an active national medicines price monitoring system for retail prices[29]. Regulations exist mandating that retail medicine price information should be publicly accessible[28], and the Consumer Affairs Department periodically publishes the information on radio.

6.4 Prices, Availability and Affordability of Key Medicines

No surveys on medicines prices, availability or affordability have been conducted in St. Vincent and the Grenadines under the World Health Organization/Health Action International (WHO/HAI) methodology in the past 5 years. Nevertheless, the OECS/PPS annually conducts a survey across all the member countries to measure inventory, service levels of prescription medicines, and availability of a special basket of essential medicines.

6.5 Price Components

No surveys on medicines price components have been conducted in St. Vincent and the Grenadines in the past 5 years. The national law, however, stipulates that the cumulative percentage mark-up between Manufacturing Selling Price (MSP) / Cost Insurance and Freight (CIF) price and final medicine price for a basket of key medicines in the private sector must be 12.5.

6.6 Duties and Taxes on Pharmaceuticals (Market)

St. Vincent and the Grenadines imposes duties on imported finished products[27]. Value-added tax (VAT) is also imposed on finished pharmaceutical products but only in the private sector. Provisions for tax exceptions or waivers for prescription medicines are in place. Taxes are applied on non-prescription medicines only.

The duty imposed on imported finished products varies from 0% to 10%[27]; and the VAT - only for Over-the-counter (OTC) medicines - corresponds to the 14%[27].

Section 7 - Pharmaceutical procurement and distribution

This section provides a short overview on the procurement and distribution of pharmaceuticals in the public sector of St. Vincent and the Grenadines.

7.1 Public Sector Procurement

Public sector procurement in St. Vincent and the Grenadines is centralized by the Central Medical Stores (CMS) using the OECS/PPS pooled procurement services[11]. The public sector procurement is centralized under the responsibility of the CMS which is a part of the Ministry of Health, Wellness and The Environment.

At the OECS/PPS, request for tender documents as well as tender awards are publicly available[19]. Procurement is based on the prequalification of suppliers[8,19].

There is no written public sector procurement policy[8]. Legal provisions do not exist to give priority to locally produced good in public procurement[8].

The key functions of the procurement unit an those of the tender committee are clearly separated. A process exists to ensure the quality of products that are publicly procured[19]. The quality assurance process includes the prequalification of products and suppliers based on explicit criteria and procedures[19]. A list of prequalified suppliers and products is available[19]. A list of samples tested during the procurement process and the results of quality testing are available[8].

The tender methods employed in public sector procurement include national competitive tenders, international competitive tenders and direct purchasing[8].

7.2 Public Sector Distribution

There is one Central Medical Store at national level which procures and distributes pharmaceutical supplies to the clinic pharmacies in the peripheral districts including the pharmacies in the rural hospitals and health centres. There are no public warehouses in the secondary tier of the public sector distribution. There are no national guidelines on Good Distribution Practices (GDP).

The Drug Inspector inspects the CMS periodically.

A number of processes are in place at the Central Medical Store[8] as detailed in Table 14.

Table 14. 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	No
Reports of products out of stock	Yes

The percentage availability of key medicines at the CMS is 93%[19].

Routine procedure to track the expiry dates of medicines at CMS exists[8]. The CMS is not ISO certified[8].

7.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector[17]. There is no legal requirement to hold a GDP certificate. Inspections are periodically carried out by the Drug Inspector. Each wholesale or distribution outlet is registered as a wholesale pharmacy and is required to have a managing Pharmacist in direct supervision of pharmaceutical sale.

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 St. Vincent and the Grenadines.

8.1 National Structures

A National Essential Medicines List (EML) exists[30]. The EML was lastly updated in 2010 and is publicly available. There are currently 291 medicines on the EML. Selection of medicines for the EML is not undertaken through a standardized written process. A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is in place. Nevertheless, National STGs for the most common illnesses are not produced/endorsed by the Ministry[xvii]. Of the public health facilities, 100% have a copy of the EML. The EML does not include specific formulations for children.

There is a public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers. Public education campaigns on rational medicine use topics have been conducted in the last two years. A survey on rational use of medicines has also been conducted in the same period. There is national programme or committee, to monitor and promote rational use of medicines. A written National strategy for containing antimicrobial resistance does not exist[xviii], and no National reference

[xvii] There are only STGs for HIV/AIDS and H. pylori.

[xviii] The strategy is being developed. It was initiated by a study by from the Pharmacy and Therapeutics Committee about antimicrobial sensitivity and prescribing patterns.

laboratory or institution is responsible for coordinating epidemiological surveillance of antimicrobial resistance. There is, however, an intersectoral taskforce to coordinate the promotion of appropriate use of the mentioned medicines and the prevention of spread of infection.

There is a formal committee for the selection of products in the National EML (Pharmacy and Therapeutics Committee); but conflict of interest declarations are not required from its members.

There is an OECS medicines formulary, but it only applies for the public sector.

8.2 Prescribing

Legal provisions do not exist to govern the licensing and prescribing practices of prescribers. However, legal provisions restricting dispensing by prescribers[xix] exist[17]. Prescribers in the private sector dispense medicines.

There are no regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs). However, there is one DTC for the whole country.

Mandatory continuing education that includes pharmaceutical issues is not required for doctors, nurses or paramedical staff.

[xix] In accordance with the Pharmacy Act, only Pharmacists can sell prescription medicines.

Prescribing by International Non-proprietary Name (INN) is not obligatory in the country. The average number of medicines prescribed per patient contact in public health facilities is 3. Of prescribed drugs, 92% are dispended to patients[19].

A professional association code of conduct which governs the professional behaviour of doctors does not exist. However a similar code exists in the case of nurses.

8.3 Dispensing

Legal provisions in St. Vincent and the Grenadines do not exist to govern dispensing practices of pharmaceutical personnel. There are no local Pharmacy schools. Mandatory continuing education that includes rational use of medicines is not 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.

A professional association code of conduct which governs the professional behaviour of pharmacists does not exist; however the Pharmacy Association is currently developing one. In practice, nurses, pharmacists and paramedics do sometimes prescribe prescription-only medicines at the primary care level in the public sector.

