

GRENADA



PHARMACEUTICAL COUNTRY PROFILE





GRENADA Pharmaceutical Country Profile

Published by the Ministry of Health in collaboration with the Pan American Health Organization / World Health Organization (PAHO/WHO)

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Foreword



The 2012 Pharmaceutical Country Profile for Grenada has been produced by the Ministry of Health, in collaboration with the Pan American Health Organization / World Health Organization (PAHO/WHO). This document contains information on existing socio-economic and health-related conditions, resources; as well as on regulatory structures, processes and outcomes relating to the pharmaceutical sector in Grenada. The compiled data comes from international sources, surveys conducted in the previous years and country level information collected in 2011. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

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

Pan American Health Organization / World Health Organization

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Ministry of Health

Ellen Gabriel (*Chief Pharmacist*)

Marcelle Belmar (*Pharmacy Inspector*)

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

A handwritten signature in black ink, reading 'Isaac Bhagwan'.

ISAAC BHAGWAN
Permanent Secretary
Ministry of Health

(Photo of Dr. Bhagwan by Mr. Keville Frederich)



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Acronyms and abbreviations

ADR	Adverse Drug Reaction
API	Active Pharmaceutical Ingredient
CARICOM	Caribbean Community
CIA	Central Intelligence Agency
CMS	Central Medical Store
CPC	Caribbean Program Coordination
CRDTL	Caribbean Regional Drug Testing Laboratory
DTC	Drug and Therapeutics Committee
EC\$	East Caribbean dollar
ECC	Eastern Caribbean Countries
EML	Essential Medicines List
FIOCRUZ	Oswaldo Cruz Foundation
GCP	Good Clinical Practice
GDP	Good Distribution Practices
GDP	Gross Domestic Product
GGHE	General Government Health Expenditure
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Points
HAI	Health Action International
HERA	Health Research for Action
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
HQ	Headquarters
INCB	International Narcotics Control Board
INN	International Nonproprietary Name
ISO	International Organization for Standardization
MoH	Ministry of Health
MRA	Medicines Regulatory Authority
NHA	National Health Account
NHP	National Health Policy
NIDCU	National Infectious Disease Control Unit
NMP	National Medicines Policy
NSHP	National Strategic Health Plan
OECS/PPS	Organization of Eastern Caribbean States / Pharmaceutical Procurement Service
PAHO	Pan American Health Organization
PHC	Primary Health Care
RUM	Rational Use of Medicines
STG	Standard Treatment Guidelines



TAMCC
TRIPS
UK
US\$
VAT
WHO
WIPO
WTO

TA Marrayshow Community College
Trade Related Aspects of Intellectual Property Rights
United Kingdom
United States dollar
Value-added Tax
World Health Organization
World Intellectual Property Organization
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 Grenada. 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 online, 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 Headquarters (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 Grenada was Ellen Gabriel (Chief Pharmacist), with support of Adriana Mitsue Ivama and the PAHO/WHO team.

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



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

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Section 1 - Health and Demographic Data

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

1.1 Demographics and Socioeconomic Indicators

The total population of Grenada in 2011 was 111,764 with an annual population growth rate of 0.6%¹. The annual Gross Domestic Product (GDP) growth rate was 1%². The GDP per capita was US\$ 6,214 in the same year.

24.8% of the population was under 15 years of age in 2010, and 11.3% was over 60 years of age in the same year¹. The urban population stood at 41% of the total population¹. The fertility rate in Grenada was 2.2 births per woman in 2010.

32% of the population was living below the nationally defined poverty line in 2010². The adult literacy rate for the population over 15 years was 96% in the same year.

1.2 Mortality and Causes of Death

The life expectancy at birth was 70.51 and 75.82 years for men and women respectively in 2010³. The infant mortality rate (i.e. children under 1 year) was 12.1/1,000 live births in the same year. For children under the age of 5, the mortality rate was 14.6/1,000 live births. The maternal mortality rate was 0/100,000 live births.

The top 10 diseases causing mortality in Grenada⁴ are listed in Table 1.



Table 1. Top 10 diseases causing mortality in Grenada (2010)

	Disease
1	<u>Malignant neoplasms</u>
2	<u>Endocrine and metabolic diseases</u>
3	<u>Ischemic heart disease</u>
4	<u>Cerebrovascular disease</u>
5	<u>Disease of the pulmonary circulation and other forms of heart disease</u>
6	<u>Disease of the respiratory system</u>
7	<u>Hypertension diseases</u>
8	<u>External causes of morbidity and mortality</u>
9	<u>Disease of the digestive system</u>
10	<u>Disease of the genitourinary system</u>

The top 10 diseases causing morbidity in Grenada⁴ are listed in Table 2.

Table 2. Top 10 diseases causing morbidity in Grenada (2010)

	Disease
1	<u>Complications of pregnancy, childbirth and puerperium</u>
2	<u>Hypertensive disease</u>
3	<u>Diabetes mellitus</u>
4	<u>Maternal conditions affecting fetus or newborn</u>
5	<u>Disease of the urinary system</u>
6	<u>Nutritional deficiencies and anemias</u>
7	<u>Disease of other parts of the digestive system</u>
8	<u>Intestinal infectious diseases</u>
9	<u>Disease of the pulmonary circulation and other forms of heart disease</u>
10	<u>Acute respiratory infection</u>



The adult mortality rate for both sexes between 15 and 60 years was 228/1,000 population in 2008⁵, while the neonatal mortality rate was 10.5/1,000 live births in 2010. The age-standardized mortality rate by non-communicable diseases in 2002 was 870/100,000, 448/100,000 by cardiovascular diseases and 199/100,000 by cancer.

The mortality rate for HIV/AIDSⁱ was 12.5/100,000⁶ and 0.9/100,000 for tuberculosis in 2010. The mortality rate for malaria was 0/100,000 in the same year.

ⁱ Due to the fact that doctors do not always report HIV/AIDS as cause of death, the figures may be underestimated. The NIDCU reported 14 deaths in 2010.



Section 2 - Health Services

This section provides information regarding public health expenditures and human resources for health in Grenada. Information on pharmaceutical expenditure is also presented.

2.1 Health Expenditures

The General Governmentⁱⁱ Health Expenditure (GGHE) in 2010 was 55.9 million East Caribbean dollars (20.57 million US dollars)⁷. That is, 9.73% of the total government budget⁷, with a total annual per capita GGHE of EC\$ 500.16 (US\$ 184.05).

Public expenditure on pharmaceuticals in 2010 was 6.126 million East Caribbean dollars (2.27 million US dollars)⁷. This converts into a per capita public expenditure on pharmaceuticals of EC\$ 54.81 (US\$ 20.13).

100% of the population is covered by a public health service.

Data on private health expenditure is unknown.

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



2.2 Health Personnel and Infrastructure

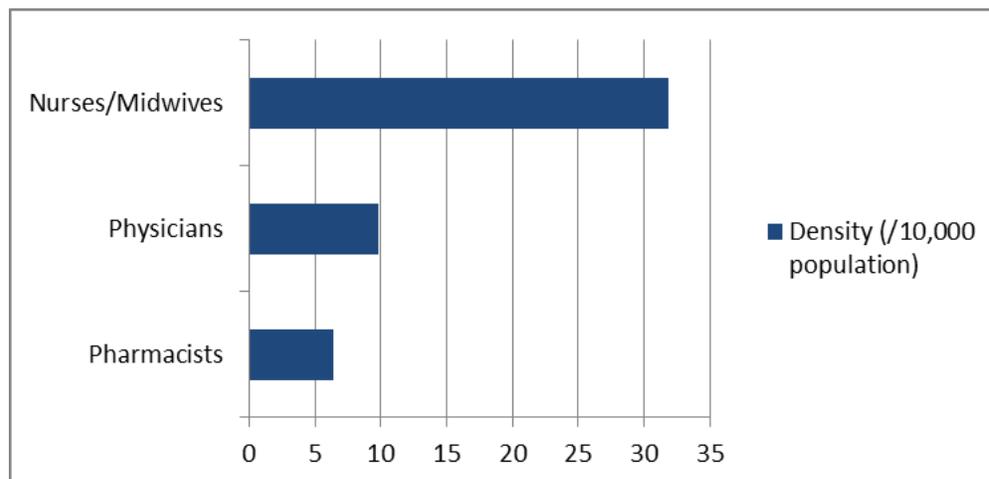
The health workforce is described in Table 3 and in Figure 1. There are 72 licensed pharmacists (2010) (115 registered although)⁸, of which 26 work in the public sector (2011). There are no pharmaceutical technicians or assistantsⁱⁱⁱ.

There are 110 physicians (2010) and 356 nursing and midwifery personnel⁹ in Grenada (2011). The ratio of doctors to pharmacies is 3.5:1 and the ratio of doctors to nurses and midwifery personnel is 1:3.2.

Table 3. Human resources for health

Human Resource	
Licensed pharmacists (all sectors)	<u>72 (6.44/10,000)</u>
Pharmacists in the public sector	<u>26 (2.32/10,000)</u>
Pharmaceutical technicians and assistants	<u>N/A</u>
Physicians (all sectors)	<u>110 (9.84/10,000)</u>
Nursing and midwifery personnel (all sectors)	<u>356 (31.85/10,000)</u>

Figure 1. Density of the health workforce (all sectors)



ⁱⁱⁱ The Pharmacy Act does not make provisions for pharmaceutical assistants / technicians.



In Grenada, there is no strategic plan for pharmaceutical human resource development in place.

