BARBADOS

PHARMACEUTICAL COUNTRY PROFILE

BARBADOS Pharmaceutical Country Profile

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Foreword

The 2011 Pharmaceutical Country Profile for Barbados 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 Barbados. The compiled data comes from international sources (e.g. the World Health Statistics [1, 2]), surveys conducted in the previous years and country level information collected in 2011. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

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

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

DR. JOY ST. JOHN
Chief Medical Officer
Barbados

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Acronyms and abbreviations

ADR	Adverse Drug Reaction
API	Active Pharmaceutical Ingredient
BDS	Barbados Drug Service
BDS$	Barbados Dollars
BNDF	Barbados National Drug Formulary
BNPP	Barbados National Pharmaceutical Policy
CAIPO	Corporate Affairs and Intellectual Property Office
CARICOM	Caribbean Community
CNCD	chronic non-communicable diseases
DTC	Drug and Therapeutics Committee
EML	Essential Medicines List
EPA	Economic Partnership Agreement
EPI	Expanded Program on Immunization
GCP	Good Clinical Practices
GDP	Gross Domestic Product
GGHE	General Government Health Expenditure
GMP	Good Manufacturing Practices
GPP	Good Pharmacy Practices
INN	International Non-Proprietyary Name
IPR	Intellectual Property Rights
MoH	Ministry of Health
MRA	Medicines Regulatory Authority
NHA	National Health Accounts
NHP	National Health Policy
NMP	National Medicines Policy
OAS	Organization of American States

OTC	Over-the-counter
PAHO	Pan American Health Organization
PANDRH	Pan American Network for Drug Regulatory Harmonization
PCP	Pharmaceutical Country Profile
PHF	Public Health Facility
QEH	Queen Elizabeth Hospital
RUM	Rational Use of Medicines
STG	Standard Treatment Guidelines
TAG	Technical Advisory Group
THE	Total Annual Expenditure on Health
TRIPS	Trade-Related Aspects of Intellectual Property Rights
US$	United States Dollars
UWI	University of the West Indies
VAT	Value-added tax
WHO	World Health Organization
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 Barbados. 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 (WHO) has supported all 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, (8) Selection and rational use, and (9) Household data/access. 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 to provide support for each of the member states.

The coordinator for Barbados from Ministry of Health was Maryam Hinds 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 Pan American Health Organization/World Health Organization in partnership with the country officials.

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

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Section 1 - Health and Demographic Data

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

1.1 Demographics and Socioeconomic Indicators

The total population of Barbados in 2010 was 276,302[3] with an annual population growth rate of 0.1%. The annual Gross Domestic Product (GDP) growth rate is 0.2%. The GDP per capita was US$ 10,271[4].

18% of the population is under 15 years of age, and 14% of the population is over 60 years of age. The urban population stands at 40% of the total population. The fertility rate in Barbados is 1.5 births per woman[1]. The adult literacy rate for the population over 15 years is 98%[5].

1.2 Mortality and Causes of Death

The life expectancy at birth is 71 and 77 years for men and women respectively[1]. The infant mortality rate (i.e. children under 1 year) is 10.9/1,000 live births. For children under the age of 5, the mortality rate is 12.8/1,000 live births. The maternal mortality rate is 84/100,000 live births[6].

The top 10 diseases causing mortality in Barbados are presented in Table 1.

Table 1. Top 10 diseases causing mortality in Barbados[7], 2010

	Disease	Total number of deaths
1	Diabetes mellitus	211
2	Diseases of pulmonary circulation and other forms of heart disease	197
3	Ischemic disease	172
4	Cerebrovascular disease	170
5	Pneumonia	142
6	Hypertension	119
7	Septicemia	99
8	Malignant neoplasm of the prostate	84
9	Disease of the urinary system	84
10	Malignant neoplasm of the sigmoid colon, rectum and anus	72

Chronic non-communicable diseases (CNCD), defined as cardiovascular diseases (including hypertension, coronary artery disease and stroke), diabetes mellitus, pulmonary disease and some cancers (prostate, cervix, breast and colon/rectal) represent the major burden of disease in Barbados[7].

The adult mortality rate for both sexes between 15 and 60 years is 138/1,000 population, while the neonatal mortality rate is 7/1,000 live births. The age-standardized mortality rate by non-communicable diseases is 531/100,000[1], 213/100,000 by cardiovascular diseases and 144/100,000 by cancer[2]. The mortality rate for HIV/AIDS, malaria[8] and tuberculosis[1] is 0/100,000 population.

Section 2 - Health Services

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

2.1 Health Expenditures

In Barbados, the total annual expenditure on health (THE) in 2008 was 497.30 million Barbadian dollars (US$ 248.65 [i] million). The total annual health expenditure was 8.76% of the GDP. The total annual expenditure on health per capita was BDS$ 1,799 (US$ 899)[ii].

The general government[iii] health expenditure (GGHE) in 2008, as reflected in the national health accounts (NHA) was BDS$ 317,330,000 (US$ 158,670,000). That corresponds to 63.81% of the total expenditure on health, with a total annual per capita public expenditure on health of BDS$ 1,148 (US$ 574). The government annual expenditure on health represents 11.91% of the total

[i] Exchange rate used: US$ 1 = BDS$ 2.

[ii] Data in this section was calculated based on the WHO National Health Account for Barbados, available online: http://apps.who.int/nha/database/StandardReport.aspx?ID=REP_WEB_MINI_TEMPLATE_WEB_VERSION&COUNTRYKEY=84005

[iii] 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.

government budget. Private health expenditure covers the remaining 36.19% of the total health expenditure[i].

The *Health Services Act of Barbados* (Cap. 44) - 1969 and the Drug Services Act - 1980 provide the framework to ensure that the population receives universal health care coverage and access to quality medicines at affordable prices regardless of their socio-economic circumstances. Public universal health care coverage is guaranteed through the government's tax revenue system. However, persons can choose to access health care services through the private sector and private health insurance schemes. In some cases, the client may pay a predetermined percentage at the time of the visit or pay out-of-pocket at the point of service and submit a claim to the health insurance provider for reimbursement.

It is estimated that approximately 25% of the population is covered by private health insurance, but 100% of the Barbados nationals and permanent residents are covered by the public health service.

The total pharmaceutical expenditure is unknown, however, the public expenditure on pharmaceuticals was BDS$ 69,109,000 (US$ 34,555,000) in 2010. The public pharmaceutical expenditure per capita in Barbados for the same year was BDS$ 250.12 (US$125.06).

Based on the Barbados National Drug Formulary (BNDF), the market share of generic pharmaceuticals (branded and INN) by value is 73% for the fiscal year of 2011/2012[iv].

[iv] The market share is estimated based on the percentage of generic medicines in the Formulary according to the Drug Service Tender Document of Maximum Price Contract (MPC) 32 (fiscal year 2011/2012).

The private out-of-pocket expenditure represents the 80.56% of the Total Private Expenditure on Health; and the premiums for private prepaid health plans represent the remaining 19.44%.

2.2 Health Personnel and Infrastructure

The health workforce is described in Table 2. There are 250 (9/10,000 inhabitants) licensed pharmacists[9], of which 75 (2.7/10,000) work in the public sector[v].

There are 766 (27.7/10,000) physicians[7] and 2631 (95.22/10,000) nursing and midwifery personnel[10] in Barbados. The ratio of doctors to pharmacies is 7:1 and the ratio of doctors to nurses and midwifery personnel is 5:1.

Table 2. Human resources for health in Barbados[7, 9, 10]

Human Resource	
Licensed pharmacists (all sectors)	250 (9 /10,000)
Pharmacists in the public sector	75 (2.7/10,000)
Physicians (all sectors)	766 (27.7 /10,000)
Nursing and midwifery personnel (all sectors)	2631 (95.22/10,000)

In Barbados, there is not a strategic plan for pharmaceutical human resource development in place[9].

The health infrastructure is described in Table 3. There are seven hospitals (2 public, 1 private and 4 Geriatric hospitals), 12 primary health care units and

[v] Including the Barbados Drug Service BDS, the Queen Elisabeth Hospital, the Psychiatric Hospital and the prison services.

centres (4 outpatient clinics and 8 polyclinics), and 111 pharmacies (public and private)[9]. There are 66 hospital beds per 10,000 population in Barbados[2].

Table 3. Health centre and hospital statistics[2, 9]

Infrastructure	
Hospitals	7
Hospital beds	66/10,000 pop.
Primary health care units and centres	12
Pharmacies	111

The annual starting salary for a newly registered pharmacist in the public sector is BDS$ 43,792[9] (US$ 21,896). The total number of pharmacists who graduated (as a first degree) in the past two years is 50. Accreditation requirements for pharmacy schools are in place. Current curriculum has not been updated in the last five years[10].

Section 3 - Policy Issues

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

3.1 Policy Framework

In Barbados, a National Health Policy (NHP) exists[11]. It was updated in 2002. An associated NHP implementation plan written in 2002 also exists.

An official National Medicines Policy (NMP) document does not exist in Barbados, however, policies addressing pharmaceuticals exist[9]. A draft Barbados National Pharmaceutical Policy (BNPP) was developed in 2011 and is waiting for approval from the Cabinet. The mentioned draft covers the aspects detailed in Table 4.

Table 4. Aspects covered by the BNPP

Aspect of policy	Covered
Selection of essential medicines	Yes
Medicines financing	Yes
Medicines pricing	Yes
Medicines Procurement	Yes
Medicines Distribution	Yes
Medicines Regulation	Yes
Pharmacovigilance	Yes
Rational use of medicines (RUM)	Yes
Human Resource Development	Yes
Research	No
Monitoring and evaluation	Yes
Traditional Medicine	Yes

A group of policies relating to clinical laboratories exists and was most recently updated in 2011. There are no official written guidelines on medicines donations[9].