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SAINT VINCENT AND THE GRENADINES

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 Vincent and the Grenadines
0.01.02	Name coordinator	Tyrone Jack
0.01.03	Address (Street, City)	Level Garden, Kingstown
0.01.04	Phone number	(H)7844562293 (M) 7844543217
0.01.05	Email address	tjreynold@yahoo.com
0.01.06	Web address	
0.01.07	Institution	Ministry of Health, Wellness and the Environment

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	Tyrone Jack
1.00.02	Phone number	784 4543217
1.00.03	Email address	tjreynold@yahoo.com
1.00.04	Other respondents for filling out this section	Dr. George Epidemiologist with the Ministry of Health

1.01 Demographic and Socioeconomic Indicators

Core questions (click here for help)

			Year	Source
1.01.01	Population, total (,000)	109.333	2010	World bank data
1.01.02	Population growth rate (Annual %)	0.1	2010	World Bank data
1.01.03	Total Gross Domestic Product (GDP) (millions US$)	570	2010	Statistical Unit Central Planning Department data
1.01.04	GDP growth (Annual %)	-1.84	2010	Statistical Unit Central Planning Department data
1.01.05C	GDP per capita (US$ current exchange rate)	5,335 5,213		
1.01.06	Comments and References	1.01.01,1.01.02 World Bank Data. St Vincent and the Grenadines. the last census was conducted in 2001. The population is a projection. Available on line:		

		http://data.worldbank.org/indicator/SP.POP.GROW 1.01.03, 1.01.04 Statistical Unit Central Planning Department data. COMMENT The last population census was conducted in 2001. The population stood at 106,253 which represented a 0.2 percent decline on the comments Previous census year 1991 and it was the first time since 1871 that a decline in the population was recorded.(ST. VINCENT AND GRENADINES country proverty assessment 2006-2007 table 3.1 by -KAIRI This year 2011 is the census year the result are not yet available. The Gov webpage figures will be the Central Planning unit best projections.

Supplementary questions (click here for help)

			Year	Source
1.01.07S	Population < 15 years (% of total population)	27	2008	WHS 2010
1.01.08S	Population > 60 years (% of total population)	9	2008	WHS 2010
1.01.09S	Urban population (% of total population)	47	2008	WHS 2010
1.01.10S	Fertility rate, total (Births per woman)	2.1	2008	WHS 2010
1.01.11S	Population living with less than $1.25/day (international PPP) (%)			
1.01.12S	Population living below nationally defined poverty line (%)	30.2	2006	SVG country Proverty Assessment
1.01.13S	Income share held by lowest 20% of the population (% of national income)	7	2008	SVG country Proverty Assessmen

1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	88.7	2008	SVG country proverty Assessment
1.01.15S	Comments and References	1.01.07S-1.01.08S World Health Statistics. Available online: http://www.who.int/whosis/whostat/EN_WHS10_Full.pdf 1.01.11S-1.01.14S ST. VINCENT AND GRENADINES country poverty assessment 2006-2007 table 3.1. by KAIRI. Available online:http://www.eclac.cl/portofspain/noticias/paginas/0/40340/4_CPA_SVG_CPA_-_FINAL_REPORT__Vol_1__Revised.pdf 1.01.11s The indigent proverty line was set on the SVg proverty assessment at $6.70 E.C (p$2.32US)er adult per day 2.7% of the population fell below that line.		

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)	70	2009	World Bank data
1.02.02	Life expectancy at birth for women (Years)	74	2009	World Bank data
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)	11	2009	World Bank data
1.02.04	Under 5 mortality rate (/1,000 live births)	12	2009	World Bank data
1.02.05	Maternal mortality ratio (/100,000 live births)	58	2005	WHS - interagency est
1.02.06	Please provide a list of top 10 diseases causing mortality		2010	Epidemiology Department /Ministry of Health

1.02.06.01	Disease 1	Neoplasms (most prevalent was Prostate Cancer)		
1.02.06.02	Disease 2	Ishemic Heart disease		
1.02.06.03	Disease 3	Hypertensive heart disease		
1.02.06.04	Disease 4	Communicable disease(most prevalent Acute respiratory infection)		
1.02.06.05	Disease 5	Cerebrovascular disease		
1.02.06.06	Disease 6	injuries + voilence		
1.02.06.07	Disease 7	Diabetes mellitus		
1.02.06.08	Disease 8	Perinatal conditionsr		
1.02.06.09	Disease 9	other heart disease		
1.02.06.10	Disease 10	disease of the digestive system		
1.02.07	Please provide a list of top 10 diseases causing morbidity 		2010	Epidemiology Department /MOH
1.02.07.01	Disease 1	Communicable disease		
1.02.07.02	Disease 2	hypertension		
1.02.07.03	Disease 3	Hypertension+ diabetes mellitus		
1.02.07.04	Disease 4	diabetes millitus		
1.02.07.05	Disease 5	musculosketal		
1.02.07.06	Disease 6	gastritis		
1.02.07.07	Disease 7	Asthma		
1.02.07.08	Disease 8	endocrine +metabolic		
1.02.07.09	Disease 9	Injuries & voilence		
1.02.07.10	Disease 10	Disabilities (mental and Physical- motor)		
1.02.08	Comments and References	1.02.01-1.02.04 World Bank data 2009. Available online:		

		http://data.worldbank.org/country/st-vincent-and-the-grenadines 1.0.2.06 and 07 Epidemilogy Dpt. Min of Health.		
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)			
1.02.10S	Neonatal mortality rate (/1,000 live births)	15.1	2008	WHS 2010
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	674	209	WHS 2010
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)		2009	WHS 2009
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	85.77	2009	WHS 2009
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	10.9	2009	WHS 2009
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	1.0	2009	WHS 2010
1.02.16S	Mortality rate for Malaria (/100,000 population)	0	2009	Epidermology Department data
1.02.17S	Comments and References	1.02.09S St.Vincent and the Grenadines-SVG mortality Servillance consulted, information not available. 1.02.10S-102.15S World Health Statistics.2009,2010. 1.02.12S IHD 23.44, CVD 30.63 1.02.16S Epidemiology Department data.		

