DOMINICA

PHARMACEUTICAL COUNTRY PROFILE

COMMONWEALTH OF DOMINICA

Pharmaceutical Country Profile

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

March 2012

This document was produced with the support of the Pan American Health Organization/World Health Organization (PAHO/WHO) Office of Caribbean Programme Coordination (CPC), and all reasonable precautions have been taken to verify the information contained herein. The published material does not imply the expression of any opinion whatsoever on the part of the PAHO/WHO, and is being distributed without any warranty of any kind – either expressed or implied. The responsibility for interpretation and use of the material lies with the reader. In no event shall the PAHO/WHO be liable for damages arising from its use.

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

Errol Thomas ***(Chief Pharmacist)***
Ministry of Health
4th Floor, Government Headquarters, Kennedy Avenue, Roseau

Email: cms@dominica.gov.dm

Foreword

The 2011 Pharmaceutical Country Profile for Dominica 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 Dominica. The compiled data comes from international sources (e.g. the World Health Statistics), 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 Dominica I would like to express my appreciation to the following persons:

Pan American Health Organization/World Health Organization

Nelly Marin Jaramillo *(Pharmaceutical Policies Regional Advisor for the Americas)*

Adriana Mitsue Ivama *(Medicines and Health Technologies Sub-regional Advisor for the Caribbean)*

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

Ernest Pate *(Caribbean Programme Coordinator, CPC)*

Robinson Rojas Cortes *(HSS-MT Consultant)*

Shirley Augustine *(Country Programme Specialist for Dominica)*

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

Arlette Scantlebury *(Administrative Assistant, CPC Office)*

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

Ministry of Health

Errol Thomas *(Chief Pharmacist)*

Marva Smith *(Statistics Officer, Health Information Unit)*

Other respondents

Yvanette Baron-George *(Ministry of Finance)*

Sandra Julien *(Companies & Intellectual Property Office)*

Prayma Carette *(Chief Statistician, Central Statistical Office)*

Stephen Nicholas *(Central Statistical Office)*

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

DAVID JOHNSON
Chief Medical Officer (CMO)
Ministry of Health
Commonwealth of Dominica

Table of content

List of tables

Acronyms and abbreviations

ADR	Adverse Drug Reaction
API	Active Pharmaceutical Ingredient
CARICOM	Caribbean Community
CMO	Chief Medical Officer
CMS	Central Medical Stores
CPC	Caribbean Programme Coordination
CRDTL	Caribbean Regional Drug Testing Laboratory
DTC	Drug and Therapeutics Committee
EC$	East Caribbean Dollar
ECC	Eastern Caribbean Countries
EML	Essential Medicines List
EPI	Expanded Programme on Immunizations
FIOCRUZ	Oswaldo Cruz Foundation
GDP	Gross Domestic Product
GDP	Good Distribution Practices
GGHE	General Government Health Expenditure
GPP	Good Pharmacy Practices
HERA	Health Research for Action
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
HQ	Headquarter
ICD	International Classification of Diseases
IPR	Intellectual Property Rights
ISO	International Organization for Standardization
MRA	Medicines Regulatory Authority
NHA	National Health Account
NMP	National Medicines Policy
OECS/PPS	Organization of East Caribbean States/Pharmaceutical Procurement Service
PAHO	Pan American Health Organization
PCP	Pharmaceutical Country Profile
R&D	Research & Development
RUM	Rational Use of Medicines
STG	Standard Treatment Guidelines
THE	Total Health Expenditure
TPHE	Total Private Health Expenditure
TRIPS	Trade Related aspects of Intellectual Property Rights
UMC	Uppsala Monitoring Centre
US$	United States Dollar
VAT	Value Added Tax

WHO	World Health Organization
WHS	World Health Statistics
WTO	World Trade Organization

Introduction

This Pharmaceutical Country Profile (PCP) provides data on existing socio-economic and health-related conditions, resources, regulatory structures, processes and outcomes relating to the pharmaceutical sector of Dominica. 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 9 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Medicines Trade and Production (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical procurement and distribution, and (8) Selection and rational use. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available).

This narrative profile is based on data derived from both the core and supplementary indicators. The tables in the annexes also present all data collected for each of the indicators in the original survey form. For each piece of information, the year and source of the data are indicated; these have been used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links have been provided to the source documents so that users can easily access these documents.

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

Data collection in all 193 member states has been conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information.

To facilitate the work of national counterparts, the questionnaires were pre-filled at WHO Head Quarter (HQ) using all publicly-available data and before being sent out to each country by the WHO Regional Office, which in the Americas corresponds to the Pan American Health Organization (PAHO). A coordinator was nominated for each of the member states.

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

This profile will be regularly updated by the PAHO/WHO in partnership with the country officials.

Users of this profile are encouraged to send comments, corrections or queries to:

Errol Thomas
Chief Pharmacist
Ministry of Health
4th Floor, Government Headquarters, Kennedy Avenue, Roseau, Dominica
Tel: (767) 266-3437
Fax: (767) 448-6086
cms@dominica.gov.dm

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

Section 1 - Health and Demographic Data

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

1.1 Demographics and Socioeconomic Indicators

The total population of Dominica in 2010 was 72,900 with an annual population growth rate of 0.46%[1]. The annual Gross Domestic Product (GDP) growth rate is 1.3%[1]. The GDP per capita was US$6,487[1].

39.0% of the population is under 15 years of age, and 13.4% is over 60 years of age[1]. The urban population currently stands at 47.2% of the total population[1]. The fertility rate is 2.6 births per woman[1]. 28.8% of the population lives below the nationally defined poverty line[2]. The income share held by the lowest 20% of the population is 5.2%[2].

1.2 Mortality and Causes of Death

The life expectancy at birth is 73.5 and 78.2 years for men and women respectively[1]. The infant mortality rate (i.e. children under 1 year) is 13.9/1,000 live births[3]. For children under the age of 5, the mortality rate is 15.1/1,000 live births[3]. The maternal mortality rate is 214.6/100,000 live births[3].

The top 10 diseases causing mortality and morbidity in Dominica are listed in Table 1 and Table 2 respectively.

Table 1. Top 10 diseases causing mortality in the country (2010)[3]

	Disease (International Classification of Diseases[4])
1	Cerebrovascular diseases (I60-I69)
2	Diabetes mellitus (E10-E14)
3	Ischemic heart disease (I20-I25)
4	Hypertensive disease (I10-I15)
5	Pulmonary heart disease, Diseases of pulmonary circulation and Other forms of heart disease (I26-I45, I47-I49, I51)
6	Acute respiratory infection (J00-J22)
7	Malignant neoplasm of digestive organs and peritoneum, except stomach and colon (C15, C17, C20-C26, C48)
8	Chronic lower respiratory diseases (J40-J47)
9	Assault (homicide) (X85-Y09)
10	Malignant neoplasm of trachea, bronchus and lung (C33-C34)

Table 2. Top 10 diseases causing morbidity in the country (2010)[3]

	Disease
1	Heart disease
2	Hypertensive disease
3	Diabetes mellitus
4	Cancer
5	Respiratory illnesses
6	Injuries
7	Cerebrovascular diseases
8	Gastroenteritis
9	Influenza-like illnesses
10	Dengue

The adult mortality rate for both sexes between 15 and 60 years is 1.8/1,000 population[3], while the neonatal mortality rate is 17.0/1,000 live births[3]. The age standardized mortality rate by non-communicable diseases is 631.0/100,000[3], 107.87/100,000 by cardiovascular diseases[3], and 167/100,000 by cancer[3]. The mortality rate for HIV/AIDS is 4.1/100,000[3], 0/100,000 for tuberculosis[3], and 0/100,000 for malaria[3].

Section 2 - Health Services

This section provides information regarding health expenditures and human resources for health in Dominica. Specific information related to public pharmaceutical expenditure is presented. The contribution of the public and private sector to overall health expenditure is also shown.

2.1 Health Expenditures

In Dominica, the total annual expenditure on health (THE) in 2008 was EC$60,770,000 (US$22,510,000)[5]. The total annual health expenditure was 4.76% of the GDP. The total annual expenditure on health per capita was EC$833.61 (US$308.78).

The general government[i] health expenditure (GGHE) in 2008, as reflected in the National Health Account (NHA)[5] was EC$37,970,000 (US$14,060,000). That is, 62.48% of the THE, with a total annual per capita public expenditure on health of EC$520.85 (US$192.87). The government annual expenditure on health represents 8.20% of the total government budget[5]. Private health expenditure covers the remaining 37.52% of the THE[5].

Private out-of pocket expenditure represents 84.21% of the Total Private Health Expenditure (TPHE). Premiums for private prepaid health plans are 15.79% of the TPHE.

[i] 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.