The health infrastructure is described in Table 4. There are five hospitals^{iv} in total and 36.9 hospital beds per 10,000 population¹⁰ in the country. There are 36 primary health care units and centers and 31 licensed pharmacies⁸.

Table 4. Health infrastructure

Infrastructure	
Hospitals	<u>5</u>
Hospital beds	<u>36.9/10,000</u>
Primary health care units and centers	<u>36</u>
Licensed pharmacies	<u>31</u>

The annual starting salary for a newly registered pharmacist in the public sector is EC\$ 26,280. Only one pharmacist graduated (as a first degree) in the past two years¹¹. Currently, there are no accreditation requirements for the Pharmacy school¹¹, however, the TA Marryshow Community College (TAMCC) and the Pharmacy school are working on this matter. The Pharmacy curriculum is regularly reviewed¹¹.

^{iv} There are four public hospitals and one private.



Section 3 - Policy Issues

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

3.1 Policy Framework

In Grenada, a National Health Policy (NHP) does not exist. However, Grenada’s National Strategic Health Plan (NSHP) for 2007-2011 was adopted by the MoH, and was updated in 2008 to reflect the period 2008-2012¹². There are implementation schedules within the document and some aspects of the NSHP are already implemented.

The Strategic goals of the NSHP are listed below:

- I. To develop a Health System that focuses on Primary Health Care (PHC).
- II. To provide professional quality health care services.
- III. To expand the health care network through collaboration between the public and private sectors and other stakeholders in the formulation of health care policy and the delivery of health services.
- IV. To enable access to affordable health care to the population.
- V. To induce and facilitate the health setting concepts.



An official National Medicines Policy (NMP) document does not exist in Grenada. Policies addressing pharmaceuticals do not either exist; however, the components of regulation and pharmacovigilance are covered.

Table 5. Components of a National Medicines Policy covered

Aspect of policy	Covered
Selection of essential medicines	<u>No</u>
Medicines financing	<u>No</u>
Medicines pricing	<u>No</u>
Medicines Procurement	<u>No</u>
Medicines Distribution	<u>No</u>
Medicines Regulation	<u>Yes</u>
Pharmacovigilance	<u>Yes</u>
Rational use of medicines	<u>No</u>
Human Resource Development	<u>No</u>
Research	<u>No</u>
Monitoring and evaluation	<u>No</u>
Traditional Medicine	<u>No</u>

A policy relating to clinical laboratories does not exist.

Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in the national legislation. There are official written guidelines on medicines donations¹³.

There is no national good governance policy in Grenada.



A policy is not in place to manage and sanction conflict of interest issues in pharmaceutical affairs. There is no formal code of conduct for public officials (it is in draft stage). However, a whistle-blowing mechanism that allows individuals to raise concerns about wrongdoing occurring in the pharmaceutical sector of Grenada exists^v.

^v The Pharmacy Council is responsible for the Pharmacy practice in Grenada. Any wrongdoing occurring in the pharmaceutical sector must be reported to the Council, which will address the matter.



Section 4 – Medicines Trade and Production

Information about the capacity for manufacturing medicines and the legal provisions governing patents is provided in this section.

4.1 Intellectual Property Laws and Medicines

Grenada is a member of the World Trade Organization¹⁴. Legal provisions granting patents pharmaceuticals, laboratory supplies, medical supplies or medical equipment do not exist^{vi,15}.

National Legislation has not been modified to implement the Trade-Related aspects of Intellectual Property Rights (TRIPS) Agreement and does not contain TRIPS-specific flexibilities or safeguards¹⁵. Grenada is eligible for the transitional period to 2016¹⁵.

Grenada is not engaged in capacity-strengthening initiatives to manage and apply Intellectual Property Rights.

^{vi} The Patent Law is substantially outdated and not TRIPS-compliant. The current legislation in force is Patents Act Ch.227 of 1898, and Registration of United Kingdom (UK) Patents Act Cap. 283, 1924. Currently, a new Patents Act is being drafted by a consultant with support from the World Intellectual Property Organization (WIPO). Grenada has expressed a desire for a new Patents Act containing all the TRIPS flexibilities and safeguards.



4.2 Manufacturing

There are no licensed pharmaceutical manufacturers in Grenada. The country has no manufacturing capacity to research/discover new active substances (API), to produce APIs, to produce formulations from pharmaceutical starting material or to repackage finished dosage forms.



Section 5 – Medicines Regulation

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

5.1 Regulatory Framework

In Grenada, there are legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA)^{vii}, which corresponds to the Pharmacy Council / Chief Pharmacist. The MRA is a part of the Ministry of Health with a number of functions outlined in Table 6. The MRA does not have a website.

Table 6. Functions of the national MRA

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

^{vii} The Pharmacy Council and the Chief Pharmacist are vested with regulatory powers and responsibilities. Nevertheless, not all the regulatory functions stated in the legal framework are in place.



In 2011, there were nine permanent staff^{viii} working for the MRA. The MRA does not receive external technical assistance to support its activities; however, it is involved in harmonization/collaboration initiatives.

An assessment of the medicines regulatory system has not been conducted in the last five years. Funding for the MRA is provided through the regular government budget^{ix}. The Regulatory Authority does not retain revenues derived from regulatory activities^x. This body utilizes a computerized information management system to store and retrieve information on processes.

5.2 Marketing Authorization (Registration)

In Grenada, legal provisions require a marketing authorization (registration) for all pharmaceutical products on the market¹⁶. The Medical Products Act of 1995¹⁶ makes provisions for the licensing of all medicinal products, whether locally manufactured or imported. However, this function is not carried out in the country.

5.3 Regulatory Inspection

In Grenada, legal provisions exist allowing for appointment of government pharmaceutical inspectors⁸. Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed¹⁷, such

^{viii} Members of the Council shall hold office for a term of two years, however, they are eligible for re-appointment. The Chief Pharmacist is the only permanent staff.

^{ix} The members of the Council receive honorarium of \$100 per meeting attended. Meetings are held quarterly.

^x Revenues derived from regulatory activities are deposited in the consolidated funds of Grenada.



inspections are required by law and are a pre-requisite for the licensing of private facilities^{xi}. Inspection requirements are the same for public and private facilities. Inspections are carried out on a number of entities¹⁷, outlined in Table 7.

Table 7. Local entities inspected

Entity	Inspection
Local manufacturers	<u>N/A</u>
Private wholesalers	<u>Yes</u>
Retail distributors	<u>Yes</u>
Public pharmacies and stores	<u>Yes</u>
Pharmacies and dispensing points if health facilities	<u>Yes</u>

The periodicity of inspection is not addressed in the Pharmacy Act. The Pharmacy department and the Inspector design a regular schedule for inspection. Private pharmacies, wholesalers and distributors are inspected twice annually. Public pharmacies are inspected quarterly. However, inspections can be carried out whenever it is deemed necessary by the inspector. All premises intended to conduct pharmaceutical business must be inspected before registration.

^{xi} The Pharmacy Act of 1987, Cap 241 makes reference to the registration of premises as a pharmacy, but did not specify private or public sector. However, in actual practice, only private pharmacies, premises of wholesalers and distributors are registered to conduct pharmaceutical activities. Public sector pharmacies are not registered but are inspected to meet established requirements.



5.4 Import Control

Legal provisions exist requiring all importers of pharmaceuticals to be registered¹⁶. Laws do not exist that allow the sampling of imported products for testing. Legal provisions do not exist requiring importation of medicines through authorized ports of entry.

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

5.5 Licensing

Grenada has no manufacturers of pharmaceuticals. However, the Food and Drug Act of 1986¹⁸ makes provision for compliance with Good Manufacturing Practices (GMP) as it relates to food^{xii,19}.

Legal provisions exist requiring importers, wholesalers and distributors to be licensed¹⁷. Legal provisions do not exist requiring wholesalers or distributors to comply with Good Distribution Practices (GDP).

Legal provisions exist requiring pharmacists to be registered¹⁷. Legal provisions also exist requiring private pharmacies^{xiii} to be licensed¹⁷. National Good Pharmacy Practice (GPP) are not published by the government. By law, a list of all licensed pharmaceutical facilities is not required to be published.

^{xii} Grenada has adopted the Hazard Analysis and Critical Control Points (HACCP) guidelines, and these contain GMP for food.

^{xiii} Public pharmacies do not pay license fees.



5.6 Market Control and Quality Control

In Grenada, legal provisions exist for controlling the pharmaceutical market¹⁶. A laboratory does not exist in the country for Quality Control testing. The regulatory authority contracts services in the Caribbean Regional Drug Testing Laboratory (CRDTL) in Jamaica (see description in Table 8).

Table 8. Reasons for medicines testing

Medicines tested:	
For quality monitoring in the public sector ^{xiv}	<u>No</u>
For quality monitoring in the private sector ^{xv}	<u>No</u>
When there are complaints or problem reports	<u>Yes</u>
For product registration	<u>No</u>
For public procurement prequalification	<u>No</u>
For public program products prior to acceptance and/or distribution	<u>No</u>

Samples are not collected by government inspectors for undertaking post-marketing surveillance testing.

The results of quality testing are not publicly available.

^{xiv} Routine sampling in pharmacy stores and health facilities.

^{xv} Routine sampling in retail outlets.



5.7 Medicines Advertising and Promotion

In Grenada, legal provisions do not exist to control the promotion/advertising of prescription and non-prescription medicines. There is no national code of conduct on this matter.

5.8 Clinical Trials

In Grenada, legal provisions do not exist requiring authorization for conducting Clinical Trials by the MRA. 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 a registry, by law.

The government does not publish Good Clinical Practice (GCP) guidelines.