There is no national good governance policy in Barbados[9].

A policy is not in place to manage and sanction conflict of interest issues in pharmaceutical affairs[9]. There is an associated formal code of conduct for public officials[12]. A whistle-blowing mechanism that allows individuals to raise concerns about wrongdoing occurring in the pharmaceutical sector of Barbados does not exist[9].

Section 4 – Medicines Trade and Production

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

4.1 Intellectual Property Laws and Medicines

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

Intellectual Property Rights (IPR) are managed and enforced by the Corporate Affairs and Intellectual Property Office (CAIPO); URL: http://www.caipo.gov.bb[15].

National Legislation has been modified to implement the trade-related aspects of intellectual property rights (TRIPS) Agreement[14] and contains TRIPS-specific flexibilities and safeguards, presented in Table 5. Barbados is not eligible for the transitional period to 2016[16].

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

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

The country is engaged in capacity-strengthening initiatives to manage and apply Intellectual Property Rights in order to contribute to innovation and promote public health[9]. Barbados is member of the Technical Advisory Group (TAG) on Intellectual Property of CARICOM.

There are legal provisions for data exclusivity for pharmaceuticals[vii16], but not for linkage between patent status and marketing authorization[9].

Barbados is bound by the European Union-CARIFORUM Economic Partnership Agreement Patent Cooperation Treaty (EU-CARIFORUM EPA).

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

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

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

[vii] Provision provided by "Protection against unfair competition Act", 1998. However, marketing authorization is not in place in the country.

4.2 Manufacturing

There is only one licensed pharmaceutical manufacturer in Barbados[16]. Manufacturing capabilities are presented in Table 6 below.

Table 6. Barbados manufacturing capabilities[9]

Manufacturing capabilities	
Research and Development for discovering new active substances	No
Production of pharmaceutical active ingredients (APIs)	No
The production of formulations from pharmaceutical starting material	Yes
The repackaging of finished dosage forms	No

In 2004, domestic manufacturers held 2.75% of the market share by value produced[9].

There are no multinational pharmaceutical companies currently manufacturing medicines locally[9].

The only local manufacturer is Good Manufacturing Practices (GMP) certified[9].

Section 5 – Medicines Regulation

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

5.1 Regulatory Framework

In Barbados, there are legal provisions establishing control of medicines[17].

According to HERA Report on Drug Registration and Regulatory Systems[18]: "Administration of the medicines laws in Barbados is vested onto a number of bodies. The Pharmacy Council is established under section 10 of the Pharmacy Act (1986) to control and regulate the practice of pharmacy, registration and control of persons admitted to practice, and registration of pharmacy premises for selling drugs and poisons. The Therapeutic Substances Act, 1950 empowers the Chief Medical Officer (CMO), under section 4 of the Act as Licensing Authority responsible for control of the manufacture for sale or supply of any drug or therapeutic substance to which the Act applies".

The Barbados Drug Service (BDS) retains administrative functions related to medicines regulation under the Drug Service Act. BDS executes inspections related to the Pharmacy Act and the control of drugs and other controled substances, under the CMO's legal mandate.

The CMO has the mandate to develop Medicines Regulatory Authority (MRA) functions as part of the Ministry of Health. The MRA functions are outlined in Table 7. These are the functions carried out by the BDS, with exception of clinical

trials control, regarding ethical aspects, which are carried out by a joint committee of MOH and UWI. Barbados does not have a website for the MRA.

Table 7. Functions of the national MRA[18]

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

As of 2011, there was three permanent staff (drug inspectors) working on MRA related functions at BDS. Barbados MRA receives external technical assistance from the Pan American Health Organization/World Health Organization (PAHO/WHO) and the Organization of American States (OAS) to support its activities. The MRA is involved in harmonization/collaboration initiatives such as the Pan American Network for Drug Regulatory Harmonization (PANDRH), Caribbean Community (CARICOM), and the World Health Organization (WHO)[9].

An assessment of the medicines regulatory system has been conducted in the last five years[18]. Funding for the MRA is provided through the regular government budget. The Medicines Regulatory Authority does not retain revenues derived from regulatory activities. This body does not use a

computerized information management system to store and retrieve information on processes[9].

5.2 Marketing Authorization (Registration)

In Barbados, legal provisions do not require marketing authorization (registration) for all pharmaceutical products on the market, and mutual recognitions mechanisms are not in place[9].

5.3 Regulatory Inspection

In Barbados, there are legal provisions for appointing government pharmaceutical inspectors[19, 20] and permitting inspectors to inspect premises where pharmaceutical activities are performed. Such inspections are required by law and are a pre-requisite for the licensing of private facilities[18]. Where inspections are legal requirements, these are not the same for public and private facilities[9]. Inspections are carried out on a number of entities, outlined in Table 8.

Table 8. Local facilities inspected for Good Practices compliance[9]

Entity	Inspection	Frequency
Local manufacturer	Yes	Annually
Private wholesalers	Yes	Not periodical
Retail distributors	Yes	Annually
Public pharmacies[viii]	No	Not periodical

[viii] There are no stand alone pharmacies. The public pharmacies are always attached to a health facility.

Pharmacies and dispensaries in health facilities	No	-

5.4 Import Control

Legal provisions exist requiring authorization to import medicines and importation of medicines through authorized ports of entry. Laws and regulations exist that allow the sampling of imported products for testing and for inspection of imported pharmaceutical products at authorized ports of entry[21].

5.5 Licensing

In Barbados, legal provisions exist requiring manufacturers to be licensed. Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP) [22]. Nevertheless, GMP requirements are not published by the government[9].

Legal provisions exist requiring importers to be licensed[21] and wholesalers and distributors to comply with Good Distributing Practices[18]. Nevertheless, Good Distribution Practices are not published by the government[9].

Table 9. Legal provisions pertaining to licensing

Entity requiring licensing	
Importers	Yes
Wholesalers	No
Distributors	No

Legal provisions exist requiring pharmacists to be registered and private and public pharmacies to be licensed[20]. National Good Pharmacy Practice (GPP) Guidelines are not published by the government. By law, a list of all licensed pharmaceutical facilities is not required to be published[9].

5.6 Market Control and Quality Control

In Barbados, legal provisions do not exist for controlling the pharmaceutical market[9]. A laboratory does not exist in Barbados for Quality Control testing. The regulatory authority contracts services elsewhere[18]. The Caribbean Regional Drug Testing Laboratory[23] and Experchem (Canada) are used for quality control testing.

Medicines are tested for a number of reasons, summarised in Table 10.

Table 10. Reason for medicines testing[9]

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

[ix] Routine sampling in public pharmacies and health facilities.

[x] Routine sampling in private pharmacies.

Samples are not collected by government inspectors for undertaking post-marketing surveillance testing[9].

5.7 Medicines Advertising and Promotion

In Barbados, legal provisions exist to control the promotion and/or advertising of prescription medicines[21]; however regulation of the promotion is not performed in the country. 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 and Regulations do not exist for advertising and promotion of non-prescription or over-the-counter (OTC) medicines. There is no national code of conduct concerning advertising and promotion of medicines.

5.8 Clinical Trials

In Barbados, there are no legal provisions requiring authorization for conducting Clinical Trials by the MRA[18]. There are no additional laws requiring the agreement by an ethics committee or institutional review board of the Clinical Trials to be performed. Clinical trials are not required to be entered into an international, national, or regional registry, by law[9].

However, there is a joint committee from the Ministry of Health and the University of the West Indies (UWI), which approves the research protocols involving humans (including clinical trials) in regards to ethical aspects.

Legal provisions do not exist for GMP compliance of investigational products. Sponsor investigators are not legally required to comply with Good Clinical Practices (GCP). National GCP regulations are not published by the Government. There are no legal provisions allowing the inspection of facilities where clinical trials are performed.

5.9 Controlled Medicines

Barbados is a signatory to a number of international conventions, detailed in Table 11.

Table 11. International Conventions to which Barbados is a signatory[24]

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 (Drug abuse – prevention and control – Act, 1990; Available online: http://www.unodc.org/enl/showDocument.do?lng=es&language=SPA&node=docs&cmd=add&documentUid=1387&country=BAR).

It is unknown if 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 or medical need.

Figures regarding the annual consumption of certain controlled substances in the country are outlined in Table 12 below.

Table 12. Annual consumption of selected controlled substances in Barbados[9]

Controlled substance	Annual consumption (mg/capita)
Morphine	4.89
Fentanyl	0.009
Pethidine	37.32
Methadone	0.02

5.10 Pharmacovigilance

In Barbados, there are no legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate**.** Laws regarding the monitoring of Adverse Drug Reactions (ADR) or requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA do not exist in Barbados.

A national pharmacovigilance centre linked to the MRA does not exist[9]. However, there is an official standardized form for reporting ADRs[xi]. Despite the inexistence of a national centre, ADRs are monitored in the HIV/AIDS public health program[9] and reports of suspected ADR are sent to Barbados Drug Service.

[xi] The form is available in the Barbados National Drug Formulary (BNDF).

Information pertaining to ADRs is not stored in a national ADR database, however, these reports are sent to the WHO collaborating centre in Uppsala[9] using VIGIFLOW.

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 and communication. A clear communication strategy for routine communication and crises communication does not exist[9].

In order to enhance the Pharmacovigilance system, a permanent staff member has just been assigned to begin the ADRs compiling process[9].

Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in Barbados, 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 Barbados, for patients seeing a doctor and filling the prescription at a pharmacy at a public health facility (PHF), medicines from the BNDF are free of charge regardless the age or condition. For inpatients at Queen Elisabeth Hospital (QEH), medicines are free of charge. Besides that, there are provisions for certain groups to receive medicines included at BNDF (formulary medicines) free of charge (see Table 13). For patients from one of the categories seeing a private doctor, formulary medicines are also provided free of charge at public facilities. For anyone from the entitled categories, the prescription can be filled in a private pharmacy, where formulary medicines are also free, but a payment for a dispensing fee should be made.

Table 13. Population groups provided with medicines free of charge[17]

Patient group	Covered
Patients who cannot afford them	Yes
Children under 16	Yes
Pregnant women	No
Elderly persons (over 65 years old)	Yes

Furthermore, the public health system or social health insurance schemes provide medicines free of charge for particular conditions (see Table 14).

Table 14. Medications provided at public health facilities, at no cost[9]

Conditions	Covered
All medicines included in the BNDF	Yes
Any non-communicable diseases	Yes
Malaria*	Yes
Tuberculosis*	Yes
Sexually transmitted diseases	Yes
HIV/AIDS*	Yes
Expanded Program on Immunization (EPI) vaccines for children	Yes

The medicines for these conditions listed are included in the BNDF but the ones marked (*) are only provided at PHF.

Private health insurance schemes provide medicines coverage, and medicines coverage is linked to the insurance contract or plan subscribed to[9].

6.2 Patients Fees and Copayments

Co-payments or fee requirements for consultations are not levied at the point of delivery at public health facilities. Furthermore, there are no copayments or fee requirements imposed for medicines[9] dispensed at public pharmacies. A dispensing fee is charged for dispensing formulary medicines at private pharmacies[25].

6.3 Pricing Regulation for the Private Sector[xii]

In Barbados, there are legal provisions affecting pricing of medicines[17]. These provisions are aimed at the level of private pharmacies for reimbursement purposes. However, prices of medicines purchased out of pocket are not controlled.

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 medicines prices, availability and affordability have been conducted in the past 5 years in Barbados.

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

6.5 Price Components and Affordability

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

6.6 Duties and Taxes on Pharmaceuticals (Market)

Barbados does not impose duties on imported active pharmaceutical ingredients (APIs) but duties on imported finished products are imposed. Value-added tax (VAT) is imposed on finished pharmaceutical products. Provisions for tax exceptions or waivers for pharmaceuticals and health products do not exist[26]; however, medicines in the BNDF, all vaccines and prescription medicines that request waiver to the BDS are duty free and VAT zero rated. Over-the-counter (OTC) medicines are not entitled to duty free status. See table Table 15.

Table 15. Duties and taxes applied to pharmaceuticals

Duty / Tax	Percentage
Duty on imported active pharmaceutical ingredients, APIs	0.0%
Duty on imported finished products	20.0%[27]
VAT on pharmaceutical products	17.5%[26]

Section 7 - Pharmaceutical procurement and distribution in the public sector

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

7.1 Public Sector Procurement

Public sector procurement in Barbados is both centralized and decentralized. The public sector procurement is partially centralized under the responsibility of Barbados Drug Service, which is linked to the Ministry of Health[9].

Public sector procurement is directed by a tender committee formed by the BDS Director, the Assistant Director of Supplies and Inventory of BDS, two members of QEH, two members of the private sector (private pharmacist and doctor), and a representative from the Chief Supply Officer (Ministry of Finance).

There is a written public sector procurement policy (1980)[28]. There are no legal provisions to give priority to locally produced goods in public procurement[9]. The key functions of the procurement unit and those of the tender committee are clearly separated[28]. A process exists to ensure the quality of products that are procured for the public sector, which includes the pre-qualification of products and suppliers. A list of pre-qualified suppliers and products is available[9].

A list of samples tested during the procurement process and the results of quality testing are not publicly available but can be provided upon request. The tender

methods employed in public sector procurement include national competitive tenders[xiii] and direct purchasing in emergency situations[9].

7.2 Public Sector Distribution

The government supply system in Barbados does not have a Central Medical Store at National Level neither public warehouses in the secondary tier. However, Barbados government has a special arrangement with the suppliers on which the storage and distribution is a part of the service. It is charged over the procurement price (currently 20%).

There are no national guidelines on Good Distribution Practices (GDP) or licensing authority that issues GDP licenses[9].

7.3 Private Sector Distribution

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

[xiii] The medicines are usually from international companies, that are required to participate in the bid through local agents. 97.25% of pharmaceuticals are supplied by foreign companies registered with the Barbados Drug Service.

[xiv] Pharmaceutical wholesaler license is issued under the Health Service Act.

Section 8 - Selection and rational use of medicines (RUM)

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

8.1 National Structures

The Barbados National Drug Formulary (BNDF) includes a National Essential Medicines List (EML) and more. It was last updated in 2011 and is publicly available. There are currently 700 medicines on the BNDF. Selection of medicines for the BNDF is undertaken through a written process. A mechanism aligning the BNDF with the Standard Treatment Guidelines (STGs) is not in place.

National Standard Treatment Guidelines (STGs) are not produced by the MoH in Barbados[9]. STGs from the Caribbean are used for HIV/AIDS, asthma, diabetes, hypertension and other diseases.

Of the public health facilities, 92% have a copy of the EML and 55% have a copy of STGs[29].

There is a public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers located at BDS. Public education campaigns on rational medicine use topics have been conducted in the last two years[9]. A survey on rational use of medicines has been conducted in 2010[29]. There is no national programme or

committee, involving government, civil society, or professional bodies, to monitor and promote rational use of medicines[9].

There are not written national guidelines or strategies. However, the Infection Control Committee (QEH) provides guidance on the matter.

The BNDF includes formulations specifically for children. Criteria for the selection of medicines to the BNDF are explicitly documented[9]. There is a formal committee for the selection of products, the Drug Formulary Committee[17]. Conflict of interest declarations are not required from members of the mentioned committee. This Committee is an advisory one to the Minister of Health.

A funded 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 or other institution 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[30]. Furthermore, legal provisions restricting dispensing by prescribers do not exist. Prescribers in the private sector dispense medicines[9].

There are regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs)[31]. QEH has its own DTC.

The training curriculum for doctors is made up of a number of core components detailed in Table 16.

Table 16. Core aspects of the medical training curriculum[32]

Curriculum	Covered
The concept of EML	No
Use of STGs	Yes
Pharmacovigilance	No
Problem based pharmacotherapy	Yes

Mandatory continuing education that includes pharmaceutical issues is required for doctors[33] but not for nurses and paramedical staff.

Prescribing by international Non-proprietary Name (INN) is not mandatory in the public or in the private sector[9]. Of the medicines prescribed in the outpatient public healthcare facilities, 99% are on the national EML and 36% are prescribed by INN. Of the patients treated in the outpatient public health care facilities, 23% received antibiotics and 7% received injections. Of prescribed medicines, 99% were dispended to patients. 100% of medicines dispensed in public health facilities were adequately labelled[29].

Table 17. Characteristics of medicines prescribing

Description	%
% of medicines prescribed in outpatient public healthcare facilities that were in the national EML (mean)	99
% of medicines in outpatient public health care facilities that were prescribed by INN (mean)	36
% of patients in outpatient public health care facilities receiving antibiotics (mean)	23
% of patients in outpatient public health care facilities receiving injections (mean)	7
% of prescribed medicines dispensed to patients (mean)	99
% of medicines adequately labeled in public health facilities (mean)	100

A professional association code of conduct which governs the professional behaviour of doctors' exists[33]. Similarly, a professional association code of conduct governing the professional behaviour of nurses exists.

8.3 Dispensing

Legal provisions in Barbados exist to govern dispensing practices of pharmaceutical personnel[20]. The basic pharmacist training curriculum includes a spectrum of components as outlined in Table 18.

Table 18. Core aspects of the pharmacist training curriculum[9]

Curriculum	Covered
The concept of EML	No
Use of STGs	No
Medicines information	No
Clinical pharmacology	Yes
Medicines supply management	No

Mandatory continuing education that includes rational use of medicines is not yet required for pharmacists, but there is work in progress to so do.

Substitution of generic equivalents at the point of dispensing is allowed in public and private sector facilities[20]. Sometimes antibiotics are sold over-the-counter without a prescription. Injectable medicines are not sold over-the-counter without a prescription[9].

There is a professional association code of conduct which governs the professional behaviour of pharmacists[9].

Section 9 - Household data/access

This section provides information derived from past household surveys in Barbados regarding actual access to medicines by regular and poor households.

In the past 5 years, one household survey has been undertaken to assess the access to medicines: World Health Organization (WHO) Level II Pharmaceutical Survey, Household survey (2010).

In Barbados, 6% of adult patients with an acute condition in a two-week recall period did not take all medicines prescribed to them because they could not afford them[29].

Of the adult patients from poor households with an acute condition in a two-week recall period, 1% did not take all medicines because they could not afford them[29].

Of the adult patient population with chronic conditions, 72% took all medicines prescribed by an authorized prescriber. In comparison, 68% of adult patients with chronic conditions coming from poor households took all medicines prescribed by an authorized prescriber[29].

Of the children from poor households with acute condition in a two-week recall period, 44% took all medicines prescribed by an authorized prescriber[29].

The percentage of people who obtained for free *the* medicines prescribed in the 15 days before the interview was 78%[29].