The public expenditure on pharmaceuticals was EC$4,890,000 (US$1,810,000) in 2009[6]. This converts into a per capita public expenditure on pharmaceuticals of EC$67.08 (US$24.84).

2.2 Health Personnel and Infrastructure

The health workforce is described in Table 3 and in Figures 1 and 2. There are 38 (5.2/10,000) licensed pharmacists, of which 16 (2.2/10,000) work in the public sector[7]. There are 10 (1.4/10,000) pharmaceutical technicians and assistants (in all sectors). The ratio of pharmaceutical technicians to pharmacists is 1:4.

There are 38 (5.2/10,000) physicians [8] and 89 (12.2/10,000) nursing and midwifery personnel in Dominica. The ratio of doctors to pharmacies is 3:1 and the ratio of doctors to nurses and midwifery personnel is 3:1.

Table 3. Human resources for health

Human Resource	
Licensed pharmacists (all sectors)	38 (5.2/10,000)
Pharmacists in the public sector	16 (2.2/10,000)
Pharmaceutical technicians and assistants (all sectors)	10 (1.4/10,000)
Physicians (all sectors)	38 (5.2/10,000)
Nursing and midwifery personnel (all sectors)	89 (12.2/10,000)

Figure 1. The density of the Health Workforce (all sectors)

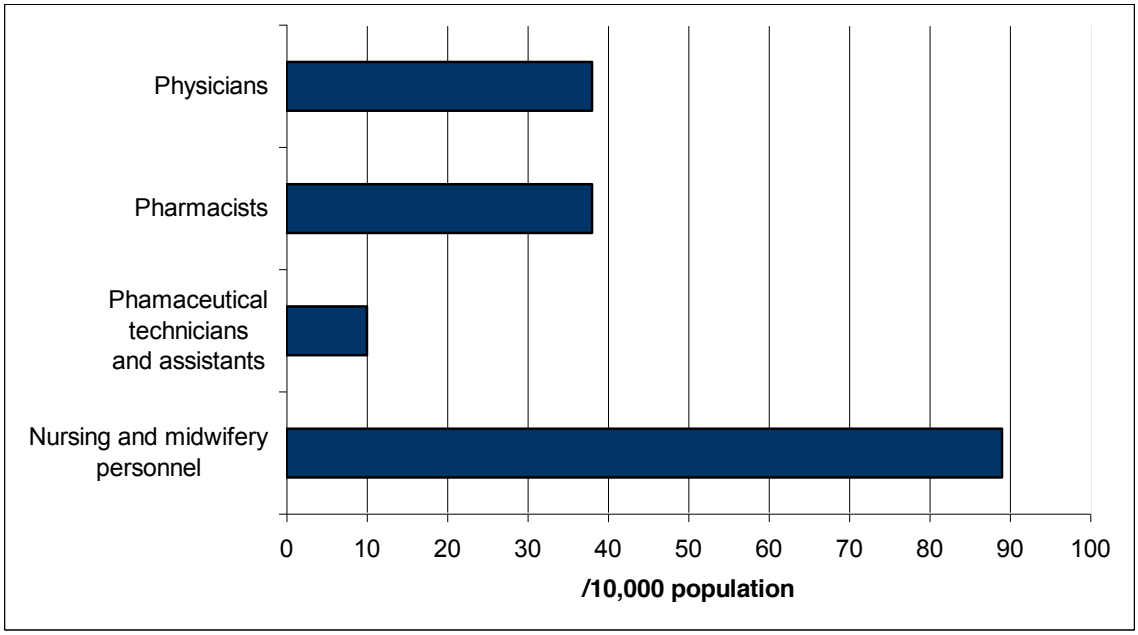
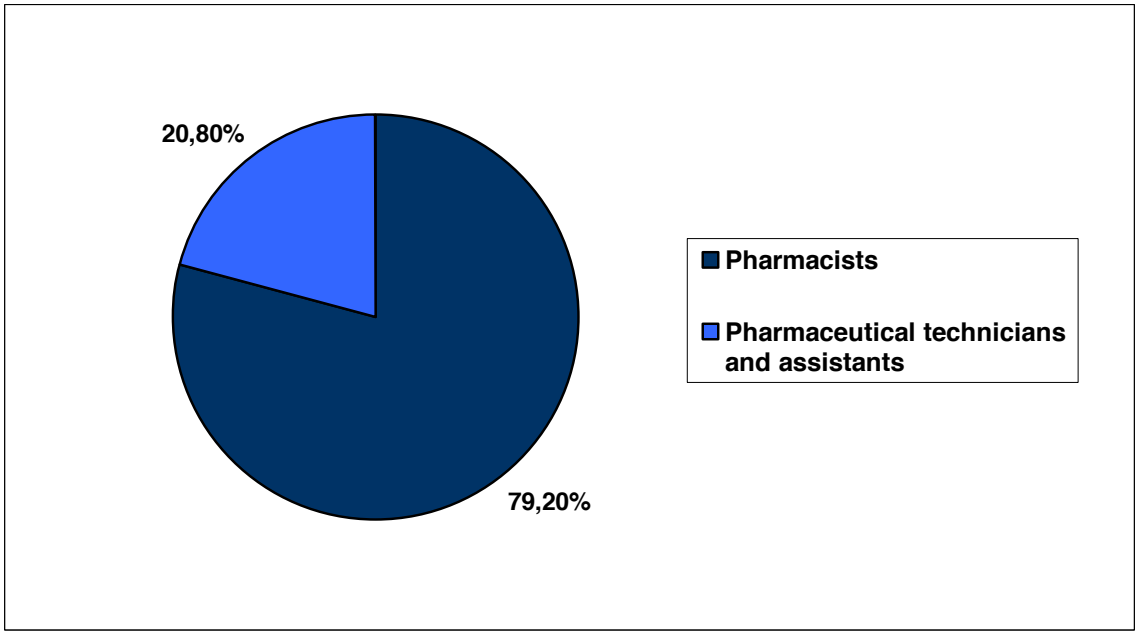


Figure 2. Distribution of Pharmaceutical Personnel



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

The health infrastructure is described in Table 4. There are three hospitals and 240 hospital beds[9] in Dominica. There are 52 primary health care units and centres and 12 licensed pharmacies[7].

Table 4. Health infrastructure

Infrastructure	
Hospitals	3
Hospital beds	240 (32.9/10,000 pop)
Primary health care units and centres	52
Licensed pharmacies	12

The annual starting salary for a newly registered pharmacist in the public sector is EC$ 26,009.04. There are no Pharmacy schools in Dominica.

Section 3 - Policy Issues

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

3.1 Policy Framework

In Dominica, a National Health Policy (NHP) does not exist. An official National Medicines Policy (NMP) document does not either exist[7].

Specific policies addressing selection of essential medicines, financing, pricing, procurement, distribution, regulation, pharmacovigilance, rational use, human resource development, research, monitoring and evaluation or traditional medicine; do not exist at present.

A policy relating to clinical laboratories does not exist. Access to essential medicines/technologies as part of the fulfillment of the right to health, is not recognized in the constitution or national legislation[10]. There are official written guidelines on medicines donations.

There is no national good governance policy in Dominica. A policy is not in place to manage and sanction conflict of interest issues in pharmaceutical affairs. There is an associated formal code of conduct for public officials. A whistle-blowing mechanism that allows individuals to raise concerns about wrongdoing occurring in the pharmaceutical sector does not exist.

Section 4 – Medicines Trade and Production

In this section, information regarding intellectual property and capacity for manufacturing medicines is provided.

4.1 Intellectual Property Laws and Medicines

Dominica is a member of the World Trade Organization (WTO)[11]. Legal provisions provide for granting of patents on pharmaceuticals, laboratory supplies, medical supplies and medical equipment[12].

Intellectual Property Rights are managed and enforced by the Companies and Intellectual Property Office[ii].

National Legislation has been modified to implement the Trade Related aspects of Intellectual Property Rights (TRIPS) Agreement[10]. The law does not contain TRIPS-specific flexibilities and safeguards[10] (Table 5).

[ii] Companies and Intellectual Property Office - 21 Kennedy Ave. Roseau, Commonwealth of Dominica.

Table 5. TRIPS flexibilities and safeguards

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

The country is not engaged in capacity-strengthening initiatives to manage and apply Intellectual Property Rights (IPR) in order to contribute to innovation and promote public health.

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

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

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

This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada - Patent Protection for Pharmaceutical Products")

[In: WTO OMC Fact sheet: TRIPS and pharmaceutical patents, can be found on line at: http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]

4.2 Manufacturing

There are no licensed pharmaceutical manufacturers in Dominica[7]. The country has no manufacturing capabilities[7] (Table 6).