5.9 Controlled Medicines

Grenada is a signatory to a number of international conventions, detailed in Table 9.

Table 9. International conventions to which Grenada is a signatory

Convention	Signatory
Single Convention on Narcotic Drugs, 1961	<u>No</u>
1972 Protocol amending the Single Convention on Narcotic Drugs 1961	<u>Yes</u> ²⁰
Convention on Psychotropic Substances, 1971	<u>Yes</u> ²⁰
United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	<u>Yes</u> ²⁰



Laws exist for the control of narcotic and psychotropic substances, and precursors.

Figures regarding the annual consumption of certain controlled substances in country are outlined in Table 10.

Table 10. Annual consumption of certain controlled substances

Controlled substance	Annual consumption (mg/capita)
Morphine	<u>0.442308</u> ²⁰
Fentanyl	<u>0.000000</u>
Pethidine	<u>5.028846</u> ²⁰
Oxycodone	<u>0.000000</u>
Hydrocodone	<u>0.000000</u>
Methadone	<u>0.000000</u>

5.10 Pharmacovigilance

In Grenada, there are legal provisions in the Medical Products Act¹⁶ that provide for pharmacovigilance activities as part of the MRA mandate. Legal provisions also exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA¹⁶. Laws regarding the monitoring of Adverse Drug Reactions (ADR) do not exist in the country.

An official standardized form for reporting ADRs is used in Grenada. However, feedback is not provided to reporters. Information pertaining to ADRs is not stored in a national database. These reports are not either sent to the WHO



Collaborating Centre in Uppsala. Medication errors (MEs) are not reported. In the past two years, only Pharmacists and consumers have reported ADRs.

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^{xvi}. A clear communication strategy for routine communication and crises communication does not exist. No regulatory decision has been taken based on local pharmacovigilance data in the last two years.

ADRs are, however, monitored in public health programs (tuberculosis, HIV/AIDS).

Approximately 35 pharmacists attended a workshop on Pharmacovigilance conducted by the Organization of Eastern Caribbean States Pharmaceutical Procurement Service (OECS/PPS) in May 2010.

Two main steps are being considered in order to enhance the pharmacovigilance system:

- I. Conduct educational sessions on pharmacovigilance with Pharmacists and other stakeholders.
- II. Increase the number of pharmaceutical inspectors.

^{xvi} ADRs are reported from the public pharmacies to the Organization of Eastern Caribbean States Pharmaceutical Procurement Service (OECS/PPS)



Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in Grenada, including the medicines coverage through public and private health insurance, use of copayments for medicines and the existence of public programs 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 Grenada, concessions are made for certain groups to receive medicines free of charge (see Table 11). Furthermore, the public health system provides medicines free of charge for particular conditions (see Table 12).

Table 11. Population groups provided with medicines free of charge²¹

Patient group	Covered
Patients who cannot afford them	<u>Yes</u>
Children under 5	<u>Yes</u>
Pregnant women	<u>No</u>
Elderly persons	<u>Yes</u>

Patients between 16 and 60 years of age accessing public pharmacies pay the cost of medication (value) if the prescription was issued by a District Medical Officer. Prescriptions from private practitioners are charged at the cost of medication plus 50% (irrespective of age).



Table 12. Medications provided publicly, at no cost

Conditions	Covered
All diseases in the EML	<u>Yes</u>
Any non-communicable diseases	<u>Yes</u>
Malaria	<u>No</u>
Tuberculosis	<u>Yes</u>
Sexually transmitted diseases	<u>Yes</u>
HIV/AIDS	<u>Yes</u>
Expanded Program on Immunization (EPI) vaccines	<u>Yes</u>
Others	<u>No</u>

Grenada has a Medication Assistance Programme managed by the Pharmacy Department and the Social Worker (MoH). There are specific criteria to enter the programme, one of which is that the patient must have no source of income. All persons interested in entering the program must first be evaluated by the Social Worker for socioeconomic status. Persons eligible are allowed EC\$ 150/month for medications if not available in the public sector. If the medication is available in public pharmacies, it is dispensed at no cost. The Medication Assistance Programme is not a health insurance scheme but a programme designed by the MoH to assist outpatients who cannot afford to purchase medications. Inpatients receive medications free of charge, except for those in private wards.

Private health insurance schemes provide medicines coverage, and they are required to provide coverage for medicines on the Essential Medicines List (EML).



6.2 Patients Fees and Copayments

Co-payments for consultations not levied at the point of delivery; however, there are fee requirements imposed for medicines²¹. In the public sector, patients accessing services from District Medical Officer (between 16 and 60 years of age) pay the cost of the medication. There is a mark-up of 50% for private prescriptions. Revenue from fees or from the sale of medicines is not used to pay the salaries or supplement the income of public health personnel in the same facility.

6.3 Pricing Regulation for the Private Sector^{xvii}

In Grenada, there are legal or regulatory provisions affecting pricing of medicines. These provisions are aimed at the level of wholesalers and retailers. Medicines prices are regulated by the Ministry of Finance. There is a 40% mark-up on pharmaceuticals in the private sector.

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

^{xvii} This section does not include information pertaining to the non-profit voluntary sector



6.4 Prices, Availability and Affordability of Key Medicines

No studies on medicine prices, availability or affordability have been conducted in Grenada in the past 5 years according to the WHO/Health Action International (HAI) methodology²².

6.5 Price Components

No surveys on medicine price components have been conducted in Grenada in the past 5 years.

6.6 Duties and Taxes on Pharmaceuticals (Market)

Grenada imposes duties on imported active pharmaceutical ingredients (APIs) and on imported finished products. Value-added tax (VAT) is imposed on finished pharmaceutical products. However, some medicines are exempted from duties. Medicines for the treatment of chronic diseases are exempted from the VAT.

A 5% duty is imposed on imported APIs and a 10% duty is imposed on imported finished products²³. The VAT corresponds to 15% for pharmaceuticals²³.



Section 7 - Pharmaceutical procurement and distribution

This section provides a short overview on the procurement and distribution of pharmaceuticals in Grenada.

7.1 Public Sector Procurement

Public sector procurement in Grenada is centralized, and is under the administration of the Ministry of Health Procurement Unit.

Grenada is part of a pool procurement system directed and managed by the Organization of Eastern Caribbean States / Pharmaceutical Procurement Service (OECS/PPS) based in St. Lucia. The OECS/PPS invites tenders from suppliers to bid on pharmaceuticals. Procurement officers from the nine OECS countries meet every 18 months (procurement cycle) to adjudicate on items from suppliers and to award tenders. Tender documents and tender awards are not publicly available. Procurement is based on the prequalification of suppliers. The key functions of the procurement unit and those of the tender committee are clearly separated.

A process exists to ensure the quality of products procured by the OECS/PPS²⁴. The quality assurance process includes prequalification of products and suppliers, for which, explicit criteria and procedures exist. A list of prequalified suppliers and products is publicly available. The list of samples tested during the procurement process and the results of the analysis are publicly available²⁴.

There is no written public sector procurement policy.



Modalities employed in public procurement include international competitive tenders and direct purchasing.

7.2 Public Sector Distribution

The government supply system department in Grenada has a Central Medical Store (CMS) at National Level. There are no public warehouses in the secondary tier of the public sector distribution. There are no national guidelines on Good Distribution Practices (GDP).

A number of processes are in place at the CMS including: forecasting of order quantities, requisition/stock orders, preparation of picking/packing slips, reports of stock on hand, reports of outstanding order lines, expiry dates management, batch tracking, reports of products out of stock.

The availability of key medicines at the CMS was 80% in 2010. The average stock-out duration for a basket of medicines at the CMS was 30 days.

The CMS is not certified by the International Organization for Standardization (ISO).

7.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector¹⁶.



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 use in Grenada.

8.1 National Structures

A reference Essential Medicines List (EML) exists^{xviii,25}. The list was updated in 2009 and contains 508 medicines. The EML contains specific formulations for children²⁴. There are explicitly documented criteria for the selection of medicines in the list²⁴. There is a formal committee for this purpose^{xix,24}; however, declaration of the potential conflict of interest is not required from the members²⁴.

100% of the public health facilities have a copy of the EML.

National Standard Treatment Guidelines (STGs) for the most common illnesses are not produced/endorsed by the MoH in Grenada²⁵.

There is no national medicines formulary^{xx,24}.

There is no public or independently funded national medicines information centre. Public education campaigns on RUM topics have not been conducted in the last

^{xviii} The OECS/PPS EML is used as a reference for the public sector. This list is supplemented with additional medicines.

^{xix} Medicines are selected by the OECS/PPS Technical Advisory Sub-committee.

^{xx} Grenada shares a common Regional Medicines Formulary with the OECS countries called the "OECS Medicines Formulary". This document is printed every three years. The latest edition (7th) was released in 2009 for the period 2009-2012.



two years. A survey on RUM has not been conducted in the same period. There is no national programme or committee, involving government, civil society, or professional bodies, to monitor and promote RUM.

A written National Strategy for containing antimicrobial resistance does not exist. There is no national intersectoral task force to coordinate the promotion of appropriate use of antimicrobials or prevention of spread of infection. No national laboratory has responsibility for coordinating epidemiological surveillance of antimicrobial resistance.

8.2 Prescribing

Legal provisions exist to govern the licensing and prescribing practices of prescribers²⁶. Prescribers in the private sector dispense medicines.