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	Tyrone Jack
2.00.02	Phone number	4543217
2.00.03	Email address	tjreynold@yahoo.com
2.00.04	Other respondents for filling out this section	Statistical Unit Central Planning division

2.01 Health Expenditures

Core questions (click here for help)

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)			
2.01.01.02	Total annual expenditure on health (millions US$ average exchange rate)			
2.01.02C	Total health expenditure as % of Gross Domestic Product	4.96		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	420.4		
2.01.03.02C	Total annual expenditure on health per capita (US$ average exchange rate)	155.7		
2.01.04.01	General government annual expenditure on health (millions NCU)	55,868278	2009	(SVG estimates of revenue and expenditure 2011
2.01.04.02	General government annual expenditure on health (millions US$ average exchange rate)	$19,545391	2009	Actural recurrent expenditure

				year 2009 (SVG estimates of revenue and espenditure 2011
2.01.05	Government annual expenditure on health as percentage of total government budget (% of total government budget)	10.18	2009	SVG estimates of revenue and espenditure 2011 .
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	61.25	2009	Drug Inspector
2.01.07.01C	Annual per capita government expenditure on health (NCU)	449.54 511.19		
2.01.07.02C	Annual per capita government expenditure on health (US$ average exchange rate)	166.50 178.83		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	38.75 undetermined	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)	100%	2010	MoH
2.01.10	Population covered by private health insurance (% of total population)			
2.01.11.01	Total pharmaceutical expenditure (millions NCU)	11253122.95	2009	Custom Department
2.01.11.02	Total pharmaceutical expenditure (millions US$ current exchange rate)	4166429.66	2009	Customs department

2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	21	$102		
2.01.12.02C	Total pharmaceutical expenditure per capita (US$ current exchange rate)	10.5	$38.10		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	3.43	0.7		
2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	6.75			
2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)	4.3		2009	Central Medical Stores (CMS) data.
2.01.15.02	Total public expenditure on pharmaceuticals (millions US$ current exchange rate)	1.6		2009	Central Medical Stores (CMS) data.
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	PREFILL CALC		2009	Drug Inspector
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	PREFILL CALC	$39.34		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	PREFILL CALC	$14.6		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)	6953122.95		2009	Drug Inspector
2.01.18.02	Total private expenditure on pharmaceuticals (millions US$ current exchange rate)	2586727.28		2009	Drug Inspector
2.01.19	Comments and References	2.01.01.01-.02 there is insufficient data to estimate private expenditure on health for any of the years in frame.			

		2.01.12.01C- 02C- My calculations give $102.00 EC or $38.10 US 2.01.09 There is no restriction on who can access the public service health facilities for medical service , one may chose to use Private medical service and in such cases , he /she is not expected to receive their medication in the public setting, (exception are in cases of orphan drugs, highly infective agents, and Class 11 control substances not normally carried in the private sector). 2.01.10 Information not available 2.01.13C- my calculation using 2009 GDP of $ 593 million US gives) 0.70 2.01.14 C- undetermined as there is insufficient info on total health expinditure 2.01.16 C :- 4.3..millions/11.25..millions to give 38% 2.01.17.01 C 4.3..millions/ 109290 to give $ 39.34 2.02.17.02C:- 1.6 millions/109290 to give $14.64

Supplementary questions (click for help)

			Year	Source
2.01.20S	Social security expenditure as % of government expenditure on health (% of government expenditure on health)	0.00	2008	NHA data
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	100	2008	NHA data

	(% of private expenditure on health)			
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	0.00	2008	NHA data
2.01.26S	Comments and References	2.01.21s-23s There is insufficient data available at this time to estimate the Values of branded or generic products.		

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	50	2011	Pharmacy Council Regrister
2.02.02C	Pharmacists per 10,000 population	3.93 4.5		
2.02.03	Total number of pharmacists working in the public sector	24	2011	chief Pharmacist Data
2.02.04	Total number of pharmaceutical technicians and assistants	2	2011	chief Pharmacist Data
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes ☐ No ☒	2011	chief Pharmacist Data
2.02.06	Total number of physicians	94	2011	Chief medical Officer's data
2.02.07C	Physicians per 10,000 pop	8.6		
2.02.08	Total number of nursing and midwifery personnel	447	2007	WHS 2009

2.02.09C	Nurses and midwives per 10,000 pop	40.9		
2.02.10	Total number of hospitals	7	2009	HERA
2.02.11	Number of hospital beds per 10,000 pop	45	2011	Ministry of Health
2.02.12	Total number of primary health care units and centers	40	2011	Ministry of Health
2.02.13	Total number of licensed pharmacies	49	2011	Pharmacy Council Register
2.02.14	Comments and References	2.02.01, 2.02.13 Pharmacy Council Register 2.02.03-2.02.05 Chief Pharmacists 2.02.06 Chief Medical Officer's 2.02.10 Health Research for Action- HERA 2.02.11, 2.02.12 Ministry of Health. 2.02.01 The # of registered Pharmacist is 50, the Population is approximately 11* 10,000s Pharmacist Per 10,000 is therefore 4.56 2.02.05,-"There is not a Human Resources development plan, nevertheless the 2011 Pharmaceutical Corporate Plan of the MOH Pharmaceutical Services proposes the expansion on the number of professionals and assistants and the review of a carrier grade, post description and organogram. 2.02.10 Secondary care is offered at Kingstown General Hospital, a 209-bed referral hospital offering various categories of specialist care. Acute care, not requiring specialist intervention, is also provided by 5 rural hospitals with a combined capacity of 58 beds. Acute and chronic psychiatric care is provided through the Mental Health Centre, which has 138 beds. There is also a geriatric instution with 100 beds giving a total of 495 beds or 45 beds to 10,000 of population 2.02.13 The pharmaceutical delivery system is comprised of 6 government hospital pharmacies, 17 private for-profit retail pharmacies and 40 government health center pharmacies. All pharmacist are required by law to be registered (St Vincent Pharmacy ACt 2002, Section :10).		