Table 6. Manufacturing capabilities

Manufacturing capabilities	
Research and Development (R&D) for discovering new active substances	No
Production of active pharmaceutical ingredients (APIs)	No
Production of formulations from pharmaceutical starting material	No
Repackaging of finished dosage forms	No

Section 5 – Medicines Regulation

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

5.1 Regulatory Framework

In Dominica, there are no Medicines Regulatory Authority (MRA)[7]. Health Research for Action (HERA) conducted an assessment of the medicines regulatory system in 2009.

5.2 Marketing Authorization (Registration)

In Dominica, legal provisions do not require marketing authorization (registration) for pharmaceutical products on the market[7]. Mutual recognition mechanisms are not in place. Information from the WHO prequalification programme is not used.

5.3 Regulatory Inspection

In Dominica, legal provisions do not exist allowing for appointment of government pharmaceutical inspectors. Legal provisions do not exist permitting inspectors to inspect premises where pharmaceutical activities are performed. Government pharmacies are, however, annually inspected by the Chief Pharmacist (see Table 7).

Table 7. Local entities inspected by the Government

Entity	Inspection	Frequency
Local manufacturers	N/A	N/A
Private wholesalers	No	N/A
Retail distributors	No	N/A
Public pharmacies and stores	Yes	Annual
Pharmacies and dispensing points of health facilities	Yes	Annual

5.4 Import Control

Legal provisions do not exist requiring authorization to import medicines[iv]. Laws do not exist that allow the sampling of imported products for testing. Legal provisions do not either exist requiring importation of medicines through authorized ports of entry. Regulations or laws do not exist to allow for inspection of imported pharmaceutical products at authorized ports of entry.

5.5 Licensing

Legal provisions do not exist requiring importers, wholesalers or distributors to be licensed. There are no national Good Distribution Practices (GDP) requirements.

Legal provisions exist requiring pharmacists to be registered. Legal provisions also exist requiring private pharmacies to be licensed. National Good Pharmacy

[iv] There is a draft Pharmacy Act (2010) that makes provisions for the importation of medicines.

Practices (GPP) are not published by the government. By law, a list of all licensed pharmaceutical facilities is not required to be published.

5.6 Market Control and Quality Control

In Dominica, legal provisions do not exist for controlling the pharmaceutical market. A laboratory does not exist in the country for Quality Control testing. However, CARICOM member states can send samples to the Caribbean Regional Drug Testing Laboratory (CRDTL) in Jamaica.

Medicines are tested for a number of reasons, summarised in Table 8.

Table 8. Reason for medicines testing

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

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

The results of the products analyzed are not publicly available.

[v] Routine sampling in pharmacy stores and health facilities

[vi] Routine sampling in retail outlets

5.7 Medicines Advertising and Promotion

In Dominica, legal provisions do not exist to control the promotion or advertising of prescription medicines. However, the Ministry of Health is responsible for regulating this matter. Legal provisions do not prohibit direct advertising of prescription medicines to the public and pre-approval for medicines advertisements and promotional materials is not required. Guidelines do not exist for advertising and promotion of non-prescription medicines.

5.8 Clinical Trials

In Dominica, legal provisions do not exist requiring authorization for conducting Clinical Trials. There are no additional laws requiring the agreement by an ethics committee or institutional review board of the Clinical Trials to be performed. Clinical Trials are not required to be entered into an international, national, or regional registry.

5.9 Controlled Medicines

Dominica is a signatory to a number of international conventions[13], detailed in Table 9.

Table 9. International Conventions to which Dominica is a signatory

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

Laws exist for the control of narcotic and psychotropic substances, and precursors. However, the legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have not been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need.

The annual consumption of certain controlled substances in the country is presented in Table 10.

Table 10. Consumption of controlled substances

Substance	Annual consumption (mg/capita)
Morphine	0.089552
Pethidine	7.014925
Oxycodone	0.000000
Phenobarbital	0.000000
Methadone	0.000000
Hydrocodone	0.000000

5.10 Pharmacovigilance

In Dominica, there are no legal provisions that provide for pharmacovigilance activities**.** Laws regarding the monitoring of Adverse Drug Reactions (ADR) do not exist in the country. A national pharmacovigilance centre does not exist. ADRs are monitored in at least one public health program.

An official standardized form for reporting ADRs is used. Information pertaining to ADRs is however, not stored in a national ADR database. The reports are submitted to the OECS Pharmaceutical Procurement Service (PPS)[14] for onward submission to the Monitoring Centre in Uppsala[15].

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

In the past two years, doctors, nurses and pharmacists have reported ADRs. No regulatory decision based on local pharmacovigilance data has been taken in the same period.

There are no training courses on pharmacovigilance.

Section 6 - Medicines Financing

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

6.1 Medicines Coverage and Exemptions

In Dominica, concessions are made for certain groups to receive medicines free of charge (see Table 11). Furthermore, the public health system provides medicines at no cost for particular conditions (see Table 12).

Table 11. Population groups provided with medicines free of charge

Patient group	Covered
Patients who cannot afford them	Yes
Children under 5	Yes
Pregnant women	Yes
Elderly persons	Yes

Table 12. Medications provided publicly, at no cost

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

All patients receive medications at no cost at Government health care facilities.

Private health insurance schemes provide different levels of medicines coverage. They are required to provide at least partial coverage for medicines that are on the EML.

6.2 Patients Fees and Copayments

Copayments or fee requirements for consultations are not levied at the point of delivery. Furthermore, there are no copayments or fee requirements imposed for medicines. Revenue from fees or from the sale of medicines is not used to pay the salaries or supplement the income of public health personnel in the same facility.

6.3 Pricing Regulation for the Private Sector[vii]

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

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

6.4 Prices, Availability and Affordability of Key Medicines

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

6.5 Price Components

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

6.6 Duties and Taxes on Pharmaceuticals (Market)

Dominica imposes duties on imported active pharmaceutical ingredients (APIs) and on imported finished products[16]. Value-added tax (VAT) is also imposed on

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

finished pharmaceutical products. Taxes are waived on pharmaceutical donations.

Duties and taxes imposed on pharmaceuticals are shown in Table 13.

Table 13. Duties and taxes imposed on pharmaceuticals

Description	Percentage
Duty on imported APIs	0 – 5%
Duty on imported finished products	5 – 10%
VAT on pharmaceuticals	15%

Section 7 - Pharmaceutical procurement and distribution

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

7.1 Public Sector Procurement

Public sector procurement in Dominica is mainly conducted [viii] through the OECS/PPS[7]. For additional procurement the Central Medical Stores only uses known suppliers[7].

Public sector requests for tender documents and tender awards are not publicly available. Procurement is based on the prequalification of suppliers.

There is no written public sector procurement policy. The key functions of the procurement unit and those of the tender committee are not clearly separated[12]. A process exists to ensure the quality of products that are publicly procured. The quality assurance process includes the prequalification of products and suppliers. A list of prequalified suppliers and products is available. The tender methods employed in public sector procurement include international competitive tenders and direct purchasing.

[viii] Approximately 95% of pharmaceuticals are procured through the OECS/PPS.

7.2 Public Sector Distribution

The government supply system department in Dominica has a Central Medical Store (CMS) at National Level[7]. There are no public warehouses in the secondary tier of the public sector distribution. There no national guidelines or requirements on Good Distribution Practices (GDP).

A number of processes are in place at the CMS as detailed in Table 14.

Table 14. Processes in place at the CMS

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

The percentage availability of key medicines at the CMS is 93%[14]. The average stock-out duration at the CMS is 3 days[14].

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

7.3 Private Sector Distribution

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

Section 8 - Selection and rational use of medicines

This section outlines the structures and policies governing the selection of essential medicines and promotion of rational use of medicines (RUM) Dominica.

8.1 National Structures

The OECS/PPS Essential Medicines List (EML) is used by the public sector as reference. The EML was lastly updated in 2009 and is publicly available. There are currently 551 medicines on the EML. Selection of medicines for the EML is undertaken through a written process.

A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is not in place. Specific STGs for primary care and for some priority conditions (e.g. hypertension, diabetes, etc) exist. 100% of the public health facilities have a copy of the EML (survey data).

There is no public or independently funded national medicines information centre. Public education campaigns on RUM have not been conducted in the last two years. A survey on rational use of medicines has not been conducted in the same period. There is no national programme or committee to monitor and promote RUM.

The OECS EML includes specific formulations for children. Criteria for the selection of medicines to the EML are explicitly documented. A national medicines formulary does exist.

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

8.2 Prescribing

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

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

The training curriculum for doctors includes problem-based pharmacotherapy. Nevertheless, mandatory continuing education that includes pharmaceutical issues is not required for doctors, nurses or paramedical staff.

Prescribing by INN name is obligatory only in the public sector. The average number of medicines prescribed per patient contact in public health facilities is 4. Of the medicines prescribed in the outpatient public health care facilities, 90% are on the EML and 95% are prescribed by INN name. Of the patients treated in the outpatient public health care facilities, 90% receive antibiotics and 92% receive injections. Of prescribed drugs, 90% are dispended to patients. Of medicines in public health facilities, 95% are adequately labelled.