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BARBADOS

Pharmaceutical Country Profile

ANNEX

Survey Data

(Fragment of the questionnaire)

2011

Section 0 General Info

0.01 Contact Info

0.01.01	Country (precoded)	Barbados
0.01.02	Name coordinator	Maryam Hinds
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0.01.04	Phone number	246 467 9334
0.01.05	Email address	bds@caribsurf.com
0.01.06	Web address	
0.01.07	Institution	Barbados Drug Service

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	Samuel Dean, Ministry of Health
1.00.02	Phone number	1-246-467-9300
1.00.03	Email address	Samuel.dean@barbados.gov.bb
1.00.04	Other respondents for filling out this section	Pamela Payne-Wilson (BDS), Maryam Hinds (BDS))

1.01 Demographic and Socioeconomic Indicators

Core questions (click here for help)

			Year	Source
1.01.01	Population, total (,000)	276.3	2010	Barbados Statistical Services
1.01.02	Population growth rate (Annual %)	0.1	2009	Barbados Social and Economic Report
1.01.03	Total Gross Domestic Product (GDP) (millions US$)	2,837.95	2009	Barbados Social and Economic Report
1.01.04	GDP growth (Annual %)	0.2	2009	Barbados Social and Economic Report
1.01.05C	GDP per capita (US$ current exchange rate)	22,271.57	2009	IMF
1.01.06	Comments and References	1.01.01 Estimated Population as at the end of 2010: 276,302, according Barbados Statistical Service, available at: http://www.barstats.gov.bb/ 1.01.03 Barbados Statistical Service, available at		

		http://www.barstats.gov.bb/ BDS$ 5675.9 = US$ 2,837.95 (exchange rate = 2 BDS /US$1) 1.01.04. The growth rate of the Barbados economy was above 1% between 2004 and 2007 but by 2008 a decline to -0.2% from the Barbados Social and Economic Report 2009.		
Supplementary questions (click here for help)				
			Year	Source
1.01.07S	Population < 15 years (% of total population)	18	2008	WHS 2010
1.01.08S	Population > 60 years (% of total population)	14	2008	WHS 2010
1.01.09S	Urban population (% of total population)	40	2008	WHS 2010
1.01.10S	Fertility rate, total (Births per woman)	1.5	2008	WHS 2010
1.01.11S	Population living with less than $1.25/day (international PPP) (%)			
1.01.12S	Population living below nationally defined poverty line (%)			
1.01.13S	Income share held by lowest 20% of the population (% of national income)			
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	98	2005	Health in the Americas
1.01.15S	Comments and References	1.01.14S Health in the Americas. PAHO. 2007. Volume II.Countries, Barbados. 1.01.07-10 World Health Statistics - 2010 http://www.who.int/whosis/whostat/EN_WHS10_Full.pdf		
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)	71	2008	WHS 2010
1.02.02	Life expectancy at birth for women (Years)	77	2008	WHS 2010
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)	10.9	2009	PAHO-IBS Barbados_ Core Data
1.02.04	Under 5 mortality rate (/1,000 live births)	12.8	2009	PAHO-IBS Barbados_ Core Data
1.02.05	Maternal mortality ratio (/100,000 live births)	84	2009	PAHO-IBS Barbados_ Core Data
1.02.06	Please provide a list of top 10 diseases causing mortality		2006	2004-2006 Annual Report of the Chief Medical Officer
1.02.06.01	Disease 1	Diabetes Mellitus- 211		
1.02.06.02	Disease 2	Diseases of Pulmonary Circulation and other forms of Heart Disease- 197		
1.02.06.03	Disease 3	Ischemic Disease- 172		
1.02.06.04	Disease 4	Cerebrovascular Disease- 170		
1.02.06.05	Disease 5	Pneumonia- 142		
1.02.06.06	Disease 6	Hypertension- 119		
1.02.06.07	Disease 7	Septicemia-99		
1.02.06.08	Disease 8	Malignant Neoplasm of the Prostate-84		
1.02.06.09	Disease 9	Disease of the Urinay System-84		

1.02.06.10	Disease 10	Malignant Neoplasm of the Sigmoid Colon, Rectum and Anus- 72		
1.02.07	Please provide a list of top 10 diseases causing morbidity		2006	2004-2006 Annual Report of the Chief Medical Officer
1.02.07.01	Disease 1			
1.02.07.02	Disease 2			
1.02.07.03	Disease 3			
1.02.07.04	Disease 4			
1.02.07.05	Disease 5			
1.02.07.06	Disease 6			
1.02.07.07	Disease 7			
1.02.07.08	Disease 8			
1.02.07.09	Disease 9			
1.02.07.10	Disease 10			
1.02.08	Comments and References	1.02.01-02:World Health Statistics 2010 http://www.who.int/whosis/whostat/EN_WHS10_Full.pdf 1.02.03-1.02.05 PAHO-IBS Barbados_Core Data - Health Information and Analysis Project Regional Core Health Data Initiative 2011. It was conducted by the Pan American Health Organisation/World Health Organisation (PAHO/WHO) in collaboration with the Chief Health Planner, Samuel Deane. 1.02.06 and 07 Annual report of the chief medical officer 2004-2006. Ministry of health. Barbados. 2010. 1.02.07 “Chronic non-communicable diseases (CNCDs), defined as cardiovascular diseases (including Hypertension, coronary artery disease and stroke), diabetes mellitus, pulmonary disease and some cancers (prostate, cervix, breast and colon/rectal) represent the major burden of disease in Barbados.		

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)	138	2008	WHS 2010
1.02.10S	Neonatal mortality rate (/1,000 live births)	7	2008	WHS 2010
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	531	2004	WHS 2010
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	213	2004	WHS 2009
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	144	2004	WHS 2009
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	0.0	2008	GHODR
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	0.0	2008	WHS 2010
1.02.16S	Mortality rate for Malaria (/100,000 population)	0.0	2008	GHODR
1.02.17S	Comments and References	1.02.09S-11S, 1.02.15. World Health Statistics 2010 http://www.who.int/whosis/whostat/EN_WHS10_Full.pdf 1.02.12S-13S. World Health Statistics 2009 http://www.who.int/whosis/whostat/EN_WHS09_Full.pdf 1.02.14S, 1.02.16S GHODR- Global Health Observatory Data Repository. Cause-specific mortality and morbidity, HIV/AIDS, Malaria and TB http://apps.who.int/ghodata/?vid=4300&theme=country		

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	Samuel Dean
2.00.02	Phone number	1-246-467-9300
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2.00.04	Other respondents for filling out this section	Leroy Williams, Barbados Drug Services (BDS); Heather Carter (BDS); Ersie Chase (BDS), Pamela Payne-Wilson (BDS), Maryam Hinds (BDS)

2.01 Health Expenditures

Core questions (click here for help)

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)	497.30	2008	NHA data
2.01.01.02	Total annual expenditure on health (millions US$ average exchange rate)	248.65	2008	NHA data
2.01.02C	Total health expenditure as % of Gross Domestic Product	6.75		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	1,950.20		
2.01.03.02C	Total annual expenditure on health per capita (US$ average exchange rate)	975.10		
2.01.04.01	General government annual expenditure on health (millions NCU)	317.33	2008	NHA data
2.01.04.02	General government annual expenditure on health (millions US$ average exchange rate)	158.67	2008	NHA data
2.01.05	Government annual expenditure on health as percentage of total government budget (% of total	11.91	2008	NHA data

	government budget)			
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	63.81	2008	NHA data
2.01.07.01C	Annual per capita government expenditure on health (NCU)	1,244.44		
2.01.07.02C	Annual per capita government expenditure on health (US$ average exchange rate)	622.22		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	36.20	2011	BDS
2.01.09	Population covered by a public health service or public health insurance or social health insurance, or other sickness funds of total population)	100	2008	PAHO
2.01.10	Population covered by private health insurance (% of total population)	25	2008	PAHO
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)	PREFILL CALC		
2.01.12.02C	Total pharmaceutical expenditure per capita (US$ current exchange rate)	PREFILL CALC		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	PREFILL CALC		
2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	PREFILL CALC		

2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)	69.109	2010	MOH
2.01.15.02	Total public expenditure on pharmaceuticals (millions US$ current exchange rate)	34.555	2010	MOH
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	PREFILL CALC		
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	PREFILL CALC		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	PREFILL CALC		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)			
2.01.18.02	Total private expenditure on pharmaceuticals (millions US$ current exchange rate)			
2.01.19	Comments and References	Exchange rate NCU (US$ 1 = BDS$ 2) 2.01.10 The last estimate made in the 1990s BDS - Barbados Drug Service MOH - Ministry of Health NHA data -National Health Account data http://www.who.int/nha/country/brb/en/ 2.01.09:The 1969 Health Services Act of Barbados, Cap. 44 and the Drug Services Act 1980 provide the framework to ensure that the population receives universal health care coverage and access to quality drugs at affordable prices regardless of their socio-economic circumstances. Public universal health care coverage is guaranteed through the government's tax revenue system. However, persons can choose to access health care services through the private sector and private health insurance schemes. In some cases, the client may pay a predetermined percentage at the time of the visit or pay out-of-pocket at the point of service and submit a claim to the health insurance provider for reimbursement.		