Supplementary questions (click here for help)				
			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist in the public sector (NCU)	41,880.00	2011	SVG estimates of revenue and expinditure
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country	6	2011	Pharmacy Council register
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes ☐ No☒	2011	MOH
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes ☐ No ☒	2011	MOH
2.02.19S	Comments and References	2.02.16S Three of the six new registrant graduated with Associated degrees and three with Bs. in Pharmacy. The Pharmacy Degree was completed overseas. 2.02.17S There are no Pharmacy School in SVG however there is a national Accrediation board under whose censorship the extablishment of such a school or program will fall		

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	Tyrone Jack		
3.00.02	Phone number	7844543217		
3.00.03	Email address	tjreynold@yahoo.com		
3.00.04	Other respondents for filling out this section	Ms. Lucine Edwaeds		

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	Health Planning Unit
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	Health Planning Unit
3.01.03	Please provide comments on the Health policy and its implementation plan	There is no written health policy and no concrete implimentation plann, but the MOHE led the process to develop the National Strategic Plan 2007-2012		
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 ☒	2011	Health Planning Unit
3.01.05	Group of policies addressing pharmaceuticals exist.	Yes ☐ No ☒	2011	Health Planning Unit
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	Drug Inspector Ministry of Health
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	Health Planning Unit
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	Health Planning Unit
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	Drug Inspector Ministry of Health

3.01.11	There are official written guidelines on medicines donations.	Yes ☒ No ☐	2007	MOH
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes ☒ No ☒	2011	Drug Inspector Ministry of Health
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	Chief medical Officer,Chief Pharmacist & The Pharmacy Council		
3.01.13	Is there a national good governance policy?	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
3.01.13.01	Multisectoral	☐Yes		
3.01.13.02	For the pharmaceutical sector	☐Yes		
3.01.13.03	Which agencies are responsible?	The Pharmacy Council and the National Pharmaceutical Association		
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
3.01.15	There is a formal code of conduct for public officials.	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
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 ☒	2011	Drug Inspector Ministry of Health
3.01.16.01	Please describe:			
3.01.17	Comments and References	3.01.01 - 3.01.06, 3.01.08,3.01.09 Health Planning Unit. 3.01.07, 3.01.10, 3.01.12-3.01.16 Ministry of Health.		

		3.01.11 WHO level I. 3.01.01 - 3.01.06, 3.01.08,3.01.09 Health Planning Unit. 3.01.06.01 and 0.8 An essential medicine list has been developed for SVS and there is a pharmacovigilance unit was established, however it is only monitored in the public sector.

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	Tyrone Jack
4.00.02	Phone number	7844543217
4.00.03	Email address	tjreynold@yahoo.com
4.00.04	Other respondents for filling out this section	Mrs Lewis Director of the Commercial and intellectural Property Office (CIPO) 7844561516.

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
4.01.02	Legal provisions provide for granting of Patents on:		2008	SVG patent ACT 2004
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	The Commerce & Intellectual Property Office (CIPO) is responsible for the grant of patents.		
4.01.03.02	Please provide URL	www.gov.vc/govt/cipo/index.asp		
4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes ☒ No ☐	2008	SVG patent ACT 2004
4.01.05	Current laws contain (TRIPS) flexibilities and safeguards	Yes ☒ No☐	2009	SVG patent ACT 2004

				and patent regulation 2009
4.01.06	Country is eligible for the transitional period to 2016	Yes ☐ No☒		
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2008	HERA
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 ☐	2008	SVG patent ACT 2004 and patent regulation 2009
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 ☐	2008	SVG patent ACT 2004 and patent regulation 2009
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes ☒ No ☐	2008	SVG patent ACT 2004 and patent regulation 2009
4.01.11	Legal provisions exist for patent extension	Yes ☐ No ☒	2008	SVG patent ACT 2004 and patent regulation 2009
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes ☐ No ☒	2008	SVG patent ACT 2004 and patent regulation 2009

4.01.13	Comments and References	4.01.01 World Trade Organization. Available online: http://www.wto.org/english/thewto_e/countries_e/saint_vincent_grenadines_e.htm 4.01.07- 4.01.12 Patent Act # 39 of 2004 and Patent regulation 2009 Note: under the newly revised laws the Patent Act is CAp 314		

4.02 Manufacturing

Core questions (click here for help)

			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country	0	2004	Pharmacy ACT 2004 Sec:27.7
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	2011	Drug Inspector Ministry of Health
4.02.04	Comments and References	4.02.01 All Drug that were on sale before the commencement of the Pharmacy act 2004 were were deemed to be registered. Nevertheless there is no manufacturer in the country		

Supplementary questions (click here for help)

		Year	Source

4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%)	0	2011	Pharmacy Council Register
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally	0	2011	Pharmacy Council Register
4.02.07S	Number of manufacturers that are Good Manufacturing Practice (GMP) certified	0	2011	ministry of Health
4.02.08S	Comments and References	No pharmaceutical are manufactured locally. the procurement for public sector is carried out by OECS-PPS.		

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	Tyrone Jack
5.00.02	Phone number	784-4562293 (H) /784-4543217 (M) / 4561111 ext. 892 (W)
5.00.03	Email address	tjreynold@yahoo.com
5.00.04	Other respondents for filling out this section	Joann Ince Jack Chief Pharmacist & Chairperson of Pharmacy Council Email jojo_annei@yahoo.com tel. 784-4856994

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 ☐	2004	Pharmacy Act
5.01.02	There is a Medicines Regulatory Authority	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
5.01.03	If yes, please provide name and address of the Medicines regulatory authority	The regulatory functions are performed by the Pharmacy council and the drug inspector. St. Vincent & the Grenadines Pharmacy Council. Address: Environmental Health Department Complex Ministry of Health and the Environment Kingstown VC0100 St. Vincent & the Grenadines. W. I.		

		Tel: (784) 485-6994 Fax: (784) 456-1483 E-mail: svgpc08@yahoo.com		
5.01.04	The Medicines Regulatory Authority is:		2011	MOH
5.01.04.01	Part of MoH	☒Yes		
5.01.04.02	Semi autonomous agency	☐Yes		
5.01.04.03	Other (please specify)	the Drug inspector is part of Ministry of Health		
5.01.05	What are the functions of the National Medicines Regulatory Authority?		2011	Pharmacy Council
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)	Registration of pharmacists, pharmacies, pharmacy students, pharmacy assistants and pharmacy owners are conducted by Pharmacy Council; the testing is conducted by CRDTL.		
5.01.06	Number of the MRA permanent staff	1	2011	MOH
5.01.06.01	Date of response	23/05/20011		
5.01.07	The MRA has its own website	Yes ☐ No ☒	2011	MOH