Table 15. Characteristics of medicines prescribing

Curriculum	%
% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	90
% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	95
% of patients in outpatient public health care facilities receiving antibiotics (mean)	90
% of patients in outpatient public health care facilities receiving injections (mean)	92
% of prescribed drugs dispensed to patients (mean)	90
% of medicines adequately labelled in public health facilities (mean)	95

A professional association code of conduct to govern the professional behaviour of doctors and nurses exist.

8.3 Dispensing

Legal provisions in Dominica exist to govern dispensing practices of pharmaceutical personnel. Mandatory continuing education that includes rational use of medicines is required for pharmacists.

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

A professional association code of conduct governing professional behaviour of pharmacists does not exist. In practice nurses and pharmacists sometimes prescribe prescription-only medicines at the primary care level in the public sector.

..

[1] Government of the Commonwealth of Dominica, Ministry of Finance, Central Statistical Office (CSO). Available online: http://www.dominica.gov.dm/cms/index.php?q=node/28

[2] Kairi Consultants Limited, Country Poverty Assessment – Dominica, Final Report, Volume 1, December 2010. Available online: http://www.caribank.org/titanweb/cdb/webcms.nsf/AllDoc/ACFD2519B736DA5A0425785C005A6513/$File/Dominica%20CPA%20-%20Main%20Report%20Final%20(Submitted).pdf!OpenElement

[3] Government of the Commonwealth of Dominica, Ministry of Health, Health Information Unit. Available online: http://www.dominica.gov.dm/cms/?q=node/21

[4] World Health Organization (WHO), International Classification of Diseases (ICD-10). Available online: http://www.who.int/classifications/icd/en/

[5] World Health Organization (WHO), National Health Account for Dominica. Available online: http://www.who.int/nha/country/dma/en/

[6] Government of the Commonwealth of Dominica, Ministry of Finance, Approved Government 2009/2010 Estimates.

[7] 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

[8] World Health Organization (WHO), World Health Statistics 2010, Geneva. Available online: http://www.who.int/entity/whosis/whostat/EN_WHS10_Full.pdf

[9] World Health Organization (WHO), World Health Statistics 2011, Geneva. Available online: http://www.who.int/entity/whosis/whostat/EN_WHS11_Full.pdf

[10] 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

[11] World Trade Organization (WTO). Available online: http://www.wto.org/

[12] World Health Organization (WHO), Level I Monitoring Inditacators – Pharmaceutical Situation, 2007.

[13] International Narcotics Control Board. Available online: http://www.incb.org

[14] Organisation of Eastern Caribbean States (OECS). Available online: http://www.oecs.org/

[15] The Uppsala Monitoring Centre. Available online: http://www.who-umc.org/

[16] Common External Tariff of the Caribbean Community, 2007

COMMONWEALTH OF DOMINICA
Pharmaceutical Country Profile

ANNEX

Survey Data

(Fragment of the instrument sent to the country by the Pan American Health Organization/World Health Organization PAHO/WHO)

2011

Section 0 General Info

0.01 Contact Info

0.01.01	Country	Commonwealth Of Dominica
0.01.02	Name coordinator	Errol Thomas
0.01.03	Address (Street, City)	Central Medical Stores, Ministry Of Health, Goodwill, Roseau
0.01.04	Phone number	1 767 448 2060
0.01.05	Email address	cms@dominica.gov.dm
0.01.06	Web address	www.dominica.gov.dm
0.01.07	Institution	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	Prayma Carrette – Chief Statistician, Central Statistical Office Marva Smith – Statistics Officer, Health Information Unit
1.00.02	Phone number	1 767 266 3400 / 767 266 3458
1.00.03	Email address	cso@dominica.gov.dm smithm@dominica.gov.dm
1.00.04	Other respondents for filling out this section	Stephen Nicholas

1.01 Demographic and Socioeconomic Indicators

Core questions (click here for help)

			Year	Source
1.01.01	Population, total (,000)	72.9	2010	CSO
1.01.02	Population growth rate (Annual %)	0.46	2010	CSO
1.01.03	Total Gross Domestic Product (GDP) (millions US$)	473.11	2010	CSO
1.01.04	GDP growth (Annual %)	1.3	2010	CSO
1.01.05C	GDP per capita (US$ current exchange rate)	6,487.00	2010	CSO
1.01.06	Comments and References	Data from the Central Statistics Office was obtained from The Demographic Statistics Report 2010 and the National Accounts Report 2009.		

Supplementary questions (click here for help)

			Year	Source
1.01.07S	Population < 15 years (% of total population)	39.02	2010	CSO
1.01.08S	Population > 60 years (% of total population)	13.38	2010	CSO
1.01.09S	Urban population (% of total	47.2	2001	CSO

	population)			
1.01.10S	Fertility rate, total (Births per woman)	2.6	2009	CSO
1.01.11S	Population living with less than $1.25/day (international PPP) (%)			
1.01.12S	Population living below nationally defined poverty line (%)	28.8	2009	Survey of Living Conditions
1.01.13S	Income share held by lowest 20% of the population (% of national income)	5.2	2009	Survey of Living Conditions
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)			
1.01.15S	Comments and References	Data from the Central Statistics Office was obtained from The Demographic Statistics Report 2009.		

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)	73.54	2010	Central Statistics Office
1.02.02	Life expectancy at birth for women (Years)	78.17	2010	Central Statistics Office
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)	13.9	2010	Health Information Unit
1.02.04	Under 5 mortality rate (/1,000 live births)	15.1	2008	Health Information Unit
1.02.05	Maternal mortality ratio (/100,000 live births)	214.6	2010	Health Information Unit
1.02.06	Please provide a list of top 10 diseases causing mortality		2010	Health Information Unit

1.02.06.01	Disease 1	Cerebrovascular Diseases (I60-I69)		
1.02.06.02	Disease 2	Diabetes Mellitus (E10-E14)		
1.02.06.03	Disease 3	Ischemic Heart Disease (I20-I25)		
1.02.06.04	Disease 4	Hypertensive Disease (I10-I15)		
1.02.06.05	Disease 5	Pulmonary heart disease, diseases of pulmonary circulation and other forms of heart disease (I26-I45, I47-I49, I51)		
1.02.06.06	Disease 6	Acute respiratory infection (J00-J22)		
1.02.06.07	Disease 7	Malignant neoplasm of digestive organs and peritoneum, except stomach and colon (C15,C17,C20-C26, C48)		
1.02.06.08	Disease 8	Chronic lower respiratory diseases (J40-J47)		
1.02.06.09	Disease 9	Assault (homicide) (X85-Y09)		
1.02.06.10	Disease 10	Malignant neoplasm of trachea, bronchus and lung (C33-C34)		
1.02.07	Please provide a list of top 10 diseases causing morbidity		2010	Health Information Unit
1.02.07.01	Disease 1	Heart Disease		
1.02.07.02	Disease 2	Hypertensive Disease		
1.02.07.03	Disease 3	Diabetes Mellitus		
1.02.07.04	Disease 4	Cancer		
1.02.07.05	Disease 5	Respiratory Illnesses		
1.02.07.06	Disease 6	Injuries		
1.02.07.07	Disease 7	Cerebrovascular Diseases		
1.02.07.08	Disease 8	Gastroenteritis		
1.02.07.09	Disease 9	Influenza like illnesses		
1.02.07.10	Disease 10	Dengue		

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)	1.8	2010	Health Information Unit
1.02.10S	Neonatal mortality rate (/1,000 live births)	17.0	2010	Health Information Unit
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	630.98	2010	Health Information Unit
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	107.87	2010	Health Information Unit
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	167	2010	Health Information Unit
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	4.1	2010	Health Information Unit
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	0	2010	Health Information Unit
1.02.16S	Mortality rate for Malaria (/100,000 population)	0	2010	Health Information Unit
1.02.17S	Comments and References			

Section 2 Health Services

2.00 Respondent Information Section 2

2.00.01	Name of person responsible for filling out this section of the instrument	Mrs. George, Ministry of Finance
2.00.02	Phone number	767 266 3923
2.00.03	Email address	
2.00.04	Other respondents for filling out this section	Mr. Stephen Nicholas, Central Statistics Office

2.01 Health Expenditures

Core questions (click here for help)