		It is estimated that approximately 25% of the population is covered by private health insurance. Source: PAHO. Barbados Health System Profile (2008) 2.01.11.01- 2.01.11.02: The private sector expenditure is not available. So these indicators are not able to be calculated. 2.01.15.01 and 02: The public pharmaceutical expenditure corresponds to BDS$ 52,712,466 (Public Pharmacies, includes BDS$ 34,295,083 correspondent to reimbursement to private pharmacies) + BDS$ 16,396,442.30 (QEH) with a total of BDS $ 69,108,908 = BDS$ 69.109 (M) = US$ 34.555 (M)		
Supplementary questions (click for help)				
			Year	Source
2.01.20S	Social security expenditure as % of government expenditure on health (% of government expenditure on health)	0.00	2008	NHA data
2.01.21S	Market share of generic pharmaceuticals [branded and INN] by value (%)	73	2011	BNDF
2.01.22S	Annual growth rate of total pharmaceuticals market value (%)			
2.01.23S	Annual growth rate of generic pharmaceuticals market value (%)			
2.01.24S	Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)	80.56	2008	NHA data
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	19.44	2008	NHA data
2.01.26S	Comments and References	2.01.21S . BNDF- Barbados National Drug Formulary 2.01.21S The Barbados National Drug Formulary is the equivalent to the National EML (but not restricted to essential medicines) . As a Formulary, it also includes medicines monographs. The % of		

		market is estimated based on the % of generic medicines in the formulary according to the Drug Service Tender Document of Maximum Price Contract (MPC) 32 (fiscal year 2011/2012). 2.01.20, 2.01.24S, 2.01.25S NHA data -National Health Account data http://www.who.int/nha/country/brb/en/		
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	250	2011	BDS
2.02.02C	Pharmacists per 10,000 population	PREFILL CALC		
2.02.03	Total number of pharmacists working in the public sector	75	2011	BDS, QEH, Psychiatric Hospital, Prison Services
2.02.04	Total number of pharmaceutical technicians and assistants			
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes ☐ No ☒	2011	BDS
2.02.06	Total number of physicians	766	2006	Annual Report of the Chief Medical Officer
2.02.07C	Physicians per 10,000 pop	PREFILL CALC		
2.02.08	Total number of nursing and midwifery personnel	2631	2011	MOH/Nursing Council
2.02.09C	Nurses and midwives per 10,000 pop	PREFILL CALC		

2.02.10	Total number of hospitals	7	2011	BDS
2.02.11	Number of hospital beds per 10,000 pop	66	2008	WHS 2009
2.02.12	Total number of primary health care units and centers	12	2011	BDS
2.02.13	Total number of licensed pharmacies	111	2011	BDS
2.02.14	Comments and References	2.02.01, 2.02.03 BDS - Barbados Drug Service 2.02.03 QHE- Queen Elisabeth Hospital. Psychiatric Hospital and prision services 2011. 2.02.04 - There is no trained technicians or assistants; There is only on the job training 2.02.06 - Annual report of the chief medical oficer 2004-2006. Ministry of Health. 2010. The estimated number of physicians for 2010 is 400 2.02.08 Ministry of Health/Nursing Council 2.02.09. 95.22/10,000 inhabitants 2.02.10. Two Public (QEH and Psychiatric) and one Private (Bay View). There are 4 Geriatric Hospitals that are public nursing homes.The Ministery Official Statistics refer to the public nursing homes as hospitals. 2.02.12. Four outpatient clinics: St. Joseph, St. John, St Thomas, St. Andrew (temporary closed - being refurbished) and Eight Polyclinics: Black Rock, Edgar Cochrane, Glebe, Maurice Byer, St. Philip, Winston Scott, Randal Phillips and Warrens. (all public) 2.02.13. Information given for both Private and Public however public pharmacies are not licensed CMO Report - Chief Medical Officer Report		

Supplementary questions (click here for help)

			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist	43,792	2010	BDS

	in the public sector (NCU)			
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country	50	2011	Barbados Community College (BCC)
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes ☒ No☐	2011	BCC
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes ☒ No ☐	2011	BCC
2.02.19S	Comments and References	2.02.16S- 2.02.18S BCC- Barbados Community College. 2.02.16S Level of graduation with Associate degree for three years with six months internship. 2.02.18 There is an annual meeting held to update the Pharmacy Curriculum. However, actual curriculum has not been updated since 5 years ago. (Remark: Please check pre-calculated fields are not working)		

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	Maryam Hinds		
3.00.02	Phone number	246 467 9334		
3.00.03	Email address	bds@caribsurf.com		
3.00.04	Other respondents for filling out this section	Dr. Joy St. John (Chief Medical Officer/Barbados), Leroy Williams, Barbados Drug Services (BDS); Heather Carter (BDS); Ersie Chase (BDS), Pamela Payne-Wilson (BDS)		

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 ☐	2002	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 ☐	2002	MOH
3.01.03	Please provide comments on the Health policy and its implementation plan			
3.01.04	National Medicines Policy official document exists. If yes, please write the year of the most recent document in the "year" field.	Yes ☐ No ☒	2011	BDS
3.01.05	Group of policies addressing pharmaceuticals exist.	Yes ☒ No ☐	2011	BDS
3.01.06	National Medicines Policy covers the following components:	—		

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

	national legislation?			
3.01.11	There are official written guidelines on medicines donations.	Yes ☐ No ☒	2011	BDS
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes ☒ No ☐	2010	BDS
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	Barbados Drug Service (BDS)		
3.01.13	Is there a national good governance policy?	Yes ☐ No ☒	2011	BDS
3.01.13.01	Multisectoral	☐Yes		
3.01.13.02	For the pharmaceutical sector	☐Yes		
3.01.13.03	Which agencies are responsible?			
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes ☐ No ☒	2011	BDS
3.01.15	There is a formal code of conduct for public officials.	Yes ☒ No ☐	2007	Public Service Act 2007 - 41 Section 2,11 Subsection (1)(b) Second Schedule page 30
3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes ☐ No ☒	2011	BDS
3.01.16.01	Please describe:	3.01.08. There is legislation for regulation of private laboratories. For the public sector, there is the policy to amalgamate all the public health labs-2010 and also a policy to accredit the		

		laboratories. HIV got accreditation 2009/2010 and Public Health Lab and QEH are working on their process.
3.01.17	Comments and References	BDS- Barbados Drug Services 3.01.01. The Barbados Strategic Plan for Health 2002-2012. Ministry of Health. 3.01.04.- 3.01.06.12 The Barbados National Pharmaceutical Policy was developed in 2011 and it is in a draft format to be submitted to Cabinet for approval. (previous draft from 2005) 3.01.12. WHO Level II Survey (Health facilities and household surveys) 3.01.15 Public Service Act 2007 - 41 Section 2,11 Subsection (1)(b) Second Schedule page 30 MOH- Ministry of Health

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	Maryam Hinds
4.00.02	Phone number	246 467 9334
4.00.03	Email address	bds@caribsurf.com
4.00.04	Other respondents for filling out this section	Leroy Williams, Barbados Drug Services (BDS); Heather Carter (BDS); Ersie Chase (BDS), Pamela Payne-Wilson (BDS)

4.01 Intellectual Property Laws and Medicines

Core questions (click here for help)

			Year	Source
4.01.01	Country is a member of the World Trade Organization	Yes ☒ No☐	1995	WTO
4.01.02	Legal provisions provide for granting of Patents on:		2001	Patent Act
4.01.02.01	Pharmaceuticals	Yes ☒ No☐		
4.01.02.02	Laboratory supplies	Yes ☒ No ☐		
4.01.02.03	Medical supplies	Yes ☒ No ☐		
4.01.02.04	Medical equipment	Yes ☒ No ☐		
4.01.03.01	Please provide name and address of the institution responsible for managing and enforcing intellectual property rights	Corporate Affairs and Intellectual Property Office (CAIPO) Keith Bourne Complex Belmont Road, St.Michael Barbados		
4.01.03.02	Please provide URL	http://www.caipo.gov.bb		
4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes ☒ No ☐	2001	Patent Act
4.01.05	Current laws contain (TRIPS) flexibilities and safeguards	Yes ☒ No☐	2009	CARICOM IP HERA

				FINAL REPORT Volume II
4.01.06	Country is eligible for the transitional period to 2016	Yes ☐ No☒	2009	CARICOM IP HERA FINAL REPORT Volume II
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2009	CARICOM IP HERA FINAL REPORT Volume Ii
4.01.07.01	Compulsory licensing provisions that can be applied for reasons of public health	Yes ☒ No ☐		
4.01.07.02	Bolar exception	Yes ☐ No ☒		
4.01.08	Are parallel importing provisions present in the national law?	Yes ☐ No ☒	2009	CARICOM IP HERA FINAL 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 ☐	2011	BDS
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes ☒ No ☐	2009	CARICOM IP HERA FINAL REPORT Volume II
4.01.11	Legal provisions exist for patent extension	Yes ☐ No ☐		
4.01.12	Legal provisions exist for linkage between patent status and Marketing	Yes ☐ No ☒	2011	BDS

	Authorization			
4.01.13	Comments and References	4.01.01 WTO- World Trade organization. http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm 4.01.02 Patent Act 2001: http://www.wipo.int/wipolex/en/details.jsp?id=326. According to HERA REport: Patent law in Barbados is governed by the Patents Act 2001 (amended 2006) and Patent Regulations 1984. 4.01.05-07, 4.05.10. Regional Assessment of Patent and Related Issues and Access to Medicines. CARICOM member states and the Dominican Republic. Final Report . Volume I and Volume II – Country Studies. 31 December 2009 4.01.09. Barbados is member of the Technical Advisory Group on Intellectual Property (TAG) of CARICOM. 4.01.10 Provision provided by Protection Against Unfair Competition Act, 1998. Nevertheless, Marketing Authorization is not in place in the Country. 4.01.12 There is no legal provision linking patent status and marketing authorization. Marketing Authorization is not in place in the country and there is public procurement of generic medicines. Barbados is bound by the following agreements: EU-CARIFORUM EPA Patent Cooperation Treaty. WTO - World Trade Organization		

4.02 Manufacturing

Core questions (click here for help)

			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country	1	2009	CARICOM IP HERA FINAL REPORT Volume II
4.02.02	Country has manufacturing capacity		2011	BDS
4.02.02.01	R&D to discover new active	Yes ☐ No ☒ Unknown ☐		

	substances			
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes ☐ No ☒ Unknown ☐		
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes ☒ No ☐ Unknown ☐		
4.02.02.04	Repackaging of finished dosage forms	Yes ☐ No ☒ Unknown ☐		
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)	2.75	2004	BDS
4.02.04	Comments and References	4.02.01 Regional Assessment of Patent and Related Issues and Access to Medicines. CARICOM member states and the Dominican Republic. Final Report . Volume II – Country Studies. 31 December 2009 4.02.01- 4.02.03 BDS- Barbados Drugs Service		