5.01.07.01	- If yes, please provide MRA Web site address (URL)			
5.01.08	The MRA receives external technical assistance	Yes ☐ No ☒	2011	MOH
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	With the Caribbean Asssociation of Pharmacists (C.A.P.) and CARICOM toward harmonization of laws and practise under CSME		
5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes ☐ No ☒	2011	Drug Inspector
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the government.	Yes ☐ No ☒	2011	MOH
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☒ No ☐	2011	MOH
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ☐ No ☒	2011	MOH
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 ☒	2011	MOH
5.01.16	Comments and References	The Function of a Drug Regulatory Authority are carried out by a ne work of hubs concerned with regulatory function; namely the		

		Pharmacy Council, and The Drug Inspector. The Pharmacy ACT # 54 0f 2002 Sec:3.(5).(c) gives the Pharmacy Council the mandate to decide on matters relating to the registration of drugs and 28 (1) (b) the council has the authority to publish a list which can only be imported into the Country under a license issued by the Council. The Drug Inspector preceded the council as a semiautonomous member of staff with responsibility to monitor the standard of product and services rendered to the public and to enforce the legislation relating to pharmaceutical used in the state. The drug Inspector is a co-opted member of the Council, howbeit, a non-voting member. The permanent staff is the drug inspector of Ministry of Health.		
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 ☐	2004	SVG Pharmacy act 2004
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes ☐ No ☒	2011	MOH
5.02.03	Are there mechanisms for recognition of registration done by other countries	Yes ☐ No ☒	2011	MOH
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 ☒	2011	MOH
5.02.05	Information from the prequalification programme managed by WHO is used for product registration	Yes ☐ No ☒	2011	MOH

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	Drug Inspector Ministry of Health
5.02.07.01	If yes, how frequently updated	not specified in parent Act.		
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 ☒	2011	MOH
5.02.10	Comments and References	5.02.01 -08 The Pharmacy ACT # 54 0f 2002 Sec:3.(5).(c) gives the Pharmacy Council the mandate to decide on matters relating to the registration of drugs, In Sec 27:6 &7 registration of drug outht to be a requirement for import and 28 (1) (b) the council has the authority to publish a list which can only be imported into the Country under a license issued by the Council although the legal position under the Pharmacy Act requires the registration of all drugs on the market,the Pharmacy Council has so far been unable to fulfill this function mainly due to insufficient competencies resources . it has sought to have a regional approach to drug registration.		

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 ☒	2011	Drug Inspector Ministry of Health
5.02.12S	Legal provisions require publication of a Summary of Product	Yes ☐ No ☒	2011	Drug Inspector

	Characteristics (SPCs) of the medicines registered			Ministry of Health
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health I
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	Drug Inspector Ministry of Health I
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 ☒	2011	Drug Inspector Ministry of Health
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US$)	no	2011	Drug Inspector Ministry of Health
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US$)	no	2011	Drug Inspector Ministry of Health
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)	no	2011	Drug Inspector Ministry of Health
5.02.20S	Comments & References	5.02 - The SVG Pharmacy Council has forwarded to Attorney General's office recommendations for Regulations that will address all these matters of Marketing Authorization. At the moment St. Vincent and the Grenadines does not have the capacity or competencies to establish drug registration. The Council recommends a regional approach to drug registration (See summary of annual report of Council).		

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 ☐	2004	Pharmacy Act Sec:33
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes ☒ No ☐	2004	pharmacy Act Sec:33
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:		2011	Drug Inspector Ministry of Hrealth
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 ☐	2011	pharmacy Council
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
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 health facilities are inspected	Yes ☒ No ☐		

5.03.05.06	Please provide details on frequency of inspections for the different categories of facilities	Retail outlets at least twice a year and wholesale at least once a year		
5.03.06	Comments and References	5.03.05.01- Currently there are no local manufacturers in S.V.G.		
5.04 Import Control **Core Questions (click here for help)**				
			Year	Source
5.04.01	Legal provisions exist requiring authorization to import medicines	Yes ☒ No ☐	2004	SVG Pharmacy Act 2004 SEC:28 :(b)
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes ☒ No ☐	2004	SVG Pharmacy Act 2004 SEC: 33 &34
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes ☒ No ☐	2011	Port authority
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
5.04.05	Comments and References			
5.05 Licensing				
			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes ☒ No ☐	2004	SVG Pharmacy Act 2004 SEC:27(4)

5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes ☐ No ☒	2011	Drug Inspector
5.05.02.01	If no, please explain	There is currently no such provision in the Pharmacy related laws, the council has made recommendation to the legal affairs department for such inclusions.		
5.05.03	GMP requirements are published by the government.	Yes ☐ No ☒	2011	Drug Inspector
5.05.04	Legal provisions exist requiring importers to be licensed	Yes ☒ No ☐	2004	SVG Pharmacy Act 2004 SEC:28(1)(b)
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ☒ No ☐	2004	SVG Pharmacy Act 2004 SEC:10(1) &27(5)
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices **When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)**	Yes ☐ No ☒	2011	Drug inspector
5.05.07	National Good Distribution Practice requirements are published by the government	Yes ☐ No ☒	2011	Drug Inspector
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes ☒ No ☐	2004	SVG Pharmacy Act 2004 SEC:8
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes ☒ No ☐	2004	SVG Pharmacy Act 2004

				SEC:8
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes ☒ No ☐	2004	SVG Pharmacy Act 2004 SEC:8
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes ☐ No ☒	2011	Drug Inspector Mnistry of Health
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes ☐ No ☒	2004	Drug Inspector Mnistry of Health
5.05.13	Comments and References	5.05.12 the law only requires that the registrar keep a register of pharmacies,		

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 ☒	2011	Drug Inspector Ministry of Health
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
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			
5.06.03	Is there any national laboratory accepted for collaboration with WHO prequalification Programme? Please	No		

	describe.			
5.06.04	Medicines are tested:		2011	Drug Inspector Ministry of Health
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	5.06.02 -The existing law does not provide for the establishment of a regulatory quality control laboratory. There is no local testing of pharmaceutical products. Samples collected by government Inspectors and procurement officer for undertaking postmarketing surveillance are sent for Quality Control testing using the		

		Caribbean Regional Drug Testing Laboratory in Jamaica, which has been established under an Agreement signed by 14 countries of CARICOM. 5.06.06, 07 and 08. Information not available. Samples for testing are collected by PPS/OECS and performed at CRDTL.		
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 ☒	2011	MOH
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Bureau of Standard has a regulatory mandate to develop advertising standards.Standards develop by other autonomous regulatory agencies will be incorporated.		
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes ☐ No ☒	2011	MOH
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional materials	Yes ☐ No ☒	2011	SVG Pharmacy Act 2004/Drug Inspector
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
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 ☒	2011	Drug Inspector Ministry of Health
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	5.07s: Recommendation for the control of advertisment and promotion are included in the regulation submitted by the Council to the Ministry of Legal Affairs for passage.