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)	60.77	2008	NHA
2.01.01.02	Total annual expenditure on health (millions US$ average exchange rate)	22.51	2008	NHA
2.01.02C	Total health expenditure as % of Gross Domestic Product	4.76		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	833.61		
2.01.03.02C	Total annual expenditure on health per capita (US$ average exchange rate)	308.78		
2.01.04.01	General government annual expenditure on health (millions NCU)	37.97	2008	NHA
2.01.04.02	General government annual expenditure on health (millions US$ average exchange rate)	14.06	2008	NHA
2.01.05	Government annual expenditure on health as percentage of total government budget (% of total	8.20	2008	NHA

	government budget)			
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	62.48	2008	NHA
2.01.07.01C	Annual per capita government expenditure on health (NCU)	520.85		
2.01.07.02C	Annual per capita government expenditure on health (US$ average exchange rate)	192.87		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	37.52	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)			
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)			
2.01.12.02C	Total pharmaceutical expenditure per capita (US$ current exchange rate)			
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)			
2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)			

2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)	4.89	2009	Ministry of Finance Approved Government 2009/2010 Estimates
2.01.15.02	Total public expenditure on pharmaceuticals (millions US$ current exchange rate)	1.81	2009	Ministry of Finance Approved Government 2009/2010 Estimates
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)	67.08		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	24.84		
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	Data was collected from the 2009/2010 Approved Government Estimates, and from the Central Statistics Office		

Supplementary questions (click for help)

			Year	Source
2.01.20S	Social security expenditure as % of government expenditure on health (% of government expenditure on health)	0.00	2008	NHA
2.01.21S	Market share of generic pharmaceuticals [branded and INN] by value (%)		2011	MOH

2.01.22S	Annual growth rate of total pharmaceuticals market value (%)		2011	MOH
2.01.23S	Annual growth rate of generic pharmaceuticals market value (%)		2011	MOH
2.01.24S	Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)	84.21	2008	NHA
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	15.79	2008	NHA
2.01.26S	Comments and References	All Pharmaceuticals are imported into the country		

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	38	2011	MOH
2.02.02C	Pharmacists per 10,000 population	5.21		
2.02.03	Total number of pharmacists working in the public sector	16	2009	CARICOM DRA HERA REPORT VOLUME II
2.02.04	Total number of pharmaceutical technicians and assistants	10	2011	MOH
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes ☐ No ☒	2011	MOH
2.02.06	Total number of physicians	38	2009	WHS

2.02.07C	Physicians per 10,000 pop	5.21		
2.02.08	Total number of nursing and midwifery personnel	89	2011	MOH
2.02.09C	Nurses and midwives per 10,000 pop	13		
2.02.10	Total number of hospitals	3	2011	MOH
2.02.11	Total number of hospitals bed	240	2011	WHS
2.02.12	Total number of primary health care units and centers	52	2011	MOH
2.02.13	Total number of licensed pharmacies	12	2009	CARICOM DRA HERA REPORT VOLUME II
2.02.14	Comments and References			

Supplementary questions (click here for help)

			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist in the public sector (NCU)	26,009.04	2011	MOH
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country	0	2011	MOH
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes ☐ No X	2011	MOH
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes ☐ No X	2011	MOH
2.02.19S	Comments and References	No Pharmacy school in Dominica		

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	Errol Thomas		
3.00.02	Phone number	1 767 448 2060		
3.00.03	Email address	cms@dominica.gov.dm		
3.00.04	Other respondents for filling out this section			

3.01 Policy Framework

Core questions (click here for help)

			Year	Source
3.01.01	National Health Policy exists. If yes, please write year of the most recent document in the "year" field.	Yes ☐ No X	2011	MOH
3.01.02	National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the "year"	Yes ☐ No X	2011	MOH
3.01.03	Please provide comments on the Health policy and its implementation plan	0		
3.01.04	National Medicines Policy official document exists. If yes, please write the year of the most recent document in the "year" field.	Yes ☐ No X	2009	CARICOM DRA HERA REPORT VOLUME II
3.01.05	Group of policies addressing pharmaceuticals exist.	Yes ☐ No X	2011	MOH
3.01.06	National Medicines Policy covers the following components:			

3.01.06.01	Selection of Essential Medicines	☐Yes		
3.01.06.02	Medicines Financing	☐Yes		
3.01.06.03	Medicines Pricing	☐Yes		
3.01.06.04	Medicines Procurement	☐Yes		
3.01.06.05	Medicines Distribution	☐Yes		
3.01.06.06	Medicines Regulation	☐Yes		
3.01.06.07	Pharmacovigilance	☐No		
3.01.06.08	Rational Use of Medicines	☐Yes		
3.01.06.09	Human Resource Development	☐Yes		
3.01.06.10	Research	☐Yes		
3.01.06.11	Monitoring and Evaluation	☐Yes		
3.01.06.12	Traditional Medicine	☐Yes		
3.01.07	National medicines policy implementation plan exists. If yes, please write year of the most recent document.	Yes ☐ No X	2009	CARICOM IP HERA REPORT VOLUME II
3.01.08	Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in the "year" field	Yes ☐ No X	2011	MOH
3.01.09	National clinical laboratory policy implementation plan exists. If yes, please write year of the most recent document in the "year" field	Yes ☐ No X	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	Yes ☐ No X	2009	CARICOM IP HERA REPORT VOLUME II

	national legislation?			
3.01.11	There are official written guidelines on medicines donations.	Yes X No ☐	2009	MOH
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes ☐ No X	2011	MOH
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	There is no Pharmaceutical policy		
3.01.13	Is there a national good governance policy?	Yes ☐ No X	2011	MOH
3.01.13.01	Multisectoral	☐Yes X	2011	MOH
3.01.13.02	For the pharmaceutical sector	☐Yes X	2011	MOH
3.01.13.03	Which agencies are responsible?			
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes ☐ No X	2011	MOH
3.01.15	There is a formal code of conduct for public officials.	Yes X No ☐	2011	MOH
3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes ☐ No X	2011	MOH
3.01.16.01	Please describe:			
3.01.17	Comments and References	Draft medicines policy 1999		

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	Ms. Sandra Julien
4.00.02	Phone number	1 767 266 3353
4.00.03	Email address	cipo@cwdom.dm
4.00.04	Other respondents for filling out this section	Errol Thomas

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 X No☐	1995	WTO
4.01.02	Legal provisions provide for granting of Patents on:		2007	WHO LEVEL I AND MOH 2011
4.01.02.01	Pharmaceuticals	Yes X No☐		
4.01.02.02	Laboratory supplies	Yes X No ☐		
4.01.02.03	Medical supplies	Yes X No ☐		
4.01.02.04	Medical equipment	Yes X No ☐		
4.01.03.01	Please provide name and address of the institution responsible for managing and enforcing intellectual property rights	Companies & Intellectual Property Office, 21 Kennedy AVE, Roseau, Commonwealth of Dominica.		
4.01.03.02	Please provide URL			
4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes X No ☐	2009	CARICOM IP HERA REPORT

				VOLUME II
4.01.05	Current laws contain (TRIPS) flexibilities and safeguards	Yes X No☐	2009	CARICOM IP HERA REPORT VOLUME II
4.01.06	Country is eligible for the transitional period to 2016	Yes ☐ No☐		
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2009	CARICOM IP HERA REPORT VOLUME II
4.01.07.01	Compulsory licensing provisions that can be applied for reasons of public health	Yes ☐ No X	2011	MOH
4.01.07.02	Bolar exception	Yes ☐ No X	2011	MOH
4.01.08	Are parallel importing provisions present in the national law?	Yes ☐ No X	2009	CARICOM IP HERA REPORT VOLUME II
4.01.09	The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes No X	2011	MOH
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes ☐ No X	2011	MOH
4.01.11	Legal provisions exist for patent extension	Yes ☐ No X	2011	MOH
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes ☐ No X	2011	MOH
4.01.13	Comments and References			

4.02 Manufacturing

Core questions (click here for help)

			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country	0	2009	CARICOM DRA HERA REPORT VOLUME II
4.02.02	Country has manufacturing capacity		2009	CARICOM DRA HERA REPORT VOLUME II
4.02.02.01	R&D to discover new active substances	Yes ☐ No X Unknown	2011	MOH
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes ☐ No X Unknown	2011	MOH
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes ☐ No X Unknown	2011	MOH
4.02.02.04	Repackaging of finished dosage forms	Yes ☐ No X Unknown	2011	MOH
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)	Not Available	2011	MOH
4.02.04	Comments and References			

Supplementary questions (click here for help)

			Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%)	Not Available	2011	MOH
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally	NIL	2011	MOH

4.02.07S	Number of manufacturers that are Good Manufacturing Practice (GMP) certified	NIL	2011	MOH
4.02.08S	Comments and References	No Pharmaceutical Manufacturing Done in Dominica		

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	Errol Thomas
5.00.02	Phone number	1 767 448 2060
5.00.03	Email address	cms@dominica.gov.dm
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 ☐ No X	2009	CARICOM DRA HERA REPORT VOLUME II
5.01.02	There is a Medicines Regulatory Authority	Yes ☐ No X	2009	CARICOM DRA HERA REPORT VOLUME II
5.01.03	If yes, please provide name and address of the Medicines regulatory authority			
5.01.04	The Medicines Regulatory Authority is:		2011	MOH
5.01.04.01	Part of MoH	☐Yes No X		
5.01.04.02	Semi autonomous agency	☐Yes No X		
5.01.04.03	Other (please specify)			
5.01.05	What are the functions of the National Medicines Regulatory Authority?			