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

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

Prescribing by International Nonproprietary Name (INN) name is obligatory only in the public sector. The average number of medicines prescribed per patient contact in public health facilities is 5²⁷. Of the medicines prescribed in the outpatient public health care facilities, 90% are on the national EML²⁷ and 60% are prescribed by INN²⁷. Of the patients treated in the outpatient public health care facilities, 50% receive antibiotics²⁷ and 2% receive injections²⁷. Of



prescribed drugs, 95% are dispensed to patients²⁷. Of medicines in public health facilities, 98% are adequately labelled²⁷.

Table 13. Characteristics of medicines prescribing²⁷

Description	%
% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	<u>90</u>
% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	<u>60</u>
% of patients in outpatient public health care facilities receiving antibiotics (mean)	<u>50</u>
% of patients in outpatient public health care facilities receiving injections (mean)	<u>2</u>
% of prescribed drugs dispensed to patients (mean)	<u>95</u>
% of medicines adequately labeled in public health facilities (mean)	<u>98</u>

Professional association codes of conduct governing the professional behavior of doctors and nurses exist.

8.3 Dispensing

Legal provisions in Grenada exist to govern dispensing practices of pharmaceutical personnel¹⁷. The basic pharmacist training curriculum includes a spectrum of components as outlined in Table 14.



Table 14. Core aspects of the pharmacist training curriculum

Curriculum	Covered
The concept of EML	<u>No</u>
Use of STGs	<u>No</u>
Drug information	<u>Yes</u>
Clinical pharmacology	<u>Yes</u>
Medicines supply management	<u>No</u>

Mandatory continuing education that includes RUM is not required for pharmacists.

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

A professional association code of conduct which governs the professional behavior of pharmacists exists¹⁷. Public Sector Pharmacists do not prescribe medication. However, if a medication is unavailable, Pharmacists are allowed to transcribe the medication on a transcript pad. The Pharmacist would sign the transcript and indicate the name of the doctor for the original prescription.

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References

- ¹ Grenada, Central Statistical Office, 2011.
- ² Central Intelligence Agency (CIA), The World Factbook, Grenada. Available online: <https://www.cia.gov/library/publications/the-world-factbook/geos/gj.html>
- ³ Grenada, Economic Statistic Database, 2011.
- ⁴ Ministry of Health, Epidemiology Unit, 2011.
- ⁵ World Health Organization (WHO), World Health Statistics 2010, Geneva. Available online: http://www.who.int/entity/whosis/whostat/EN_WHS10_Full.pdf
- ⁶ Ministry of Health, National Infectious Disease Control Unit (NIDCU), 2011.
- ⁷ Ministry of Finance, Budget Department, 2011.
- ⁸ Grenada, Pharmacy Council, 2011.
- ⁹ Grenada, Chief Nursing Officer, 2011.
- ¹⁰ St. Augustine Medical Center, Hospital Administration, 2011.



¹¹ T. A. Marryshow Community College (TAMCC). Available online:

<http://www.tamcc.edu.gd/>

¹² Grenada's National Strategic Health Plan (NSHP) for 2007-2011.

¹³ Ministry of Health, Policy on Donated Goods.

¹⁴ World Trade Organization (WTO), Members and observers. Available online:

http://www.wto.org/spanish/thewto_s/whatis_s/tif_s/org6_s.htm

¹⁵ Health Research for Action (HERA), Regional Assessment of Patent and Related Issues and Access to Medicines – CARICOM Member States and the Dominican Republic – Final Report – Volume II – Country Studies, 2009.

Available online:

<http://apps.who.int/medicinedocs/documents/s18707en/s18707en.pdf>

¹⁶ Grenada, Medical Products Act, 1995.

¹⁷ Grenada, Pharmacy Act of 1987.

¹⁸ Grenada, Food and Drug Act, 1986.

¹⁹ Grenada, Bureau of Standards, 2011.

²⁰ International Narcotics Control Board (INCB). Available online:

<http://www.incb.org>



²¹ Grenada, Medical Officers Act, 1903.

²² World Health Organization (WHO) – Health Action International (HAI), Measuring medicine prices, availability, affordability and price components, 2nd edition. Available online:

<http://apps.who.int/medicinedocs/index/assoc/s14868e/s14868e.pdf>

²³ Ministry of Health, Custom Clerk, 2011.

²⁴ Organization of Eastern Caribbean States / Pharmaceutical Procurement Service (OECS/PPS), 2011.

²⁵ Health Research for Action (HERA), Regional Assessment of Drug Registration and Regulatory Systems in CARICOM Member States and the Dominican Republic – Final Report – Volume II. July 2009. Available online:

<http://apps.who.int/medicinedocs/documents/s18706en/s18706en.pdf>

²⁶ Grenada, Medical Act, 1992.

²⁷ Ministry of Health, Pharmacy Department, 2011.

GRENADA
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ANNEX

Survey Data

(Fragment of the questionnaire)

2011

Section 0 General Info

0.01 Contact Info

0.01.01	Country (precoded)	Grenada
0.01.02	Name coordinator	Ellen Gabriel
0.01.03	Address (Street, City)	Ministerial Complex, Botanical Gardens, St. George's, Grenada
0.01.04	Phone number	473-405-2407 / 473-440-4955 ext 2110
0.01.05	Email address	chpharmgda@gmail.com
0.01.06	Web address	
0.01.07	Institution	Pharmacy Department, Ministry of Health

Section 1 Health and Demographic data

1.00 Respondent Information Section 1

1.00.01	Name of person responsible for filling out Survey section 1	Ellen Gabriel
1.00.02	Phone number	473-405-2407
1.00.03	Email address	chpharmgda@gmail.com
1.00.04	Other respondents for filling out this section	

1.01 Demographic and Socioeconomic Indicators

Core questions ([click here for help](#))

			Year	Source
1.01.01	Population , total (,000)	111,764	2011	Central Statistical Office
1.01.02	Population growth rate (Annual %)	0.6	2011	Central Statistical Office
1.01.03	Total Gross Domestic Product (GDP) (millions US\$)	694.58	2011	Central Statistical Office
1.01.04	GDP growth (Annual %)	1	2011	CIA Factbook
1.01.05C	GDP per capita (US\$ current exchange rate)	6,029		
1.01.06	Comments and References	1.01.05C		

Supplementary questions ([click here for help](#))

			Year	Source
1.01.07S	Population < 15 years (% of total population)	24.8	2010	Central Statistical Office

1.01.08S	Population > 60 years (% of total population)	11.3%	2010	Central Statistical Office
1.01.09S	Urban population (% of total population)	41	2010	Central Statistical Office
1.01.10S	Fertility rate, total (Births per woman)	2.2	2010	Ministry of Health
1.01.11S	Population living with less than \$1.25/day (international PPP) (%)			
1.01.12S	Population living below nationally defined poverty line (%)	32	2010	Central Statistical Office
1.01.13S	Income share held by lowest 20% of the population (% of national income)			
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	96	2010	Central Statistical Office
1.01.15S	Comments and References	<p>1.01.11S Information not available</p> <p>1.01.12S- source of information from web page www.indexmundi.com/grenada/population_below_poverty_line.html Source: CIA World Fact Book - information is accurate as of October 14th, 2011</p> <p>1.01.13S - Information unavailable</p>		

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)	70.51	2010	economic Statistic Data Base
1.02.02	Life expectancy at birth for women	75.82	2010	economic Statistic

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	(Years)			Data Base
1.02.03	Infant mortality rate , between birth and age 1 (/1,000 live births)	12.1	2010	Ministry of Health
1.02.04	Under 5 mortality rate (/1,000 live births)	14.6	2010	Ministry of Health
1.02.05	Maternal mortality ratio (/100,000 live births)	0	2010	Ministry of Health
1.02.06	Please provide a list of top 10 diseases causing mortality 		2010	Epi Unit, Ministry of Health
1.02.06.01	Disease 1	Malignant Neoplasms		
1.02.06.02	Disease 2	Endocrine and Metabolic Diseases		
1.02.06.03	Disease 3	Ishaemic Healt Disease		
1.02.06.04	Disease 4	Cerebro Vascular Disease		
1.02.06.05	Disease 5	Disease of the Pulmonary Circulation and other forms of Heart Diseases		
1.02.06.06	Disease 6	Disease of the Respiratory system		
1.02.06.07	Disease 7	Hypertension Diseases		
1.02.06.08	Disease 8	External causes of Morbidity and Mortality		
1.02.06.09	Disease 9	Disease of the Digestive System		
1.02.06.10	Disease 10	Disease of the Genitourinary System		
1.02.07	Please provide a list of top 10 diseases causing morbidity 		2010	Epi Unit, MOH
1.02.07.01	Disease 1	Complications of pregnancy, childbirth & the puerperium		
1.02.07.02	Disease 2	Hypertensive disease		
1.02.07.03	Disease 3	Diabetes Mellitus		

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1.02.07.04	Disease 4	Maternal conditions affecting fetus or newborn		
1.02.07.05	Disease 5	Disease of the Urinary System		
1.02.07.06	Disease 6	Nutritional deficiencies and anemias		
1.02.07.07	Disease 7	Disease of other parts of the Digestive System		
1.02.07.08	Disease 8	Intestinal Infectious diseases		
1.02.07.09	Disease 9	Disease of the pulmonary circulation & other forms of heart disease		
1.02.07.10	Disease 10	Acute respiratory infection		
1.02.08	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
1.02.09S	Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	228	2008	WHS 2010
1.02.10S	Neonatal mortality rate (/1,000 live births)	10.5	2010	Ministry of Health
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	870	2002	WHO
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	448	2002	WHO
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	199	2002	WHO
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	12.5	2010	NIDCU, Ministry of Health
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	0.9	2010	Ministry of Health
1.02.16S	Mortality rate for Malaria (/100,000 population)	0	2010	Ministry of Health