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
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 ☒	2011	Drug Inspector Ministry of Health
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
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	Yes ☐ No ☒	2011	Drug Inspector

	products			Ministry of Health
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
5.08.07S	National GCP regulations are published by the Government.	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☐ No ☒	2011	Drug Inspector Ministry of Health
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 ☐	2001	Annual INCB report2002
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	2002	Annual INCB report2002
5.09.01.03	Convention on Psychotropic Substances 1971	Yes ☒ No ☐	2002	Annual INCB report2002
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes ☒ No ☐	1994	Annual INCB report2002
5.09.02	Laws for the control of narcotic and psychotropic substances, and	Yes ☒ No ☐	2011	Drug(prevention of

	precursors exist			Misuse) Act .
5.09.03	Annual consumption of Morphine (mg/capita)	1.220183	2010	Drug Inspector INCB Form C for the year 2010
5.09.04	Comments and References	The 1961 and 1971convention were signed in december 2001		

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	Drug inspector
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.002	2010	Form C INCB report
5.09.07S	Annual consumption of Pethidine (mg/capita)	7	2010	Annual statistic Form C Internation al Narcotics Control Board, 2010
5.09.08S	Annual consumption of Oxycodone (mg/capita)	0	2010	Annual statistic Form C Internation al Narcotics Control Board,

				2010
5.09.09S	Annual consumption of Hydrocodone (mg/capita)	0	2010	Annual statistic Form C International Narcotics Control Board, 2010
5.09.10S	Annual consumption of Phenobarbital (mg/capita)	3.2	2010	Form P INCB report
5.09.11S	Annual consumption of Methadone (mg/capita)	0	2010	Annual statistic Form C INCB Report
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 ☒	2011	Drug Inspector Officer
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 ☒	2011	Drug Inspector Office
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes ☐ No ☒	2011	Drug Inspector Office
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes ☒ No ☐	2010	UMC

5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time	1		
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 ☐	2010	O.E.C.S.P.P.S.
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes ☒ No ☐	2011	Chief Pharmacist Office
5.10.07	How many ADR reports are in the database?	46	2011	Pharmacovigilance unit & chief Pharmacist advance report
5.10.08	How many reports have been submitted in the last two years?	30 (2009 - 2010)	2011	Pharmacovigilance unit
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes ☒ No ☐	2010	UMC
5.10.09.01	If yes, number of reports sent in the last two years	30	2011	Pharmacovigilance unit
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management,	Yes ☐ No ☒	2011	Pharmacovigilance unit

	case investigation and, where necessary, crisis management including crisis communication?			
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	Increase the options for persons to submit ADR reports e.g. facsimile, establishing a website where reporters can either download the ADR form or complete the form on-line. An option to submit reports via telephone will also be considered		
5.10.14	Comments and References	5.10.01.01 the ADR reports submitted are from 2009 - 2010		
Supplementary questions (click here for help)				
			Year	Source
5.10.15S	Feedback is provided to reporters	Yes ☒ No ☐	2011	Pharmacovigilance unit
5.10.16S	The ADR database is computerized	Yes ☒ No ☐	2011	Pharmacovigilance unit
5.10.17S	Medication errors (MEs) are reported	Yes ☐ No ☒	2011	Pharmacovigilance unit
5.10.18S	How many MEs are there in the ADRs database?	0	2011	Pharmacovigilance unit
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	pharmacovigalance officer
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			
5.10.21S	Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?	Yes ☐ No ☒	2011	pharmacovigalance officer
5.10.22S	Are there training courses in pharmacovigilance?	Yes ☒ No ☐	2011	pharmacovigalance officer's report
5.10.22.01S	If yes, how many people have been trained in the last two years?	154	2010	SVG Pharmaceutical Service Corporate plan 2011
5.10.23S	Comments and References	5.10.05 - The O.E.C.S Pharmaceutical Procurement Service (O.E.C.S.P.P.S.) is the regional pharmacovigilance centre for all O.E.C.S. territories. An ADR report form was designed by the O.E.C.S.P.P.S. for use in all O.E.C.S. territories. 5.10.06 - A simple database has been developed (using MS Access) which captures most of the information submitted in ADR report forms. 5.10.08 - Collection of ADR reports only began in earnest in 2010. 5.10.11 - A mailing list of physicians, nurses and pharmacists has been established which to date contains over 200 addresses. F.D.A. Alerts and W.H.O. Pharmaceutical Newsletters are sent via e-mail to persons on the list on a regular basis.		

		5 10.19 No dossiers are received locally. 5.10.22S - There are no on-going pharmacovigilance training courses however in 2010 presentations were held to sensitize physicians, pharmacists and nurses about pharmacovigilance.

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	Tyrone Jack
6.00.02	Phone number	784-4543217
6.00.03	Email address	tjreynold@yahoo.com
6.00.04	Other respondents for this sections	government Pharmaceutical Services

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:		1994	S R &O # 23 of 1994
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	Children under 17 and persons over sixty are exempted from paying the $5.00 user fee normally required before the public receive medication, the general public who are registered on public assistance (poor relief) are automatically exempted, also there are provisions for the patients who claim they cannot afford to pay to carry their cases to the Social Welfare Officer and if approved they will receive an exemption stamp. Source: SRO = Statutary Rules and Orders, # 23 of 1994; # 3 of 1995		
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 medicines	Yes ☒ No ☐		
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	Contraceptives are provided free of cost in government health centres		
6.01.02.09	Please describe/explain your yes answers for questions above	the medicines are provided free of charge or with a fee according to the categories included in 6.01.01. in the public facilities. ARVs are supplied free of cost through international donor agencies e.g. Clinton Foundation, Global Fund and the Brazilian Government. Under the laws of St. Vincent & the Grenadines all children must be vaccinated under the EPI.		
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?	Yes ☐ No ☒	2011	National Insurance Services
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	Sagicor Life Inc.