5.01.05.01	Marketing authorization / registration	Yes ☐ No ☐		
5.01.05.02	Inspection	Yes ☐ No ☐		
5.01.05.03	Import control	Yes ☐ No ☐		
5.01.05.04	Licensing	Yes ☐ No ☐		
5.01.05.05	Market control	Yes ☐ No ☐		
5.01.05.06	Quality control	Yes ☐ No ☐		
5.01.05.07	Medicines advertising and promotion	Yes ☐ No ☐		
5.01.05.08	Clinical trials control	Yes ☐ No ☐		
5.01.05.09	Pharmacovigilance	Yes ☐ No ☐		
5.01.05.10	Other: (please explain)			
5.01.06	Number of the MRA permanent staff			
5.01.06.01	Date of response			
5.01.07	The MRA has its own website	Yes ☐ No ☐		
5.01.07.01	- If yes, please provide MRA Web site address (URL)			
5.01.08	The MRA receives external technical assistance	Yes ☐ No ☐		
5.01.08.01	If yes, please describe:			
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes ☐ No ☐		
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 X No	2009	CARICOM DRA HERA REPORT VOLUME II

5.01.11	Medicines Regulatory Authority gets funds from regular budget of the government.	Yes ☐ No ☐		
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☐ No ☐		
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ☐ No ☐		
5.01.13.01	- If yes, please specify			
5.01.14	Revenues derived from regulatory activities are kept with the Regulatory Authority	Yes ☐ No ☐		
5.01.15	The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes ☐ No ☐		
5.01.16	Comments and References	Dominica has no medicines regulatory Authority	2011	MOH

5.02 Marketing Authorization (Registration)

Core questions (click here for help)

			Year	Source
5.02.01	Legal provisions require a Marketing Authorization (registration) for all pharmaceutical products on the market	Yes No X	2009	CARICOM DRA HERA REPORT VOLUME II
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes No X	2011	MOH
5.02.03	Are there mechanisms for recognition of registration done by other	Yes No ☐ X	2011	MOH

	countries			
5.02.03.01	If yes, please explain:			
5.02.04	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes ☐ No X	2011	MOH
5.02.05	Information from the prequalification programme managed by WHO is used for product registration	Yes No X	2011	MOH
5.02.06	Number of pharmaceutical products registered in your country	Products are not registered in Dominica	2011	MOH
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes ☐ No X	2011	MOH
5.02.07.01	If yes, how frequently updated			
5.02.07.02	If yes, please provide updated list or URL *			
5.02.08	Medicines registration always includes the INN (International Non-proprietary Names)	Yes No ☐ X	2011	MOH
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes ☐ No X	2011	MOH
5.02.10	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
5.02.11S	Legal provisions require Marketing Authorization holders to provide information about variations to the existing Marketing Authorization	Yes ☐ No X	2011	MOH

5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes ☐ No X	2011	MOH
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☐ No X	2011	MOH
5.02.14S	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes ☐ No X	2011	MOH
5.02.15S	Legal provisions require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	Yes ☐ No X	2011	MOH
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes ☐ No X	2011	MOH
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US$)	0	2011	MOH
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US$)	0	2011	MOH
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)	0	2011	MOH
5.02.20S	Comments & References			

5.03 Regulatory Inspection

Core Questions(click here for help)

	Year	Source

5.03.01	Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes ☐ No X	2009	CARICOM DRA HERA REPORT VOLUME II
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes ☐ No X	2009	CARICOM DRA HERA REPORT VOLUME II
5.03.02.01	If yes, legal provisions exist requiring inspections to be performed	Yes ☐ No ☐		
5.03.03	Inspection is a pre-requisite for licensing of:			
5.03.03.01	Public facilities	Yes ☐ No ☐		
5.03.03.02	Private facilities	Yes ☐ No ☐		
5.03.04	Inspection requirements are the same for public and private facilities	Yes ☐ No ☐		
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes ☐ No ☐	2011	MOH
5.03.05.02	Private wholesalers are inspected	Yes ☐ No X		
5.03.05.03	Retail distributors are inspected	Yes ☐ No X		
5.03.05.04	Public pharmacies and stores are inspected	Yes X No ☐		
5.03.05.05	Pharmacies and dispensing points of health facilities are inspected	Yes X No ☐		
5.03.05.06	Please provide details on frequency of inspections for the different categories of facilities	Public pharmacies are inspected annually by Government's chief Pharmacist		
5.03.06	Comments and References	Inspection done only in Government Pharmacies		

5.04 Import Control

Core Questions (click here for help)				
			Year	Source
5.04.01	Legal provisions exist requiring authorization to import medicines	Yes ☐ No X	2011	MOH
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes ☐ No X	2011	MOH
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes ☐ No X	2011	MOH
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes ☐ No X	2011	MOH
5.04.05	Comments and References	There is a draft Pharmacy act of 2010 that makes provision for the importation of medicines.		
5.05 Licensing				
			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes ☐ No X	2011	MOH
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes ☐ No X	2011	MOH
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by the government.	Yes ☐ No X	2011	MOH
5.05.04	Legal provisions exist requiring importers to be licensed	Yes ☐ No X	2011	MOH
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ☐ No X	2011	MOH

5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices **When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)**	Yes ☐ No X	2011	MOH
5.05.07	National Good Distribution Practice requirements are published by the government	Yes ☐ No X	2011	MOH
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes X No ☐	2011	MOH
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes X No ☐	2011	MOH
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes No X	2011	MOH
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes ☐ No X	2011	MOH
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes ☐ No X	2011	MOH
5.05.13	Comments and References	Pharmaceuticals are not manufactured in Dominica		

5.06 Market Control and Quality Control

Core Questions (click here for help)

			Year	Source
5.06.01	Legal Provisions for regulating the pharmaceutical market exist	Yes ☐ No X	2011	MOH
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes ☐ No X	2011	MOH

5.06.02.01	If yes, is the laboratory part of the MRA?	Yes ☐ No ☐		
5.06.02.02	Does the regulatory authority contract services elsewhere?	Yes X No		
5.06.02.03	If yes, please describe	CRDTL: as CARICOM Members have access to the Caribbean Drug Test 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 X No ☐		
5.06.04.02	For quality monitoring in private sector (routine sampling in retail outlets)	Yes ☐ No X		
5.06.04.03	When there are complaints or problem reports	Yes X No ☐		
5.06.04.04	For product registration	Yes ☐ No X		
5.06.04.05	For public procurement prequalification	Yes ☐ No X		
5.06.04.06	For public program products prior to acceptance and/or distribution	Yes ☐ No X		
5.06.05	Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes ☐ No X	2011	MOH
5.06.06	How many Quality Control samples were taken for testing in the last two years?	Not Available	2011	MOH

5.06.07	Total number of samples tested in the last two years that failed to meet quality standards	Not Available	2011	MOH
5.06.08	Results of quality testing in past two years are publicly available	Yes ☐ No X	2011	MOH
5.06.09	Comments and References	5.06.02.02 Medicines from the public sector are sent to Caribbean Regional Drug Testing Laboratory for testing in Jamaica. - CARICOM DRA HERA REPORT VOLUME II		

5.07 Medicines Advertising and Promotion

Core Questions (click here for help)

			Year	Source
5.07.01	Legal provisions exist to control the promotion and/or advertising of prescription medicines	Yes ☐ No X	2011	MOH
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Ministry Of Health		
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes ☐ No X	2011	MOH
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional materials	Yes ☐ No X	2011	MOH
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes ☐ No X	2011	MOH
5.07.06	A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly	Yes ☐ No X	2011	MOH

	available			
5.07.06.01	If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both			
	Domestic only	☐Yes		
	Multinational only	☐Yes		
	Both	☐Yes		
5.07.06.02	If yes, adherence to the code is voluntary	Yes ☐ No ☐		
5.07.06.03	If yes, the code contains a formal process for complaints and sanctions	Yes ☐ No ☐		
5.07.06.04	If yes, list of complaints and sanctions for the last two years is publicly available	Yes ☐ No ☐		
5.07.07	Comments and References			

5.08 Clinical trials

Core Questions (click here for help)

			Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes ☐ No X	2011	MOH
5.08.02	Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes ☐ No X	2011	MOH
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes ☐ No X	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 ☐ No X	2011	MOH
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes ☐ No X	2011	MOH
5.08.07S	National GCP regulations are published by the Government.	Yes ☐ No X	2011	MOH
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☐ No X	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 X No ☐	1993	International Narcotics control Board
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes X No ☐	1993	INCB
5.09.01.03	Convention on Psychotropic Substances 1971	Yes X No ☐	1993	INCB
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes X No ☐	1993	INCB