Supplementary questions (click here for help)

			Year	Source
4.02.05S	Percentage of market share by volume produced by domestic manufacturers (%)			
4.02.06S	Number of multinational pharmaceutical companies manufacturing medicines locally	0	2011	BDS
4.02.07S	Number of manufacturers that are Good Manufacturing Practice (GMP) certified	1	2011	BDS
4.02.08S	Comments and References	4.02.07S Certification of GMP of manufacturers follows the Annual Inspection according to the WHO Standards No Local caertificate available. 4.02.06S, 4.02.07S BDS- Barbados Drugs Service		

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	Heather Carter (BDS)
5.00.02	Phone number	1-246-467-9511
5.00.03	Email address	heacart@yahoo.com
5.00.04	Other respondents for filling out this section	Trevor Richards (BDS), Pamela Payne-Wilson (BDS), Maryam Hinds (BDS)

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 ☐	1970	Health Services (Control of Drugs Regulations) 1970
5.01.02	There is a Medicines Regulatory Authority	Yes ☐ No ☒	2009	HERA
5.01.03	If yes, please provide name and address of the Medicines regulatory authority	Chief Medical Officer Ministry of Health Frank Walcott Building Collymore Rock, St Michael, Barbados.		
5.01.04	The Medicines Regulatory Authority is:		1970	Health Services (Control of Drugs Regulations) 1970

5.01.04.01	Part of MoH	☒Yes		
5.01.04.02	Semi autonomous agency	☐Yes		
5.01.04.03	Other (please specify)	According to HERA Report: "Administration of the medicines laws in Barbados is vested onto a number of bodies. The Pharmacy Council is established under section 10 of the Pharmacy Act, 1986 to control and regulate the practice of pharmacy, registration and control of persons admitted to practice, and registration of pharmacy premises for selling drugs and poisons. The Therapeutic Substances Act, 1950 empowers the Chief Medical Officer, under section 4 of the Act as Licensing Authority responsible for control of the manufacture for sale or supply of any drug or therapeutic substance to which the Act applies". Health Services (Control of Drugs Regulations) 1970. Barbados Drug Service retain administrative functions related to medicines under the drug service act. BDS executes inspections related to the Pharmacy Act and the control of drugs and other controles substances, under the CMO's legal mandate.		
5.01.05	What are the functions of the National Medicines Regulatory Authority?		2009	CARICOM DRA HERA FINAL REPORT Volume II
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)	These are the functions carried out by Barbados Drug Service. The Pharmacy Council regulates the Pharmacy Practice and premises. At BDS, the functions are executed by 3 Drug Inspectors. except the Clinical Trials - that have to be approved by the National Ethics Committee (MOH/UWI).		
5.01.06	Number of the MRA permanent staff	3	2011	BDS
5.01.06.01	Date of response	26/05/2011		
5.01.07	The MRA has its own website	Yes ☐ No ☒	2011	BDS
5.01.07.01	- If yes, please provide MRA Web site address (URL)			
5.01.08	The MRA receives external technical assistance	Yes ☒ No ☐	2011	BDS
5.01.08.01	If yes, please describe:	Technical cooperation from PAHO/WHO, OAS		
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes ☒ No ☐	2011	BDS
5.01.09.01	- If yes, please specify	PANDRH, CARICOM, WHO		
5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes ☒ No ☐	2009	CARICOM DRA HERA FINAL REPORT Volume II
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the government.	Yes ☒ No ☐	2011	BDS
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☐ No ☒	2011	BDS
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ☐ No ☒	2011	BDS

5.01.13.01	- If yes, please specify			
5.01.14	Revenues derived from regulatory activities are kept with the Regulatory Authority	Yes ☐ No ☒	2011	BDS
5.01.15	The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes ☐ No ☒	2011	BDS
5.01.16	Comments and References	5.01.01 and 02: Drug Service Act (1980) and Financial Administration and Audit (Drug Service) Rules, 1980. provides for control of medicines within BDS. 5.01.04 BDS- Barbados Drugs Service 5.01.05, 5.01.10 Regional Assessment of Drug Registration and Regulatory Systems in CARICOM member states and the Dominican Republic. Final Report . Volume II. 2009 5.01.06- 5.01.15 BDS- Barbados Drug Service. 5.01.06 Three only represent the number of Drug Inspectors and does not include the CMO, the Director and Secretaries and other support staff. These are the functions carried out by Barbados Drug Service. The Pharmacy Council regulates the Pharmacy Practice and premises. At BDS, the functions are executed by 3 Drug Inspectors, except the Clinical Trials - that have to be approved by the National Ethics Committee (MOH/UWI). 5.01.07.01. The website is being constructed There are 3 drug inspectors, working at Barbados Drug Service		

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	Yes ☐ No ☒	2011	BDS

	market			
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes ☐ No ☒	2011	BDS
5.02.03	Are there mechanisms for recognition of registration done by other countries	Yes ☐ No ☒	2011	BDS
5.02.03.01	If yes, please explain:			
5.02.04	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes ☐ No ☒	2011	BDS
5.02.05	Information from the prequalification programme managed by WHO is used for product registration	Yes ☐ No ☒	2011	BDS
5.02.06	Number of pharmaceutical products registered in your country	0	2011	BDS
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes ☐ No ☒	2011	BDS
5.02.07.01	If yes, how frequently updated			
5.02.07.02	If yes, please provide updated list or URL *			
5.02.08	Medicines registration always includes the INN (International Non-proprietary Names)	Yes ☐ No ☒	2011	BDS
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes ☐ No ☒	2011	BDS
5.02.10	Comments and References	5.02.01 - 5.02.09 BDS- Barbados Drug Service 5.02.04 The quality of pharmaceutical products is ensured by The		

		Drug Service wich is the regulatory Autrhority.		
Supplementary questions (click here for help)				
			Year	Source
5.02.11S	Legal provisions require Marketing Authorization holders to provide information about variations to the existing Marketing Authorization	Yes ☐ No ☒	2011	BDS
5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes ☐ No ☒	2011	BDS
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☐ No ☒	2011	BDS
5.02.14S	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes ☐ No ☒	2011	BDS
5.02.15S	Legal provisions require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	Yes ☐ No ☒	2011	BDS
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes ☐ No ☒	2011	BDS
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US$)	0	2011	BDS
5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US$)	0	2011	BDS
5.02.19S	Time limit for the assessment of a Marketing Authorization application	0	2011	BDS

	(months)			
5.02.20S	Comments & References	5.02.01 - 5.02.19 BDS- Barbados Drug Service No medicines registration is in place.		

5.03 Regulatory Inspection

Core Questions(click here for help)

			Year	Source
5.03.01	Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes ☒ No ☐	2001	Civil Establishment Act,Cap.21 (Qualifications) Order Section 33 page 123
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes ☒ No ☐	1970	Health Services (Control of Drugs) Regulations
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:		2009	CARICOM DRA HERA REPORT Volume II
5.03.03.01	Public facilities	Yes ☐ No ☒		
5.03.03.02	Private facilities	Yes ☒ No ☐		
5.03.04	Inspection requirements are the same for public and private facilities	Yes ☐ No ☒	2011	BDS
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes ☒ No ☐	2011	BDS

5.03.05.02	Private wholesalers are inspected	Yes ☒ No ☐
5.03.05.03	Retail distributors are inspected	Yes ☒ No ☐
5.03.05.04	Public pharmacies and stores are inspected	Yes ☐ No ☒
5.03.05.05	Pharmacies and dispensing points of health facilities are inspected	Yes ☐ No ☒
5.03.05.06	Please provide details on frequency of inspections for the different categories of facilities	At Manufacturing Laboratory and private pharmacies, inspections are conducted annualy; for the public sector pharmacies and wholesalers/distributers the inspections are not periodical.
5.03.06	Comments and References	5.03.01. See also Pharmacy Act (1993) art. 32. 5.03.03 -5.03.03.02 Regional Assessment of Drug Registration and Regulatory Systems in CARICOM member states and the Dominican Republic. Final Report . Volume II. 2009 5.03.04 There is currently no legal requirement for public pharmacies 5.03.05.06 BDS- Barbados Drug Service. Not applicable (no stand alone pharmacies). No stand alone pharmacie: Public Pharmacies are always attached to a health facility, either a policlinic, an outpatient clinic or geriatric hospital

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 ☐	2011	Health Services (Control of Drugs) Regulations,1970 Section 10 Therapeutic Substances Regulation

				1950, Section 3 Drug Abuse (Prevention and Control) Act 1990 Part II Restricting to Controlled Drugs Section 4
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes ☒ No ☐	1970	Health Services (Control of Drugs) Regulations,1970 Section 10
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes ☒ No ☐	1970	Health Services (Control of Drugs) Regulations Section 13
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes ☒ No ☐	1970	Health Services (Control of Drugs) Regulations Section 13
5.04.05	Comments and References	5.04.01-5.04.05 Drug abuse prevention and control Act. http://www.unodc.org/enl/showDocument.do?lng=es&language=SPA&node=docs&cmd=add&documentUid=1387&country=BAR		

5.05 Licensing				
			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes ☒ No ☐	1980	Barbados Drug Service (Rule 41) of Financial Drug Services
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes ☒ No ☐	1980	Barbados Drug Service (Rule 41) of Financial Drug Services
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by the government.	Yes ☐ No ☒	2011	BDS
5.05.04	Legal provisions exist requiring importers to be licensed	Yes ☒ No ☐	1970	Health Services (Control of Drugs) Regulations Section 9 subsection 1
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ☐ No ☒	2011	BDS
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**	Yes ☒ No ☐	2009	CARICOM DRA HERA FINAL REPORT Volume II

	section (Section 7)			
5.05.07	National Good Distribution Practice requirements are published by the government	Yes ☐ No ☒	2011	BDS
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes ☒ No ☐	1993	Pharmacy Act Section 14
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes ☒ No ☐	1993	Pharmacy Act Section 16
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes ☒ No ☐	1993	Pharmacy Act Section 16
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes ☐ No ☒	2011	BDS
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes ☐ No ☒	2011	BDS
5.05.13	Comments and References	5.05.01, 5.05.02 Barbados Drug Service (Rule 41) of Financial Drug Services. 1980 5.05.03, 5.05.05, 5.05.07, 5.05.11, 5.05.12 BDS- Barbados Drug Service 5.05.06. Regional Assessment of Drug Registration and Regulatory Systems in CARICOM member states and the Dominican Republic. Final Report . Volume II. 2009. 5.05.08 - 5.05.10 Pharmacy act, sections 14 and 16. 1993 The Good Distribution Practices Guidelines are not published.		