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	6.01.03 the National inservices would provide up to 80 % coverage but only if you are injured on the Job. 6.01.03s :the laws provide for exemption in the public service for indegent , unimployed pentioners, handicap, children under 17, doctors and nurses, antenatals and post natal care, family planning services and psychetriatic treatment. 6.01.04.01: eighty percent coverage is provided for behind the counter prescription medicine only.

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 consultations	Yes ☐ No ☒	2011	rug Inspector
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes ☒ No ☐	1995	SR&O # of 1995
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	Hospital fees These are collect post consultation (1) maintaince and nursing per day $25 private $10.00 public (2)for sergical operations ,anaesthetic and gases major = $50.00 intermediate $35.00 and minor $ 20.00 out patient prescription $5.00		

		the laws provide for exemption for indegent , unimployed pentioners, handicap, children under 17, doctors and nurses, antenatals and post natal care, family planning services and psychetriatic treatment.		
6.02.04	Comments and References			

6.03 Pricing Regulation for the Private Sector

Core Questions (click here for help)

			Year	Source
6.03.01	Are there legal or regulatory provisions affecting pricing of medicines	Yes ☒ No ☐	1996	Value Added Tax Act The Price and distribution of Good Act Cap 117
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.)	Medicine are price control in the Private sector the rate is 12% at the wholesale level and 13 percent at the retail level		
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes ☒ No ☐	2011	Consumer Affairs Department in the Ministry of Foreign Affairs and Trade

6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes ☒ No ☐	2011	price and distribution of Good Act Cap 117
6.03.03.01	-if yes, please explain how the information is made publically available	The department of Consumer Affairs put out the information on public radio periodically		
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. **If yes**, please indicate the year of the survey and use the results to fill in this table ***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 93	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		6.04.01.01. OECS/PPS conduct an annual survey across all OECs Countries to measure Inventory variation, service levels of prescribe drugs, average available drugs from a basket of essentialdrugs , stock out of key basket of drugs, Annual Drug Indicator Report				

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)	0		

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)	12.5
6.05.04	Comment and References	Cap 117 of the revised Laws of SVG 1988 stipulate the Markups on retail and Wholesale of Pharmaceutical Products
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 ☒		CARICUOM common external Terrif
6.06.02	There are duties on imported finished products	Yes ☒ No ☐	2006	value added tax Act 2006 Schedule # 4 :14
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes ☒ No ☐	2006	VAT unit in the Valuation department
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes ☒ No ☐	2006	VAT unit in the Valuation department
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist	Tax is applied on non prescription drug Items ond other health products. There is a waver on prescription drug items..		
6.06.06	Comments and References	6.06.03 the VAT are applicable for private sector not for medicines purchased to be used in the public sector. 6.06.04- "The Value Added Tax Act " # 25 0f 2006 make provision for the exepmtion of the supply of prescription medicines in Schedule 4 :14 of the Act Cap 117 of the revised Laws of SVG 1988 stipulate the Markups on retail and Wholesale of Pharmaceutical Products		

Supplementary questions (click here for help)

	Year	Source

6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)	0-10	2006	value added tax Act 2006 Schedule # 4 :14
6.06.08S	Duty on imported finished products (%)	0-10	2006	value added tax Act 2006 Schedule # 4 :14
6.06.09S	VAT on pharmaceutical products (%)	14	2006	.value added tax Act 2006 Schedule # 4 :14;
6.06.10S	Comments and References	6.06.07.08 duties on active and finish Pharmaceutical are charged in accordance with the CARICOM common external tariff i.e. zero (0) % on some items 5 or 10 % on others; 6.06.09S it is applicable for OTC as prescription medicines are excempt of VAT.		

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	Tyrone Jack
7.00.02	Phone number	784-4500892 (Office) 784- 4543217(mobile)
7.00.03	Email address	tjreynold@yahoo.com
7.00.04	Other respondents for filling out this section	Mr. Levi Walker, Central Medical Stors Manager(784-4561483 or 4500520)

7.01 Public Sector Procurement

Core Questions (click here for help)

			Date	Source
7.01.01	Public sector procurement is:		2009	HERA
7.01.01.01	Decentralized	☐Yes		
7.01.01.02	Centralized and decentralized	☐Yes		
7.01.01.03	Please describe	Within the public sector, the only measure taken is centralized procurement by the Central Medical Stores mainly using the OECS/PPS pooled procurement services.		
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:		2011	Central Medical Stores Manager
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	OECS-PPS
7.01.04	Public sector tender awards are publicly available	Yes ☒ No ☐	2011	Oecs PPS
7.01.05	Procurement is based on prequalification of suppliers	Yes ☒ No ☐	2011	OECE-PPS Central Medical Stores Manager
7.01.05.01	If yes, please describe how it works	Prequalification of suppliers is done by OECS/PPS on behalf of member OECS countries. Contracts are then awarded to approved suppliers.		
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 ☒	2011	Central Medical Stores Manager
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes ☐ No ☒	2011	Central Medical Stores Manager
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 ☐	2010	OECSPPS
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	Central Medical Stores Manager
7.01.12S	Which of the following tender methods are used in public sector procurement:		2011	Central Medical Stores Manager
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			

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	Yes ☐ No ☒	2011	MOH

	Good Distribution Practices (GDP)			
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	7.0205-06- There is only one public warehouse (i.e. Central Medical Stores (CMS)) which procure and distribute pharmaceutical supplies to the forthy clinic pharmacies in the peripherial districts including the Pharmacies in the rural hospitals and health centers.This is done on a monthly rotation. The Drug Inspector inspects the CMS and the public District pharmacies periodically.		