5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes X No ☐	2011	MOH
5.09.03	Annual consumption of Morphine (mg/capita)	0.089552	2009	INCB
5.09.04	Comments and References			

Supplementary questions (click here for help)

			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Yes ☐ No X Unknown ☐	2011	MOH
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)			
5.09.07S	Annual consumption of Pethidine (mg/capita)	7.014925	2009	INCB
5.09.08S	Annual consumption of Oxycodone (mg/capita)	0	2011	MOH
5.09.09S	Annual consumption of Hydrocodone (mg/capita)	0	2011	MOH
5.09.10S	Annual consumption of Phenobarbital (mg/capita)	0	2011	MOH
5.09.11S	Annual consumption of Methadone (mg/capita)	0	2011	MOH
5.09.12S	Comments and References			

5.10 Pharmacovigilance

Core Questions (click here for help)				
			Year	Source
5.10.01	There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	Yes ☐ No X	2011	MOH
5.10.02	Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA	Yes ☐ No X	2011	MOH
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes ☐ No X	2011	MOH
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes ☐ No X	2011	MOH
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time			
5.10.04.02	If a national pharmacovigilance center exists in your country, an analysis report has been published in the last two years.	Yes ☐ No ☐		
5.10.04.03	If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes ☐ No ☐		
5.10.05	An official standardized form for reporting ADRs is used in your country	Yes X No ☐	2011	MOH
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes ☐ No X	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 X No ☐	2011	MOH
5.10.09.01	If yes, number of reports sent in the last two years			
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication?	Yes ☐ No X	2011	MOH
5.10.11	Is there a clear communication strategy for routine communication and crises communication?	Yes ☐ No X	2011	MOH
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 X No ☐	2011	MOH
5.10.13	Please describe how you intend to enhance the Pharmacovigilance system			
5.10.14	Comments and References	All ADRs reports are submitted to OECS Pharmaceutical Procurement Service for onward submission to Uppsala		

Supplementary questions (click here for help)

			Year	Source
5.10.15S	Feedback is provided to reporters	Yes ☐ No ☐		
5.10.16S	The ADR database is computerized	Yes ☐ No ☐		
5.10.17S	Medication errors (MEs) are reported	Yes ☐ No ☐		
5.10.18S	How many MEs are there in the			

	ADRs database?			
5.10.19S	There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes ☐ No X	2011	MOH
5.10.20S	In the past two years, who has reported ADRs?			
5.10.20.01S	Doctors	X Yes		
5.10.20.02S	Nurses	X Yes		
5.10.20.03S	Pharmacists	X Yes		
5.10.20.04S	Consumers	☐Yes		
5.10.20.05S	Pharmaceutical Companies	☐Yes		
5.10.20.06S	Others, please specify whom			
5.10.21S	Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?	Yes ☐ No X	2011	MOH
5.10.22S	Are there training courses in pharmacovigilance?	Yes ☐ No X	2011	MOH
5.10.22.01S	If yes, how many people have been trained in the last two years?			
5.10.23S	Comments and References			

Section 6 Medicines Financing

6.00 Respondent Information Section 5

6.00.01	Name of person responsible for filling out this section of the instrument	Errol Thomas
6.00.02	Phone number	1 767 448 2060
6.00.03	Email address	cms@dominica.gov.dm
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:			
6.01.01.01	Patients who cannot afford them	Yes X No☐	2011	MOH
6.01.01.02	Children under 5	Yes X No☐	2011	MOH
6.01.01.03	Pregnant women	Yes X No☐	2011	MOH
6.01.01.04	Elderly persons	Yes X No☐	2011	MOH
6.01.01.05	Please describe/explain your yes answers for questions above	Patients receive medicines at no charge once they attend Governments health care facilities.		
6.01.02	Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for :		2011	MOH
6.01.02.01	All medicines included in the EML	Yes X No ☐		
6.01.02.02	Any non-communicable diseases	Yes X No ☐		
6.01.02.03	Malaria medicines	Yes ☐ No X		
6.01.02.04	Tuberculosis medicines	Yes X No ☐		

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

6.02 Patients Fees and Copayments

Core Questions (click here for help)

	Year	Source

6.02.01	In your health system, at the point of delivery, are there any co-payment/fee requirements for consultations	Yes ☐ No X	2011	MOH
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes ☐ No X	2011	MOH
6.02.03	In practice, (even though this may be contrary to regulations) is revenue from fees or sales of medicines sometimes used to pay the salaries or supplement the income of public health personnel in the same facility?	Yes ☐ No X	2011	MOH
6.02.03.01	Please describe the patient fees and copayments system			
6.02.04	Comments and References			

6.03 Pricing Regulation for the Private Sector

Core Questions (click here for help)

			Year	Source
6.03.01	Are there legal or regulatory provisions affecting pricing of medicines	Yes ☐ No X	2011	MOH
6.03.01.01	If yes, are the provisions aimed at Manufacturers	Yes ☐ No ☐		
6.03.01.02	If yes, are the provisions aimed at Wholesalers	Yes ☐ No ☐		
6.03.01.03	If yes, are the provisions aimed at Retailers	Yes ☐ No ☐		
6.03.01.04	Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.)			

6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes ☐ No X	2011	MOH
6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes ☐ No X	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 prices and availability have been conducted, please do not use them to fill in this section, but rather use the comment box to write some of the results and attach the report to the questionnaire	Yes ☐ No X Unknown ☐	2011	MOH

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

		Median (%)	**Orig**		6.04.02.01	6.04.02.03	
			LPG		6.04.02.02	6.04.02.04	
	Price	**Median Price Ratio**	**Orig**	6.04.03.01	6.04.03.03	6.04.03.05	
			LPG	6.04.03.02	6.04.03.04	6.04.03.06	
	Affordability Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection	**Number of days' wages**	**Orig**		6.04.04.01	6.04.04.03	
			LPG		6.04.04.02	6.04.04.04	
6.04.05	Comments and References						

6.05 Price Components and Affordability

Core Questions (click here for help)

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

	medicines in the private sector (Median % contribution)		
6.05.04	Comment and References	No Survey was conducted	MOH
Supplementary questions (click here for help)			
6.05.05S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)		
6.05.06S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution)		
6.05.07S	Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%)		
6.05.08S	Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%)		
6.05.09S	Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)		
6.05.10S	Median percentage contribution of the wholesale mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)		
6.05.11S	Median percentage contribution of the retail mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)		
6.05.12S	Comment and References	No Survey was conducted	MOH
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 X No ☐	2007	Tariff Document
6.06.02	There are duties on imported finished products	Yes X No ☐	2007	Tariff Document
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes X No ☐	2007	Tariff Document
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes X No ☐	2007	Tariff Document
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist	Taxes are applied on all Active pharmaceutical ingredients and finished pharmaceutical products. Taxes are waived on pharmaceutical donations.		
6.06.06	Comments and References	Common External Tariff of the Caribbean Community 2007		
Supplementary questions (click here for help)				
			Year	Source
6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)		2007	Common External Tariff book
6.06.08S	Duty on imported finished products (%)		2007	Common External Tariff book
6.06.09S	VAT on pharmaceutical products (%)		2007	Common External Tariff book
6.06.10S	Comments and References	Duty varies on APIs and on imported finished products, 6.06.07S. 0-5% 6.06.08S. 5-10% 6.06.09S. 15%		

		Common External Tariff of the Caribbean Community 2007.