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1.02.17S	Comments and References	1.02.14 The NIDCU unit of the MOH reported 14 deaths from AIDS in 2010. The figure may vary from Births and Death unit as most doctors do not record AIDS as cause of death on death certificate.
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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	Ellen Gabriel
2.00.02	Phone number	473-405-2407
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2.00.04	Other respondents for filling out this section	

2.01 Health Expenditures

Core questions ([click here for help](#))

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)			
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	7.11		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	1,177.88		
2.01.03.02C	Total annual expenditure on health per capita (US\$ average exchange rate)	436.25		
2.01.04.01	General government annual expenditure on health (millions NCU)	55.9	2010	Ministry of Finance, Budget Dept.
2.01.04.02	General government annual expenditure on health (millions US\$ average exchange rate)	20.57	2010	Ministry of Finance, Budget Dept.
2.01.05	Government annual expenditure on health as percentage of total	9.73	2010	Ministry of Finance,

	government budget (% of total government budget)			Budget Dept.
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	48.90	2008	NHA
2.01.07.01C	Annual per capita government expenditure on health (NCU)	575.96		
2.01.07.02C	Annual per capita government expenditure on health (US\$ average exchange rate)	213.32		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	51.10	2008	NHA
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	2011	MOH
2.01.10	Population covered by private health insurance (% of total population)			
2.01.11.01	Total pharmaceutical expenditure (millions NCU)			
2.01.11.02	Total pharmaceutical expenditure (millions US\$ current exchange rate)			
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	0		
2.01.12.02C	Total pharmaceutical expenditure per capita (US\$ current exchange rate)	0		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	0		
2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	-		

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2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)	6.126	2010	Ministry of Finance
2.01.15.02	Total public expenditure on pharmaceuticals (millions US\$ current exchange rate)	2.27	2010	Ministry of Finance
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)			
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	0		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US\$ current exchange rate)	0		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)			
2.01.18.02	Total private expenditure on pharmaceuticals (millions US\$ current exchange rate)			
2.01.19	Comments and References	2.01.01.01 Information unavailable 2.01.01.02 Information unavailable 2.01.07.01C Public health expenditure per capita: EC\$ 500.16 2.01.07.02C Public health expenditure per capita: USD 184.05 2.01.11.01 This information is unavailable 2.01.11.02 Information unavailable 2.01.17.01C Public pharmaceutical expenditure per capita: EC\$ 54.81 2.01.17.02C Public pharmaceutical expenditure per capita: USD 20.13		
Supplementary questions (click for help)				
			Year	Source
2.01.20S	Social security expenditure as % of government expenditure on health (%)	0.00	2008	NHA data

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	of government expenditure on health)			
2.01.21S	Market share of generic pharmaceuticals [branded and INN] by value (%)			
2.01.22S	Annual growth rate of total pharmaceuticals market value (%)			
2.01.23S	Annual growth rate of generic pharmaceuticals market value (%)			
2.01.24S	Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)			
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	0.00		
2.01.26S	Comments and References	2.01.01.02 Exchange rate = 2.70v		

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		72	2010 Pharmacy Council
2.02.02C	Pharmacists per 10,000 population		6.635	
2.02.03	Total number of pharmacists working in the public sector		26	2011 Ministry of Health
2.02.04	Total number of pharmaceutical technicians and assistants		0	2011 MOH

2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country? 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
2.02.06	Total number of physicians	110	2010	Ministry of Health
2.02.07C	Physicians per 10,000 pop			
2.02.08	Total number of nursing and midwifery personnel	356	2011	Chief Nursing Officer, MOH
2.02.09C	Nurses and midwives per 10,000 pop			
2.02.10	Total number of hospitals	5	2011	Ministry of Health
2.02.11	Number of hospital beds per 10,000 pop	36.9	2011	Hospital Admin. St. Augustine Medical Center
2.02.12	Total number of primary health care units and centers	36	2011	Ministry of Health
2.02.13	Total number of licensed pharmacies 	31	2011	Pharmacy council
2.02.14	Comments and References	<p>2.02.04 Pharmacy technician training is not provided. The Pharmacy Act does not make provision for Pharmacy Attendants/Technicians</p> <p>2.02.02C Pharmacists per capita: 6.44</p> <p>2.02.10 There are 4 Public Sector Hospitals and 1 Private Hospital</p> <p>2.02.09C Nurses and Midwives per 10,000 = 31.85</p>		
Supplementary questions (click here for help)				
			Year	Source

2.02.15S	Starting annual salary for a newly registered pharmacist in the public sector (NCU) 	26,280	2011	Ministry of Health
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country 	1	2011	TAMCC Pharmacy Tutor
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	TAMCC Pharmacy Tutor
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	TAMCC Pharmacy Tutor
2.02.19S	Comments and References	<p>2.02.01 There are 115 Registered Pharmacists in Grenada but only 72 are licenced to practice Pharmacy. Some have migrated to other countries and some pay their annual licence fee even if they are not practicing Pharmacy.</p> <p>2.02.17S The TA Marryshow College and the Pharmacy School are currently working on the accreditation requirements for the Pharmacy School</p>		

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	Ellen Gabriel		
3.00.02	Phone number	473-405-2407		
3.00.03	Email address	chpharmgda@gmail.com		
3.00.04	Other respondents for filling out this section			

3.01 Policy Framework

Core questions ([click here for help](#))

			Year	Source
3.01.01	National Health Policy exists. If yes, please write year of the most recent document in the "year" field. 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
3.01.02	National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the "year" 	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
3.01.03	Please provide comments on the Health policy and its implementation plan	<p>The strategic goals of the NSPH are the following:</p> <ul style="list-style-type: none"> To develop a health system that focuses on primary health care To provide professional quality health care services To expand the Health care network through collaboration between the public and private sectors and other stakeholders in the formulation of health care policy and the delivery of health services. To enable access to affordable health care to the population To introduce and facilitate the health setting concepts. 		

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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
3.01.05	Group of policies addressing pharmaceuticals exist. 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
3.01.06	National Medicines Policy covers the following components:			
3.01.06.01	Selection of Essential Medicines	<input type="checkbox"/> Yes		
3.01.06.02	Medicines Financing	<input type="checkbox"/> Yes		
3.01.06.03	Medicines Pricing	<input type="checkbox"/> Yes		
3.01.06.04	Medicines Procurement	<input type="checkbox"/> Yes		
3.01.06.05	Medicines Distribution	<input type="checkbox"/> Yes		
3.01.06.06	Medicines Regulation	<input checked="" type="checkbox"/> Yes		
3.01.06.07	Pharmacovigilance	<input checked="" type="checkbox"/> Yes		
3.01.06.08	Rational Use of Medicines	<input type="checkbox"/> Yes		
3.01.06.09	Human Resource Development	<input type="checkbox"/> Yes		
3.01.06.10	Research	<input type="checkbox"/> Yes		
3.01.06.11	Monitoring and Evaluation	<input type="checkbox"/> Yes		
3.01.06.12	Traditional Medicine	<input type="checkbox"/> Yes		
3.01.07	National medicines policy implementation plan exists. If yes, please write year of the most recent document. 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
3.01.08	Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH

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	the "year" field			
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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
3.01.10	Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
3.01.11	There are official written guidelines on medicines donations.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2010	Policy on Donated Goods, MOHI
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed? 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	Chief Pharmacist		
3.01.13	Is there a national good governance policy ?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
3.01.13.01	Multisectoral 	<input type="checkbox"/> Yes		
3.01.13.02	For the pharmaceutical sector 	<input type="checkbox"/> Yes		
3.01.13.03	Which agencies are responsible?			
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
3.01.15	There is a formal code of conduct for public officials.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH

country (ombudsperson)?

3.01.16.01 Please describe: The Pharmacy Council is responsible for the conduct of Pharmacy Practice in Grenada. Any wrong doing occurring in the Pharmaceutical sector must be reported to the Council who will then address the matter.

3.01.17	Comments and References	3.01.01 Grenada's National Strategic Health Plan for 2007 - 2011 is officially adapted by MOH but was updated in 2008 to reflect the years 2008 - 2012. 3.01.02 There are implementation schedules within the document and some aspects of the Plan are already implemented. 3.01.15. The Formal Code of Conduct for Public Officers is in Draft Stage. The final document is not yet implemented
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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	Ellen Gabriel
4.00.02	Phone number	473-405-2407
4.00.03	Email address	chpharmgda@gmail.com
4.00.04	Other respondents for filling out this section	

4.01 Intellectual Property Laws and Medicines

Core questions ([click here for help](#))

			Year	Source
4.01.01	Country is a member of the World Trade Organization	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1996	WTO
4.01.02	Legal provisions provide for granting of Patents on:		2009	HERAI
4.01.02.01	Pharmaceuticals	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.02.02	Laboratory supplies	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.02.03	Medical supplies	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.02.04	Medical equipment	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.03.01	Please provide name and address of the institution responsible for managing and enforcing intellectual property rights			
4.01.03.02	Please provide URL			
4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	HERA/CAR ICOM REPORT ON IP 2009
4.01.05	Current laws contain (TRIPS)	Yes <input checked="" type="checkbox"/> No <input checked="" type="checkbox"/>	2009	HERA

	flexibilities and safeguards			
4.01.06	Country is eligible for the transitional period to 2016	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	HERA
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2009	HERA
4.01.07.01	Compulsory licensing provisions that can be applied for reasons of public health	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.07.02	Bolar exception	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
4.01.08	Are parallel importing provisions present in the national law?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	HERA
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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	HERA
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	HERA
4.01.11	Legal provisions exist for patent extension	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	HERA
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	HERA
4.01.13	Comments and References	<p>4.01.04 Patent Law in Grenada is substantially outdated and not TRIPS compliant. The Legislation currently in force is Patents Act Ch.227 of 1898, and Registration of UK Patents Act Cap. 283, 1924.</p> <p>Currently, a new Patents Act is being drafted by a Belize consultant with WIPO support, but not available for analysis.</p> <p>Grenada has expressed a desire for the new Patents Act to contain maximal TRIPS flexibilities.</p>		