5.06 Market Control and Quality Control

Core Questions (click here for help)

	Year	Source

5.06.01	Legal Provisions for regulating the pharmaceutical market exist	Yes ☐ No ☒	2011	BDS
5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes ☐ No ☒	2009	CARICOM DRA HERA FINAL REPORT Volume II
5.06.02.01	If yes, is the laboratory part of the MRA?	Yes ☐ No ☐		
5.06.02.02	Does the regulatory authority contract services elsewhere?	Yes ☒ No ☐		
5.06.02.03	If yes, please describe	The Caribbean Regional DrugTesting Laboratory is used as well		
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	BDS
5.06.04.01	For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities)	Yes ☐ No ☒		
5.06.04.02	For quality monitoring in private sector (routine sampling in retail outlets)	Yes ☐ No ☒		
5.06.04.03	When there are complaints or problem reports	Yes ☒ No ☐		
5.06.04.04	For product registration	Yes ☐ No ☒		
5.06.04.05	For public procurement prequalification	Yes ☒ No ☐		
5.06.04.06	For public program products prior to acceptance and/or distribution	Yes ☐ No ☒		

5.06.05	Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes ☐ No ☒	2011	BDS
5.06.06	How many Quality Control samples were taken for testing in the last two years?	138	2009	BDS
5.06.07	Total number of samples tested in the last two years that failed to meet quality standards			
5.06.08	Results of quality testing in past two years are publicly available	Yes ☐ No ☒	2011	BDS
5.06.09	Comments and References	5.06.01 Not in the country's legislation, but Caribbean Regional Drug Testing Laboratory Agreement establishes a regional quality control laboratory in force in 14 countries including Barbados. 5.06.02 Regional Assessment of Drug Registration and Regulatory Systems in CARICOM member states and the Dominican Republic. Final Report . Volume II. 2009. BDS- Barbados Drug Service, uses Caribbean Drug Test Laboratory and Experchem (Canada)		

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 ☐	1970	Health Services (Control of Drugs) Regulations,Section 4 Subsection (a)
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:			

5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes ☐ No ☒	2011	BDS
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional materials 	Yes ☐ No ☒	2011	BDS
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes ☐ No ☒	2011	BDS
5.07.06	A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes ☐ No ☒	2011	BDS
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	5.07.01. Despite of the existece of legal provisions, regulation of medicines promotion is not performed in the country.		

		5.07.03-5.07.06 BDS- Barbados Drug Service		

5.08 Clinical trials

Core Questions (click here for help)

			Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes ☐ No ☒	2009	CARICOM DRA HERA FINAL REPORT Volume II
5.08.02	Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes ☐ No ☒	2011	BDS
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes ☐ No ☒	2011	BDS
5.08.04	Comments and References	5.08.02. There is a joint Ethics Committee from MOH and UWI. This is the ethical committee to approve the research protocols involving humans, including clinical trials in regards to ethical aspects. 5.08.01 Regional Assessment of Drug Registration and Regulatory Systems in CARICOM member states and the Dominican Republic. Final Report . Volume II. 2009.		

Supplementary questions (click here for help)

			Year	Source
5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes ☐ No ☒	2011	BDS
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes ☐ No ☒	2011	BDS

5.08.07S	National GCP regulations are published by the Government.	Yes ☐ No ☒	2011	BDS
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☐ No ☒	2011	BDS
5.08.09S	Comments and References	5.08.02- 5.08.08S BDS- Barbados Drug Service		

5.09 Controlled Medicines

Core Questions (click here for help)

			Date	Source
5.09.01	The country has adopted the following conventions:			
5.09.01.01	Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1976	International Narcotics Control Board, 2010
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1976	International Narcotics Control Board, 2010
5.09.01.03	Convention on Psychotropic Substances 1971	Yes ☒ No ☐	1975	International Narcotics Control Board, 2010
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes ☒ No ☐	1992	International Narcotics Control Board, 2010
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes ☒ No ☐	1990	Drug Abuse (Prevention and

				Control) Act 14, ection 3
5.09.03	Annual consumption of Morphine (mg/capita)		2010	BDS
5.09.04	Comments and References	5.09.01- 5.09.01.04 Report of the International Narcotics Control Board for 2010. International Narcotics Control Board. 5.09.02 Drug Abuse (Prevention and Control Act), 1990 - 14 50. http://www.unodc.org/enl/showDocument.do?lng=es&language=SPA&node=docs&cmd=add&documentUid=1387&country=BAR 5.09.03. 4.89mg/capita - Interview with Mr. David Crawford (BDS)		

Supplementary questions (click here for help)

			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Yes ☐ No ☐ Unknown ☒	2011	BDS
5.09.05.01S	If yes, year of review			
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.009	2010	BDS
5.09.07S	Annual consumption of Pethidine (mg/capita)	37.32	2010	BDS
5.09.08S	Annual consumption of Oxycodone (mg/capita)			
5.09.09S	Annual consumption of Hydrocodone (mg/capita)			
5.09.10S	Annual consumption of Phenobarbital (mg/capita)			
5.09.11S	Annual consumption of Methadone	0.018	2010	BDS

	(mg/capita)			
5.09.12S	Comments and References	5.09.08S - Oxycodone and 5.09.09S - Hydrocodone Barbados Drug Service (BDS) does not import these medicines 5.09.06S, 07S, 11S - Interview with Mr. David Crawford (BDS)		

5.10 Pharmacovigilance

Core Questions (click here for help)

			Year	Source
5.10.01	There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	Yes ☐ No ☒	2011	BDS
5.10.02	Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA	Yes ☐ No ☒	2011	BDS
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes ☐ No ☒	2011	BDS
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes ☐ No ☒	2011	BDS
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time			
5.10.04.02	If a national pharmacovigilance center exists in your country, an analysis report has been published in the last two years.	Yes ☐ No ☐		
5.10.04.03	If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes ☐ No ☐		

5.10.05	An official standardized form for reporting ADRs is used in your country	Yes ☒ No ☐	2011	BDS
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes ☐ No ☒	2011	BDS
5.10.07	How many ADR reports are in the database?			
5.10.08	How many reports have been submitted in the last two years?			
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes ☒ No ☐	2011	BDS
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 ☒	2011	BDS
5.10.11	Is there a clear communication strategy for routine communication and crises communication?	Yes ☐ No ☒	2011	BDS
5.10.12	In the absence of a national pharmacovigilance system, ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)?	Yes ☒ No ☐	2011	BDS
5.10.13	Please describe how you intend to enhance the Pharmacovigilance system	We just had a staff member assigned to work in Pharmacovigilance. She will commence compiling ADRs in September		
5.10.14	Comments and References	5.10.01- 5.10.14 BDS- Barbados Drug Sevice 5.10.05. Forms are available in the Barbados National Drug		

		Formulary 5.10.06. the VIGIFLOW is used. 5.10.12. Despite of the inexistence of the National Centre, some Pharmacovigilance activities are conducted for HIV/AIDS programme		
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 ☐		
5.10.20S	In the past two years, who has reported ADRs?			
5.10.20.01S	Doctors	☐Yes		
5.10.20.02S	Nurses	☐Yes		
5.10.20.03S	Pharmacists	☐Yes		
5.10.20.04S	Consumers	☐Yes		
5.10.20.05S	Pharmaceutical Companies	☐Yes		
5.10.20.06S	Others, please specify whom			
5.10.21S	Was there any regulatory decision based on local pharmacovigilance	Yes ☐ No☐		

	data in the last 2 years?			
5.10.22S	Are there training courses in pharmacovigilance?	Yes ☐ No☐		
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	Leroy Williams (BDS)
6.00.02	Phone number	246 467 9510
6.00.03	Email address	williams.leroy53@yahoo.com
6.00.04	Other respondents for this sections	

6.01 Medicines Coverage and Exemptions

Core Questions (click here for help)

			Year	Source
6.01.01	Do the followings receive medicines free of charge:		1991	Drug Service Act Section 7 subsection (a)
6.01.01.01	Patients who cannot afford them	Yes ☒ No☐		
6.01.01.02	Children under 5	Yes ☒ No☐		
6.01.01.03	Pregnant women	Yes ☐ No☒		
6.01.01.04	Elderly persons	Yes ☒ No☐		
6.01.01.05	Please describe/explain your yes answers for questions above	Drug Service Act 1991. Special Benefit Service regulations.MOH. 6.01.01.02. Children under 16 are entitled to free medicines. 6.01.01.05. Elderly over 65 years old are entitled to free medicines Free medicines provided - from the Barbados National Drug Formulary (BNDF) to children, elderly and for certain conditions, regardless the age (eg. Diabetes, Hypertension, Asthma, Cancer, Epilepsy).		
6.01.02	Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for :		2011	BDS