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	Errol Thomas
7.00.02	Phone number	1 767 448 2060
7.00.03	Email address	cms@dominica.gov.dm
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:		2009	CARICOM DRA HERA REPORT VOLUME II
7.01.01.01	Decentralized	☐Yes		
7.01.01.02	Centralized and decentralized	☐Yes		
7.01.01.03	Please describe	For the public sector Central Medical Stores is procuring pharmaceuticals mainly from OECS/PPS. For additional procurement Central Medical Stores only uses known suppliers. - CARICOM DRA HERA REPORT VOLUME II		
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is: Ministry OF Health		2011	MOH

7.01.02.01	Part of MoH	Yes X No ☐		
7.01.02.02	Semi-Autonomous	Yes X No ☐		
7.01.02.03	Autonomous	Yes ☐ No ☐		
7.01.02.04	A government procurement agency which procures all public goods	Yes ☐ No X		
7.01.03	Public sector requests for tender documents are publicly available	Yes ☐ No X	2011	MOH
7.01.04	Public sector tender awards are publicly available	Yes ☐ No X	2011	MOH
7.01.05	Procurement is based on prequalification of suppliers	Yes X No ☐	2011	MOH
7.01.05.01	If yes, please describe how it works	Pharmaceutical suppliers have to meet certain criteria before purchases can be done.		
7.01.06	Comments and References	Approximately 95% of Pharmaceuticals are procured through the OECS Pharmaceutical Service		

Supplementary questions (click here for help)

			Year	Source
7.01.07S	Is there a written public sector procurement policy?. If yes, please write the year of approval in the "year" field	Yes ☐ No X	2011	MOH
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local manufacturers?	Yes ☐ No X	2011	MOH
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes ☐ No X	2007	WHO Level
7.01.10S	A process exists to ensure the quality of products procured	Yes X No ☐	2011	MOH

7.01.10.01S	If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes X No ☐		
7.01.10.02S	If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Yes X No ☐		
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly available	Yes X No ☐		
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes ☐ No ☐ Not Available	2011	MOH
7.01.12S	Which of the following tender methods are used in public sector procurement:		2007	WHO Level 1
7.01.12.01S	National competitive tenders	Yes No X		
7.01.12.02S	International competitive tenders	Yes X No ☐		
7.01.12.03S	Direct purchasing	Yes X No ☐		
7.01.13S	Comments and References	Procurement done through the OECS Procurement Service		

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 X No ☐	2009	CARICOM DRA HERA REPORT VOLUME II
7.02.02	Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	0	2011	MOH

7.02.03	There are national guidelines on Good Distribution Practices (GDP)	Yes ☐ No X	2011	MOH
7.02.04	There is a licensing authority that issues GDP licenses	Yes ☐ No X	2011	MOH
7.02.04.01	If a licensing authority exists, does it accredit public distribution facilities?	Yes ☐ No ☐		
7.02.05	List of GDP certified warehouses in the public sector exists	Yes ☐ No X	2011	MOH
7.02.06	List of GDP certified distributors in the public sector exists	Yes ☐ No X	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 X No ☐		
7.02.08.02S	Requisition/Stock orders	Yes X No ☐		
7.02.08.03S	Preparation of picking/packing slips	Yes X No ☐		
7.02.08.04S	Reports of stock on hand	Yes X No ☐		
7.02.08.05S	Reports of outstanding order lines	Yes X No ☐		
7.02.08.06S	Expiry dates management	Yes X No ☐		
7.02.08.07S	Batch tracking	Yes X No ☐		
7.02.08.08S	Reports of products out of stock	Yes X No ☐		
7.02.09S	Percentage % availability of key medicines at the Central Medical	93	2010	OECS/PPS Annual

	Store			Report
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days	3	OECS/PPS Annual Report 2010	
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes X No ☐	2011	MOH
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ☐ No X	2011	MOH
7.02.13S	The Public Central Medical Store is ISO certified	Yes ☐ No X	2011	MOH
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes ☐ No X	2011	MOH
7.02.15S	The second tier public warehouses are ISO certified	Yes ☐ No X	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 X No	2011	MOH
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes X No ☐	2011	MOH
7.03.03	List of GDP certified wholesalers in the private sector exists	Yes ☐ No X	2011	MOH
7.03.04	List of GDP certified distributors in the private sector exists	Yes ☐ No X	2011	MOH
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	Errol Thomas
8.00.02	Phone number	1 767 448 2060
8.00.03	Email address	cms@dominica.gov.dm
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 X No	2009	CARICOM DRA HERA REPORT VOLUME II
8.01.01.01	If yes, number of medicines on the EML (no. of INN)	551		
8.01.01.02	If yes, there is a written process for selecting medicines on the EML	Yes X No ☐		
8.01.01.03	If yes, the EML is publicly available	Yes X No ☐		
8.01.01.04	If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG)	Yes ☐ No X		
8.01.02	National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field	Yes ☐ No ☐		

8.01.03	STGs specific to Primary care exist. Please use the "year" field to write the year of last update of primary care guidelines	Yes X No ☐	2011	HBP & DM Manual
8.01.04	STGs specific to Secondary care (hospitals) exists. Please use the "year" field to write the year of last update of secondary care STGs.	Yes ☐ No X	2011	MOH
8.01.05	STGs specific to Paediatric conditions exist. Please use the "year" field to write the year of last update of paediatric condition STGs	Yes ☐ No X	2011	MOH
8.01.06	% of public health facilities with copy of EML (mean)- Survey data	100%	2011	MOH
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data	Not Available	2011	MOH
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes ☐ No X	2011	MOH
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes ☐ No X	2011	MOH
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes No X	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 ☐ No X	2011	MOH
8.01.12	A written National strategy exists to contain antimicrobial resistance. If yes, please write year of last	Yes ☐ No X	2011	MOH

	update of the strategy in the "year" field			
8.01.13	Comments and References	8.01.01 The OECS/PPS essential medicines list is used by the public sector as a reference. - CARICOM DRA HERA REPORT VOLUME II 8.01.02 National Treatment Guidelines exist for some priority health conditions (e.g. hypertension, diabetes). - CARICOM DRA HERA REPORT VOLUME II		
Supplementary questions (click here for help)				
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes X No ☐	2011	MOH
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes X No ☐	2011	MOH
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes X No ☐	2011	MOH
8.01.16.01S	If yes, conflict of interest declarations are required from members of national EML committee	Yes No X		
8.01.17S	National medicines formulary exists	Yes X No ☐	2011	MOH
8.01.18S	Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection?	Yes ☐ No X	2011	MOH
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☐ No X	2011	MOH
8.01.20S	Comments and References			

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

8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes No X	2011	MOH
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes No X	2011	MOH
8.02.12	Prescribing by INN name is obligatory in:		2011	MOH
8.02.12.01	Public sector	Yes X No ☐	2011	MOH
8.02.12.02	Private sector	Yes ☐ No X	2011	MOH
8.02.13	Average number of medicines prescribed per patient contact in public health facilities (mean)	4	2011	MOH
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	90	2011	MOH
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	95	2011	MOH
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)	90	2011	MOH
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)	92	2011	MOH
8.02.18	% of prescribed drugs dispensed to patients (mean)	90	2011	MOH
8.02.19	% of medicines adequately labeled in public health facilities (mean)	95	2011	MOH
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 X No ☐	2011	MOH
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes X No ☐		
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 X No ☐	2011	MOH
8.03.02	The basic pharmacist training curriculum includes components on:		2011	MOH
8.03.02.01	Concept of EML	Yes X No ☐		
8.03.02.02	Use of STGs	Yes X No ☐		
8.03.02.03	Drug Information	Yes X No ☐		
8.03.02.04	Clinical pharmacology	Yes X No ☐		
8.03.02.05	Medicines supply management	Yes X No ☐		
8.03.03	Mandatory continuing education that includes rational use of medicines is required for	Yes X No	2011	MOH

	pharmacists			
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes X No ☐	2011	MOH
8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes X No	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 X No ☐ Unknown ☐	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 X No ☐ Unknown ☐	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 No X	2011	MOH
8.03.10S	In practice, (even though this may be contrary to regulations) do the following groups of staff *sometimes* prescribe prescription-only medicines at the primary care level in the public sector?		2011	MOH
8.03.10.01S	Nurses	Yes X No ☐ Unknown ☐	2011	MOH
8.03.10.02S	Pharmacists	Yes X No ☐ Unknown ☐	2011	MOH
8.03.10.03S	Paramedics	Yes ☐ No X Unknown ☐	2011	MOH

8.03.10.04S	Personnel with less than one month training	Yes ☐ No X Unknown ☐	2011	MOH
8.03.11S	Comments and References			

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	Errol Thomas
9.00.02	Phone number	1 767 448 2060
9.00.03	Email address	cms@dominica.gov.dm
9.00.04	Other respondents for filling out this section	

9.01 Data from Household Surveys

Core Questions (click here for help)

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

9.01.06	Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)			
9.01.07	Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)			
9.01.08	Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)			
9.01.09	Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			
9.01.10	Percentage of people who obtained the medicines prescribed in the 15 days before the interview (%) Nil			
9.01.11	People who obtained prescribed medicines for free in the 15 days before the interview (%)			
9.01.12	Comments and References	No surveys were conducted		
Supplementary questions (click here for help)				
			Year	Source
9.01.13S	Adults with acute conditions not taking all medicines because the medicines were not available (%)			
9.01.14S	Adults with chronic conditions not taking all medicines because they cannot afford them (%)			
9.01.15S	Adults with chronic conditions not taking all medicines because the medicines were not available (%)			

9.01.16S	Children with acute conditions taking all medicines prescribed by an authorized prescriber (%)			
9.01.17S	Children with acute conditions not taking all medicines because they cannot afford them (%)			
9.01.18S	Children with acute conditions not taking all medicines because the medicines were not available (%)			
9.01.19S	Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%)			
9.01.20S	Comments and References	No surveys were conducted		