4.02 Manufacturing

Core questions ([click here for help](#))

			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country 	0	2011	MOH
4.02.02	Country has manufacturing capacity		2011	MOHI
4.02.02.01	R&D to discover new active substances	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
4.02.02.04	Repackaging of finished dosage forms	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)			
4.02.04	Comments and References	Grenada does not have any licenced Pharmaceutical Manufacturers or any Manufacturing capabilities		

Supplementary questions ([click here for help](#))

			Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%) 	0	2011	MOH
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally	0	2011	MOH
4.02.07S	Number of manufacturers that are Good Manufacturing Practice (GMP) certified 	0	2011	MOH
4.02.08S	Comments and References			

Section 5 Medicines Regulation

5.00 Respondent Information Section 4

5.00.01	Name of person responsible for filling out this section of the instrument	Ellen Gabriel
5.00.02	Phone number	473-405-2407
5.00.03	Email address	ellengab2003@yahoo.com
5.00.04	Other respondents for filling out this section	

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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
5.01.02	There is a Medicines Regulatory Authority	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
5.01.03	If yes, please provide name and address of the Medicines regulatory authority	The Pharmacy Council C/O Chief Pharmacist Ministry of Health		
5.01.04	The Medicines Regulatory Authority is: 		2011	MOH
5.01.04.01	Part of MoH	<input checked="" type="checkbox"/> Yes		
5.01.04.02	Semi autonomous agency	<input type="checkbox"/> Yes		
5.01.04.03	Other (please specify)			
5.01.05	What are the functions of the National Medicines Regulatory Authority?		2011	MOH

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5.01.05.01	Marketing authorization / registration	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.01.05.02	Inspection	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.01.05.03	Import control	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.01.05.04	Licensing	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.01.05.05	Market control	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.01.05.06	Quality control	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.01.05.07	Medicines advertising and promotion	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.01.05.08	Clinical trials control	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.01.05.09	Pharmacovigilance	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.01.05.10	Other: (please explain)			
5.01.06	Number of the MRA permanent staff	9	2011	MOH
5.01.06.01	Date of response	14/07/2011		
5.01.07	The MRA has its own website	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.01.08.01	If yes, please describe:			
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
5.01.09.01	- If yes, please specify			
5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH

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	government.			
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
5.01.16	Comments and References	<p>5.01.02 The Pharmacy Council and the Chief Pharmacist are vested with regulatory powers and responsibilities. Nevertheless, not all the regulatory functions stated in the legal provisions are in place in Grenada.</p> <p>5.01.06 Members of the Council shall hold office for a term of two years, with the exception of the Chief Pharmacist who is Permanent on the Council, but are eligible for re-appointment. The Chief Pharmacist is the only permanent staff on the Council vested with regulatory functions that is dedicated to these functions.</p> <p>5.01.11 The Pharmacy Council gets its funds from regular Government Budget to perform regulatory activities. Members receive honorarium of \$100.00 per meeting attended. meetings are held quarterly.</p> <p>5.01.14 Revenue derived from Regulatory Activities of the Pharmacy Council is deposited in the consolidated funds of Grenada.</p>		

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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	Medical Product Act, MOH
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	Medical Product Act, MOH
5.02.03	Are there mechanisms for recognition of registration done by other countries	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.02.05	Information from the prequalification programme managed by WHO is used for product registration	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.02.06	Number of pharmaceutical products registered in your country	0	2011	MOH
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.02.07.01	If yes, how frequently updated 			
5.02.07.02	If yes, please provide updated list or URL *			
5.02.08	Medicines registration always	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH

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	includes the INN (International Non-proprietary Names)			
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	Medical Products Act of 1995
5.02.10	Comments and References	5.02.01 The Medical Product Act of 1995 makes provision for the licencing of all medicinal products, whether locally manufactured or imported. However this function is not carried out in Grenada.		
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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.02.14S	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.02.15S	Legal provisions require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	Medicinal Products Act of 1995

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5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US\$) 			
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US\$) 			
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)			
5.02.20S	Comments & References	5.02.16s - 19s Not applicable to Grenada		

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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	1987	Pharmacy Council
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1987	Pharmacy Act of 1987, Cap 241
5.03.02.01	If yes, legal provisions exist requiring inspections to be performed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.03	Inspection is a pre-requisite for licensing of:		1987	Pharmacy Act of 1987, Cap 241
5.03.03.01	Public facilities	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.03.03.02	Private facilities	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.04	Inspection requirements are the same for public and private facilities 	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH

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5.03.05.01	Local manufactures are inspected for GMP compliance	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	1987	Pharmacy Act of 1987, Cap 241
5.03.05.02	Private wholesalers are inspected	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.05.03	Retail distributors are inspected	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.05.04	Public pharmacies and stores are inspected	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.05.05	Pharmacies and dispensing points of health facilities are inspected	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.03.05.06	Please provide details on frequency of inspections for the different categories of facilities	<p>There is no part of the Pharmacy Act that addresses the periodicity of inspection. The Pharmacy Department and the Inspector design a regular schedule for inspection. Inspection of Private Pharmacies, wholesalers and distributors are inspected twice annually approx. Public Sector Pharmacies are inspected quarterly. However, an inspection can be carried out whenever it is deemed necessary by the Inspector.</p> <p>All Premises intended to conduct pharmaceutical business must be inspected before registration..</p>		
5.03.06	Comments and References	<p>5.03.03 The Pharmacy Act of 1987, Cap 241 makes reference to the registration of premises as a Pharmacy but did not specify private or public sector Pharmacy. However, in actual practice, only Private Pharmacies, premises of Wholesalers and Distributors are registered to conduct pharmaceutical activities. Public Sector Pharmacies are not registered but are inspected to meet established requirements.</p>		
5.04 Import Control				
Core Questions (click here for help)				
			Year	Source
5.04.01	Legal provisions exist requiring authorization to import medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	Medical Products Act of 1995
5.04.02	Legal provisions exist allowing the sampling of imported products for	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	1995	Medical Products

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	testing			Act of 1995
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.04.05	Comments and References	<p>5.04.01 The Medical Product Act of 1995 requires that all Importers of Pharmaceuticals must be registered</p> <p>5.04.02 The Medical Product Act does not provision for sampling of imported products</p> <p>The quality of medicines imported by the private sector is not controlled adequately. The system relies on registration of importers and wholesalers.</p>		

5.05 Licensing

		Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995 Medical Products Act of 1995
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011 Bureau of Standards
5.05.02.01	If no, please explain	Grenada has no Manufacturers of Pharmaceuticals. However the Food and Drug Act of 1986 makes provision for compliance with GMP as it relates to food	
5.05.03	GMP requirements are published by the government.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011 Bureau of Standards
5.05.04	Legal provisions exist requiring importers to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1987 Pharmacy Act 1987, Cap 241
5.05.05	Legal provisions exist requiring wholesalers and distributors to be	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1987 Pharmacy Act of

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	licensed			1987, Cap 241
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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.05.07	National Good Distribution Practice requirements are published by the government	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1987	Pharmacy Act of 1987, Cap 241
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1987	Pharmacy Act, Cap 241 of 1987
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.05.13	Comments and References	5.05.09 & 5.05.10 Grenada Pharmacy Council is vested with the responsibility to license pharmacies, Pharmacists, Wholesalers and Distributors in the Private Sector. Public Sector Pharmacists and Pharmacies do no pay license fees. 5.05.03 Grenada has adapted the HACCP and these contain GMP as it relates to food		

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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	Medical Products Act of 1995
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.06.02.01	If yes, is the laboratory part of the MRA ?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.06.02.02	Does the regulatory authority contract services elsewhere?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.06.02.03	If yes, please describe	Grenada uses the services of the Caribbean Regional Drug Testing Laboratory		
5.06.03	Is there any national laboratory accepted for collaboration with WHO prequalification Programme ? Please describe.	No		
5.06.04	Medicines are tested:		2011	MOH
5.06.04.01	For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.06.04.02	For quality monitoring in private sector (routine sampling in retail outlets)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.06.04.03	When there are complaints or problem reports	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.06.04.04	For product registration	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.06.04.05	For public procurement prequalification	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		

5.06.04.06	For public program products prior to acceptance and/or distribution	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
5.06.05	Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.06.06	How many Quality Control samples were taken for testing in the last two years?		2011	MOH
5.06.07	Total number of samples tested in the last two years that failed to meet quality standards		2011	MOH
5.06.08	Results of quality testing in past two years are publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.06.09	Comments and References	<p>5.06.02 Quality control can be done using the Caribbean Regional Drug Testing Laboratory which has been established under the Agreement establishing the Caribbean Regional Drug Testing Laboratory Act and is in force in 14 countries.</p> <p>5.06.06 Data are not available</p> <p>5.06.07 Data not available</p>		

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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:			
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.07.04	Legal provisions require a pre-	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH