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	Central Medical Stores Manager
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	93%	2009	OECS-PPS annual report
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days	4%		
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes ☒ No ☐	2011	Central Medical Stores Manager
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ☐ No ☒	2011	Central Medical Stores Manager
7.02.13S	The Public Central Medical Store is ISO certified	Yes ☐ No ☒	2011	Central Medical Stores Manager
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes ☐ No ☒	2011	Central Medical Stores Manager
7.02.15S	The second tier public warehouses are ISO certified	Yes ☐ No ☒	2011	CMS
7.02.16S	Comments and References	7.02.15-16There is only one public warehouse		
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 ☐	2002	Pharmacy Act
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes ☒ No ☐	2002	Pharmacy Act
7.03.03	List of GDP certified wholesalers in	Yes ☐ No ☒	2011	MOH

	the private sector exists			
7.03.04	List of GDP certified distributors in the private sector exists	Yes ☐ No ☒	2011	MOH
7.03.05	Comments and References	There is no legal requirement to issue good distribution practice certificate. Inspections are roteinly carried out by the Government Drug Inspector. Each wholesale or distribution outlet are registered as a wholesale Pharmacy and is required to have a managing Pharmacist in direct supervision od Pharmaceutical sale.The Pharmacy Council has the mandate to maintain a high standard of Practise and conduct of Pharmacist.		

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	Mr. Tyrone Jack
8.00.02	Phone number	(H)784-4562293/ (m) 784-4543217 Office 784 4561111 Ext. 892
8.00.03	Email address	tjreynold@ yahoo.com
8.00.04	Other respondents for filling out this section	Mrs. Joann Ince Jack (Chief Pharmacist)

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 ☐	2010	SVG Pharmacy and Therapeutic Committee/ MOH
8.01.01.01	If yes, number of medicines on the EML (no. of INN)	291		
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	Yes ☐ No ☒	2011	Drug Inspector

	update of STGs in the "year" field			
8.01.03	STGs specific to Primary care exist. Please use the "year" field to write the year of last update of primary care guidelines	Yes ☐ No ☒	2011	Drug Inspector
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	Drug Inspector
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 ☒	2011	Drug Inspector
8.01.06	% of public health facilities with copy of EML (mean)- Survey data	100	2010	Government Pharmaceutical Service
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data	0	2010	Joann Jack Chief Pharmacist
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes ☒ No ☐	2011	Chief Pharmacist Office
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes ☒ No ☐	2010	Joann Jack Chief Pharmacist
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes ☒ No ☐	2010	Joann Jack Chief Pharmacist
8.01.11	A national programme or committee (involving government, civil society, and professional	Yes ☐ No ☒	2011	Drug Inspector

	bodies) exists to monitor and promote rational use of medicines			
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	Drug Inspector
8.01.13	Comments and References	8.01.01- The St. Vincent and the Grenadines Essential Medicine list was Launch on September 18, 2010 8.01.02 -There treatment guidelines for HIV/AIDS and H. Pylori. 8.01.08-.This unit is combined with Pharmacovigilence and is in its embryotic stage 8.01.12 Stratergy is being developed it was initiated by a study from the Pharmacy and Therapeutic Committee . The Study looked at Antimicrobial Sensitivity and Prescribing Pattern in SVG. { Joann Jack, Dr Diane Hindman, Illonka O'Garro et.al. One of the out come of the study is the development of an Antibiogram.		
Supplementary questions (click here for help)				
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes ☐ No ☒	2010	Joann Jack Chief Pharmacist
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes ☐ No ☒	2010	Joann Jack Chief Pharmacist
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes ☒ No ☐	2010	Joann Ince Jack Chief Pharmacist and Cordinator of the Pharmacy and Therapeutic Committee

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	Drug Inspector
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 ☐	2010	MoH I
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☐ No ☒	2011	MOH
8.01.20S	Comments and References	8.01.16S- A Pharmacy and therapeutic committee was establish in 2007 and the promotion of ration drug use is one of its mandate. 8.0117- There is an OECS medicine formulary but this applies only to the public sector in The St. Vincent and the Grenadines. The National Essential Medicine list was Launch on September 18, 2010		

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	Drug Inspector
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes ☒ No ☐	2002	Pharmacy Act (see Sec 27:8)
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	Yes ☐ No ☒	2011	Drug Inspector

	Therapeutics Committees (DTCs)			
8.02.05	Do more than half of referral hospitals have a DTC?	Yes ☒ No ☐ Unknown ☐	2011	Drug Inspector
8.02.06	Do more than half of general hospitals have a DTC?	Yes ☒ No ☐ Unknown ☐	2011	Drug Inspector
8.02.07	Do more than half of regions/provinces have a DTC?	Yes ☒ No ☐ Unknown ☐	2011	Drug Inspector
8.02.08	The core medical training curriculum includes components on:			
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	Drug Inspector
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes ☐ No ☒	2011	Drug Inspector
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes ☐ No ☒	2011	Drug Inspector
8.02.12	Prescribing by INN name is obligatory in:		2011	Drug Inspector
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	2010	Chief Pharmacist Data

8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)			
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)			
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)			
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)			
8.02.18	% of prescribed drugs dispensed to patients (mean)	92	2009	Oecs -PPS annual reports MoH pharmaceutical records
8.02.19	% of medicines adequately labelled in public health facilities (mean)			
8.02.20	Comments and References	8.02.06 an 07 there is one DTC for the whole country.		
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	Drug Inspector
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes ☒ No ☐		
8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)			

8.02.24S	Comments and References	8.02.05-8.02.08 .04 there is olly one general hospital which is the same as the referal hospital. there are no locally bases medical School 8.02.14-18; 8.02.23S data not available. 8.02.02 &8.02.03 In accordance with the Pharmacy Act Sec:27:8 only Pharmacist can sell prescription drugs . other health car professsionals can administer; however the List of Prescription items has not been publish, and the term "administer or supplied to a patient by a medical practioner' as it appears in as it appears in section 29:2 has not been defined and is some what ambiguous in terms of the duration. (I presumed the word dispense here is used synonymous with sale)		
8.03 Dispensing **Core Questions (click here for help)**				
			Year	Source
8.03.01	Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes ☐ No ☒	2011	MOH
8.03.02	The basic pharmacist training curriculum includes components on:			
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	Drug Inspector
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes ☒ No ☐	2011	Drug Inspectorl

8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes ☒ No ☐	2011	Drug Inspector
8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-the-counter without any prescription?	Yes ☒ No ☐ Unknown ☐	2011	Drug Inspector
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 ☒	2011	Drug Inspector
8.03.08	Comments and References	8.03.02. There are no local Pharmacy Schools 8.03.04 There are no legislative provisions promoting the use of generic medicines.		
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 ☒	2011	MOH
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	Pharmacy Association is currently developing a code of conduct.		

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	Tyrone Jack
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?	nil		
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	There has been no household survey in the last five years		