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	approval for medicines advertisements and promotional materials 			
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.07.06	A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.07.06.01	If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both			
	Domestic only	<input type="checkbox"/> Yes		
	Multinational only	<input type="checkbox"/> Yes		
	Both	<input type="checkbox"/> Yes		
5.07.06.02	If yes, adherence to the code is voluntary	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.07.06.03	If yes, the code contains a formal process for complaints and sanctions	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.07.06.04	If yes, list of complaints and sanctions for the last two years is publicly available	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.07.07	Comments and References			
5.08 Clinical trials				
Core Questions (click here for help)				
			Year	Source
5.08.01	Legal provisions exist requiring	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH

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

5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1998	International Narcotics Control Board
5.09.01.03	Convention on Psychotropic Substances 1971	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1980	International Narcotics Control Board
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances , 1988	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1990	International Narcotics Control Board
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.09.03	Annual consumption of Morphine (mg/capita)	0.442308	2009	International Narcotics Control Board
5.09.04	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>		
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.000		
5.09.07S	Annual consumption of Pethidine (mg/capita)	5.028846	2009	International Narcotics Control

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				Board
5.09.08S	Annual consumption of Oxycodone (mg/capita)	0.000		
5.09.09S	Annual consumption of Hydrocodone (mg/capita)	0.000		
5.09.10S	Annual consumption of Phenobarbital (mg/capita)			
5.09.11S	Annual consumption of Methadone (mg/capita)	0.000		
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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	Medical Product Act of 1995
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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	Medical Product Act of 1995
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time			
5.10.04.02	If a national pharmacovigilance center exists in your country, an	Yes <input type="checkbox"/> No <input type="checkbox"/>		

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analysis report has been published in the last two years.				
5.10.04.03	If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.05	An official standardized form for reporting ADRs is used in your country	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.10.07	How many ADR reports are in the database? 			
5.10.08	How many reports have been submitted in the last two years? 			
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.10.09.01	If yes, number of reports sent in the last two years 			
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.10.11	Is there a clear communication strategy for routine communication and crises communication?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
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 <input checked="" type="checkbox"/> No <input type="checkbox"/>		
5.10.13	Please describe how you intend to enhance the Pharmacovigilance	Conduct Educational sessions on Pharmacovigilance with		

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	system	Pharmacists and other stakeholders Employ more Pharmacy Inspectors to enhance Pharmacovigilance on port of entry of Pharmaceuticals and other Private Facilities where Pharmaceuticals are been sold		
5.10.14	Comments and References	ADR's are reported from the public sector pharmacies to OECS/PPS using a standardized Reporting Form .		
Supplementary questions (click here for help)				
			Year	Source
5.10.15S	Feedback is provided to reporters	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.10.16S	The ADR database is computerized	Yes <input type="checkbox"/> No <input type="checkbox"/>		
5.10.17S	Medication errors (MEs) are reported	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.10.18S	How many MEs are there in the ADRs database?			
5.10.19S	There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
5.10.20S	In the past two years, who has reported ADRs?		2011	MOH
5.10.20.01S	Doctors	<input type="checkbox"/> Yes		
5.10.20.02S	Nurses	<input type="checkbox"/> Yes		
5.10.20.03S	Pharmacists	<input checked="" type="checkbox"/> Yes		
5.10.20.04S	Consumers	<input checked="" type="checkbox"/> Yes		
5.10.20.05S	Pharmaceutical Companies	<input type="checkbox"/> 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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH

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5.10.22S	Are there training courses in pharmacovigilance?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
5.10.22.01S	If yes, how many people have been trained in the last two years?	35		
5.10.23S	Comments and References	A workshop in Pharmacovigilance was conducted by OECS/PPS in May, 2010. Approx. 35 Pharmacists attended.		

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	Ellen Gabriel
6.00.02	Phone number	473-405-2407 , 440-4955 ext 2110
6.00.03	Email address	chpharmgda@gmail.com
6.00.04	Other respondents for this sections	

6.01 Medicines Coverage and Exemptions

Core Questions ([click here for help](#))

		Year	Source
6.01.01	Do the followings receive medicines free of charge:	1903	Medical Officers Act, Cap 188
6.01.01.01	Patients who cannot afford them	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.02	Children under 5	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.03	Pregnant women	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
6.01.01.04	Elderly persons	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.01.05	Please describe/explain your yes answers for questions above	Persons between the ages of 16 - 60 years accessing the public sector Pharmacies pay the cost of medication on the prescription (value) if the prescription is from a District Medical Officer. Prescriptions from Private Practitioners are charged the cost of prescription plus 50%, irrespective of age.	
6.01.02	Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for :	2011	MOHI
6.01.02.01	All medicines included in the EML	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
6.01.02.02	Any non-communicable diseases	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	

6.01.02.03	Malaria medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
6.01.02.04	Tuberculosis medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.02.05	Sexually transmitted diseases medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.02.06	HIV/AIDS medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.02.07	Expanded Program on Immunization (EPI) vaccines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.02.08	If others, please specify			
6.01.02.09	Please describe/explain your yes answers for questions above	6.01.02 Grenada has a Medication Assistance Programme managed by the Pharmacy Department and the Social Worker, MOH. There are criterias for entry into the Programme , one of which is that the person must be poor with no source of income. All persons desirous of entering the Programme must first be evaluated by the Social Worker for socio-economic status. Persons eligible are allowed EC \$150.00 per month of medications if not available in the public sector.		
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage ?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
6.01.03.01	Does it provide coverage for medicines that are on the EML for inpatients	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
6.01.03.02	Does it provide coverage for medicines that are on the EML for outpatients	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.03.03	Please describe the medicines benefit of public/ social insurance schemes	6.01.03 The Medication Assistance Programme is not a health insurance scheme but a programme designed by the MOH to assist outpatients of poor socio-economic status who cannot afford to purchase medication. The funds covers all medications including those on the EML. If the medication is available at public Pharmacies, then it is given free of cost. If not, Patients are allowed \$150.00 for the purchase of the medication. 6.03.01.01 inpatients receive medications free of charge, except for Private Wards where patients pay for their medication.		

6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the EML ?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.01.05	Comments and References	6.01.04 - 01 All private health insurance schemes provide medicine coverage and they provide coverage for medicines on the EML		

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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
6.02.03	In practice, (even though this may be contrary to regulations) is revenue from fees or sales of medicines sometimes used to pay the salaries or supplement the income of public health personnel in the same facility?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
6.02.03.01	Please describe the patient fees and copayments system	In the Public Sector, Patients accessing services from district Medical Officer Clinic who are between the ages of 16 - 60 pay the cost of the medication on the prescription. there is a mark-up of 50% for Private Prescriptions.		
6.02.04	Comments and References	6.02.02 Medical Officers Act, Cap 188 allows for charging for medication		

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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
6.03.01.01	If yes, are the provisions aimed at Manufacturers	Yes <input type="checkbox"/> No <input type="checkbox"/>		
6.03.01.02	If yes, are the provisions aimed at Wholesalers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
6.03.01.03	If yes, are the provisions aimed at Retailers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
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 prices, like all other consumables, are regulated by the Ministry of Finance. There is a 40% markup on Pharmaceuticals in the Private Sector.		
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
6.03.03	Regulations exist mandating that retail medicine price information should be publicly accessible	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
6.03.03.01	-if yes, please explain how the information is made publically available			
6.03.04	Comments and References			

6.04 Prices, Availability and Affordability

Core Questions ([click here for help](#))

			Year	Source
6.04.01-04	Please state if a medicines price survey using the WHO/HAI methodology has been conducted in the past 5 years in your country. 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	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	2011	MOH

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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

Basket Of key medicines				Public procurement	Public patient	Private patient		
	Availability (one or both of)	Mean (%)	Orig		6.04.01.01	6.04.01.03		
			LPG		6.04.01.02	6.04.01.04		
		Median (%)	Orig		6.04.02.01	6.04.02.03		
			LPG		6.04.02.02	6.04.02.04		
	Price	Median Price Ratio	Orig	6.04.03.01	6.04.03.03	6.04.03.05		
			LPG	6.04.03.02	6.04.03.04	6.04.03.06		
	Affordability Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection	Number of days' wages	Orig		6.04.04.01	6.04.04.03		
			LPG		6.04.04.02	6.04.04.04		
6.04.05	Comments and References							

6.05 Price Components and Affordability

Core Questions ([click here for help](#))

Year Source

6.05.01	Please state if a survey of medicines price components has been conducted in the past 5 years in your country	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	2011	MOH
6.05.02	Median cumulative percentage mark-up between Manufacturer Selling Price (MSP)/ Cost Insurance and Freight (CIF) price and final medicine price for a basket of key medicines in the public sector (Median % contribution)			
6.05.03	Median cumulative percentage mark-up between MSP/CIF price and final medicine price for a basket of key medicines in the private sector (Median % contribution)	40		
6.05.04	Comment and References			
Supplementary questions (click here for help)				
6.05.05S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)			
6.05.06S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution)			
6.05.07S	Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%)			
6.05.08S	Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%)			
6.05.09S	Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)			

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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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
6.06.02	There are duties on imported finished products	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist			
6.06.06	Comments and References	6.06.02 There are some medicines that are exempted from duties 6.06.03 VAT tax is exempted from Chronic communicable and non-communicable diseases medicines		

Supplementary questions ([click here for help](#))

			Year	Source
6.06.07S	Duty on imported active	5	2011	Custom

	pharmaceutical ingredients, APIs (%)			Clerk, MOH
6.06.08S	Duty on imported finished products (%)	10	2011	Custom Clerk, MOH
6.06.09S	VAT on pharmaceutical products (%)	15	20	Custom Clerk, MOH
6.06.10S	Comments and References			

Section 7 Pharmaceutical procurement and distribution

7.00 Respondent Information Section 6

7.00.01	Name of person responsible for filling out this section of the instrument	Ellen Gabriel
7.00.02	Phone number	473-405-2407, 473-440-4955 ext 2110
7.00.03	Email address	ellengab2003@yahoo.com
7.00.04	Other respondents for filling out this section	

7.01 Public Sector Procurement

Core Questions ([click here for help](#))

		Date	Source
7.01.01	Public sector procurement is:	2011	MOH
7.01.01.01	Decentralized <input type="checkbox"/> Yes 		
7.01.01.02	Centralized and decentralized <input type="checkbox"/> Yes 		
7.01.01.03	Please describe		Public Sector Procurement is wholly centralized and is under the Ministry of Health administration and the country is also part of the Pharmaceutical Procurement Service/Organization of the Eastern Caribbean States (PPS/OECS)
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is: 	2011	MOH
7.01.02.01	Part of MoH	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
7.01.02.02	Semi-Autonomous	Yes <input type="checkbox"/> No <input type="checkbox"/>	

7.01.02.03	Autonomous	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.02.04	A government procurement agency which procures all public goods	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.03	Public sector requests for tender documents are publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.01.04	Public sector tender awards are publicly available	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.01.05	Procurement is based on prequalification of suppliers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
7.01.05.01	If yes, please describe how it works	Grenada is part of a pool procurement system directed and managed by OECS/Pharmaceutical Procurement Service based in St. Lucia. OECS/PPS invites tenders from suppliers to bid on Pharmaceuticals. Procurement Officers from the 9 OECS countries meet every 18 months (Procurement Cycle) to adjudicate on items from suppliers and to award tenders.		
7.01.06	Comments and References	7.01.02.01 For the public sector the Ministry of Health Procurement Unit is procuring pharmaceuticals.		
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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
7.01.10S	A process exists to ensure the quality of products procured	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	OECS/PPS MOH

7.01.10.01S	If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.10.02S	If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly available	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	OECS/PPS
7.01.12S	Which of the following tender methods are used in public sector procurement:		2011	MOH
7.01.12.01S	National competitive tenders	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.01.12.02S	International competitive tenders	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.12.03S	Direct purchasing	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.01.13S	Comments and References	<p>7.01.10 Grenada is part of a pool procurement system,(managed and directed by OECS/PPS),with the other OECS countries in which 80% of all Pharmaceuticals are purchased. Through this process, the quality of product procured is ensured.</p> <p>The quality assurance process for products and suppliers is conducted by OECS/PPS prior to the process of adjudication. (Only public sector)</p> <p>7.01.10.02S Criteria and procedures for prequalification of Suppliers are the responsibility of OECS/PPS</p>		

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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH

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7.02.02	Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial) 	0	2011	MOH
7.02.03	There are national guidelines on Good Distribution Practices (GDP)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.02.04	There is a licensing authority that issues GDP licenses	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.02.04.01	If a licensing authority exists, does it accredit public distribution facilities?	Yes <input type="checkbox"/> No <input type="checkbox"/>		
7.02.05	List of GDP certified warehouses in the public sector exists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.02.06	List of GDP certified distributors in the public sector exists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.02.07	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
7.02.08S	Which of the following processes is in place at the Central Medical Store:		2011	MOH
7.02.08.01S	Forecasting of order quantities	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.02S	Requisition/Stock orders	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.03S	Preparation of picking/packing slips	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.04S	Reports of stock on hand	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.05S	Reports of outstanding order lines	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.06S	Expiry dates management	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.08.07S	Batch tracking	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		

7.02.08.08S	Reports of products out of stock	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
7.02.09S	Percentage % availability of key medicines at the Central Medical Store	80	2010	MOH
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days	30		
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.02.13S	The Public Central Medical Store is ISO certified	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.02.15S	The second tier public warehouses are ISO certified	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.02.16S	Comments and References			

7.03 Private Sector Distribution

Core Questions ([click here for help](#))

			Year	Source
7.03.01	Legal provisions exist for licensing wholesalers in the private sector	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	Medical Product Act
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1995	Medical Product Act
7.03.03	List of GDP certified wholesalers in the private sector exists	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
7.03.04	List of GDP certified distributors in	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH

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	the private sector exists			
7.03.05	Comments and References			

Section 8 Selection and rational use

8.00 Respondent Information Section 7

8.00.01	Name of person responsible for filling out this section of the instrument	Ellen Gabriel
8.00.02	Phone number	473-405-2407
8.00.03	Email address	chpharmgda@gmail.com
8.00.04	Other respondents for filling out this section	

8.01 National Structures

Core Questions ([click here for help](#))

			Year	Source
8.01.01	National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	HERA
8.01.01.01	If yes, number of medicines on the EML (no. of INN)	508		
8.01.01.02	If yes, there is a written process for selecting medicines on the EML	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.01.01.03	If yes, the EML is publicly available	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.01.01.04	If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG)	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.01.02	National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2009	HERA
8.01.03	STGs specific to Primary care exist. Please use the "year" field to	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH

	write the year of last update of primary care guidelines			
8.01.04	STGs specific to Secondary care (hospitals) exists. Please use the "year" field to write the year of last update of secondary care STGs.	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.01.05	STGs specific to Paediatric conditions exist. Please use the "year" field to write the year of last update of paediatric condition STGs	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.01.06	% of public health facilities with copy of EML (mean)- Survey data	100		
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data			
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.01.11	A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.01.12	A written National strategy exists to contain antimicrobial resistance . If yes, please write year of last update of the strategy in the "year" field	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH

8.01.13	Comments and References	8.01.01 The OECS/PPS essential medicines list is used as a reference for the public sector. This list is supplemented with additional medicines that are being used.		
Supplementary questions (click here for help)				
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	OECS/PPS
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	OECS/PPS
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	OECS/PPS I
8.01.16.01S	If yes, conflict of interest declarations are required from members of national EML committee	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.01.17S	National medicines formulary exists	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2009	OECS/PPS
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 <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.01.20S	Comments and References	<p>8.01.17s Grenada shares a common Regional Medicine Formulary with the OECS countries called the OECS Medicine Formulary. This Formulary is printed every three years. The latest edition, the 7th edition, was released in 2009 and is for the period 2009 - 2012.</p> <p>The formulary is also used as the Essential Medicine List</p> <p>8.01.16s The medicines in the OECS formulary are selected by</p>		

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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	1992	Medical Act 1992 Cap 189
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.03	Do prescribers in the private sector dispense medicines?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
8.02.04	Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.02.05	Do more than half of referral hospitals have a DTC?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	2011	MOH
8.02.06	Do more than half of general hospitals have a DTC?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	2011	MOH
8.02.07	Do more than half of regions/provinces have a DTC?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>	2011	MOH
8.02.08	The core medical training curriculum includes components on:		2011	MOH
8.02.08.01	Concept of EML	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.08.02	Use of STGs	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.08.03	Pharmacovigilance	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.08.04	Problem based pharmacotherapy	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH

	physician)			
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.02.12	Prescribing by INN name is obligatory in:		2011	MOH
8.02.12.01	Public sector	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.12.02	Private sector	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
8.02.13	Average number of medicines prescribed per patient contact in public health facilities (mean)	5	2011	Pharmacy Department , MOH
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	90	2011	Pharmacy Department , MOH
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	60	2011	Pharmacy Department , MOH
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)	50	2011	Pharmacy Department , MOH
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)	2	2011	Pharmacy Department , MOH
8.02.18	% of prescribed drugs dispensed to patients (mean)	95	2011	Pharmacy Department , MOH
8.02.19	% of medicines adequately labeled in public health facilities (mean)	98	2011	Pharmacy Department , MOH

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8.02.20	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
8.02.21S	A professional association code of conduct exists governing professional behaviour of doctors	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)			
8.02.24S	Comments and References			
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 <input checked="" type="checkbox"/> No <input type="checkbox"/>	1987	Pharmacy Act 1987
8.03.02	The basic pharmacist training curriculum includes components on:		2011	MOH
8.03.02.01	Concept of EML	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.03.02.02	Use of STGs	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.03.02.03	Drug Information	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.03.02.04	Clinical pharmacology	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
8.03.02.05	Medicines supply management	Yes <input type="checkbox"/> No <input type="checkbox"/>		
8.03.03	Mandatory continuing education that includes rational use of medicines is required for	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH

	pharmacists			
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	2011	MOH
8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2011	MOH
8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-the-counter without any prescription?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	2011	MOH
8.03.07	In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/>	2011	MOH
8.03.08	Comments and References			

Supplementary questions ([click here for help](#))

			Year	Source
8.03.09S	A professional association code of conduct exists governing professional behaviour of pharmacists	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	1987	Pharmacy Act
8.03.10S	In practice, (even though this may be contrary to regulations) do the following groups of staff <i>sometimes</i> prescribe prescription-only medicines at the primary care level in the public sector?		2011	MOH
8.03.10.01S	Nurses 	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input checked="" type="checkbox"/>		
8.03.10.02S	Pharmacists 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		
8.03.10.03S	Paramedics 	Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input checked="" type="checkbox"/>		
8.03.10.04S	Personnel with less than one month training 	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Unknown <input type="checkbox"/>		

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8.03.11S	Comments and References	
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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	Ellen Gabriel
9.00.02	Phone number	473-405-2407
9.00.03	Email address	chpharmgda@gmail.com
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?	0	
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			

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	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			