6.01.02.01	All medicines included in the EML	Yes ☒ No ☐		
6.01.02.02	Any non-communicable diseases	Yes ☒ No ☐		
6.01.02.03	Malaria medicines	Yes ☒ No ☐		
6.01.02.04	Tuberculosis medicines	Yes ☒ No ☐		
6.01.02.05	Sexually transmitted diseases medicines	Yes ☒ No ☐		
6.01.02.06	HIV/AIDS medicines	Yes ☒ No ☐		
6.01.02.07	Expanded Program on Immunization (EPI) vaccines	Yes ☒ No ☐		
6.01.02.08	If others, please specify	Patients seeing a doctor at Queen Elisabeth Hospital, who had their prescription filled at the hospital, medicines are free of charge, nevertheless, if patients fill the prescription in private pharmacy patients have to pay for it.		
6.01.02.09	Please describe/explain your yes answers for questions above	6.01.02.01 - For patients doctor consultation and filling the prescription in a public facility, medicines are free of charge regardless the age and condition for medicines from the BNDF. For patients seing a private doctor, and are from one of the entitled categories they can obtain the medicines free of charge at public facilities or from private pharmacies, paying a dispensing fee. See - 6.01.01.05.		
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?	Yes ☐ No ☒	2011	BDS
6.01.03.01	Does it provide coverage for medicines that are on the EML for inpatients	Yes ☐ No ☐		
6.01.03.02	Does it provide coverage for medicines that are on the EML for outpatients	Yes ☐ No ☐		
6.01.03.03	Please describe the medicines benefit of public/social insurance schemes			

6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes ☒ No ☐	2011	BDS
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the EML?	Yes ☐ No ☒		
6.01.05	Comments and References	6.01.01- 6.01.01.05 Drug service act. Section 7 6.01.02 - 6.01.05 BDS- Barbados Drug Service 6.01.04. Most of private insurances cover medicines. The percentage of coverage and medicines depend on the type of contract or insurance plan.		

6.02 Patients Fees and Copayments

Core Questions (click here for help)

			Year	Source
6.02.01	In your health system, at the point of delivery, are there any co-payment/fee requirements for consultations	Yes ☐ No ☒	2011	BDS
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes ☐ No ☒	2011	BDS
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 ☒	2007	WHO level I
6.02.03.01	Please describe the patient fees and copayments system	No, dispensing fee for public sector patients filling prescription at private pharmacies		
6.02.04	Comments and References	6.02.01, 6.02.02 BDS - Barbados Drug Service 6.02.03.01 Medicines from the BNDF are free in public pharmacies, a dispensing fee should be paid by beneficiaries if they choose to use the private sector, but the cost of the medication is free, just the		

		dispensing fee and others pay a subsidized rate (no duties, no VAT).		
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 ☐	1991	Drug Service Act Section 4 Subsection 2d
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.)	6.03.01. Prices regulation only for medicines from BNDF at private pharmacies for reimbursement purposes. Prices for medicines purchased out of pocket are not controlled.		
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes ☐ No ☒	2011	BDS
6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes ☐ No ☒	2011	BDS
6.03.03.01	-if yes, please explain how the information is made publically available			
6.03.04	Comments and References	6.03.01 Drug Service Act….. 6.03.02, 6.03.03 BDS- Barbados Drug Service		

6.04 Prices, Availability and Affordability

Core Questions (click here for help)

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

	Basket Of key medicines			Public procurement	Public patient	Private patient		
	Availability (one or both of)	**Mean (%)**	**Orig**		6.04.01.01	6.04.01.03		
			LPG		6.04.01.02	6.04.01.04		
		Median (%)	**Orig**		6.04.02.01	6.04.02.03		
			LPG		6.04.02.02	6.04.02.04		
	Price	**Median Price Ratio**	**Orig**	6.04.03.01	6.04.03.03	6.04.03.05		
			LPG	6.04.03.02	6.04.03.04	6.04.03.06		

	Affordability Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection	**Number of days' wages**	**Orig**		6.04.04.01	6.04.04.03	
			LPG		6.04.04.02	6.04.04.04	
6.04.05	Comments and References						

6.05 Price Components and Affordability

Core Questions (click here for help)

			Year	Source
6.05.01	Please state if a survey of medicines price components has been conducted in the past 5 years in your country	Yes ☐ No ☒ Unknown ☐	2011	BDS
6.05.02	Median cumulative percentage mark-up between Manufacturer Selling Price (MSP)/ Cost Insurance and Freight (CIF) price and final medicine price for a basket of key medicines in the public sector (Median % contribution)			
6.05.03	Median cumulative percentage mark-up between MSP/CIF price and final medicine price for a basket of key medicines in the private sector (Median % contribution)			
6.05.04	Comment and References			
Supplementary questions (click here for help)				
6.05.05S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)			
6.05.06S	Median percentage contribution of			

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

6.06 Duties and Taxes on Pharmaceuticals (Market)

Core Questions (click here for help)

			Year	Source
6.06.01	There are duties on imported active pharmaceutical ingredients (APIs)	Yes ☐ No ☒	1997	VAT Act Section 29 -31 Third Schedule page 129

6.06.02	There are duties on imported finished products	Yes ☒ No ☐	1997	VAT Act Section 29 -31 Third Schedule page 129 Customs Act -1998
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes ☒ No ☐	1997	Vat Act First Schedule Section 8 page 111
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes ☐ No ☒	1997	VAt Act Second Schedule Section 7 and 8
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist	Medicines in the BNDF, all vaccines and prescription medicines that request waiver to BDS are duty free and VAT zero rated. OTC medicines are not entitled for duty free. See Valued Added Tax (VAT) Act.		
6.06.06	Comments and References	6.06.01- 6.06.05 Value added Tax Act. http://www.lexadin.nl/wlg/legis/nofr/oeur/lxwebar.htm		
Supplementary questions (click here for help)				
			Year	Source
6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)	0		N/A
6.06.08S	Duty on imported finished products (%)	20	1998	Customs and Tariff Act Section 19
6.06.09S	VAT on pharmaceutical products (%)	17.50	1997	VAT Act Section 7 subsection

				(2)-(3)
6.06.10S	Comments and References	6.06.08S, 6.06.09S Value added Tax Act. http://www.lexadin.nl/wlg/legis/nofr/oeur/lxwebar.htm		

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	Maryam Hinds
7.00.02	Phone number	246 467 9334
7.00.03	Email address	bds@caribsurf.com
7.00.04	Other respondents for filling out this section	Heather Carter and Trevor Richards

7.01 Public Sector Procurement

Core Questions (click here for help)

			Date	Source
7.01.01	Public sector procurement is:		2011	BDS
7.01.01.01	Decentralized	☐Yes		
7.01.01.02	Centralized and decentralized	☒Yes		
7.01.01.03	Please describe	The public sector procurement is governed by the same rules. Financial Administration and Audit Acts (financial rules) (1980) with a Drug Service Regulation (1980). For medicines, there is a national bid and the procurement is conducted by each institution at contracted prices - for both public and private facilities.		
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:		2011	BDS
7.01.02.01	Part of MoH	Yes ☒ No ☐		

7.01.02.02	Semi-Autonomous	Yes ☐ No ☒		
7.01.02.03	Autonomous	Yes ☐ No ☒		
7.01.02.04	A government procurement agency which procures all public goods	Yes ☒ No ☐		
7.01.03	Public sector requests for tender documents are publicly available	Yes ☐ No ☐		
7.01.04	Public sector tender awards are publicly available	Yes ☐ No ☐		
7.01.05	Procurement is based on prequalification of suppliers	Yes ☐ No ☐		
7.01.05.01	If yes, please describe how it works			
7.01.06	Comments and References	7.01.02. The tender committee is composed by: BDS Director (Chairman) Assistant Director of Supplies and Inventory/BDS (Deputy Chair) 2 members from QEH- Chief of medical staff and Chief Pharmacist 2 members from private sector - private pharmacist and private doctor Representative from the Chief Supply Officer/Ministry of Finance 7.01.01- 7.01.02.04 BDS- Barbados Drug 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 ☐	1980	Financial Administration and (Drug Service) Audit Rules Section 3
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local	Yes ☐ No ☒	2011	BDS

	manufacturers?			
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes ☒ No ☐	1980	Financial Administration and Audit (Drug Service) Rules, 1980 Section 25
7.01.10S	A process exists to ensure the quality of products procured	Yes ☒ No ☐	2011	BDS
7.01.10.01S	If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes ☒ No ☐		
7.01.10.02S	If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Yes ☐ No ☒		
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly available	Yes ☒ No ☐		
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes ☐ No ☒	2011	BDS
7.01.12S	Which of the following tender methods are used in public sector procurement:		2011	BDS
7.01.12.01S	National competitive tenders	Yes ☒ No ☐		
7.01.12.02S	International competitive tenders	Yes ☐ No ☒		
7.01.12.03S	Direct purchasing	Yes ☒ No ☐		
7.01.13S	Comments and References	7.01.07S, 7.01.09S Financial Administration and Audit. FINANCIAL ADMINISTRATION AND AUDIT CAP 5. (DRUG SERVICE) RULES, 1980 7.01.08S therefore, the Tender Committee gives preference to local		

		providers 7.01.11S. It can be available upon request. 7.01.12.01S. The medicines are usually from international companies, that are required to participate in the bid through local agents. Distributors who represents international manufacturers. 97.25% of pharmaceutical drugs are supplied by foreign companies registered with the Drug Service 7.01.12.03S. Direct purchasing is conducted in emergency situation BDS- Barbados Drugs 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 ☐ No ☒	2011	BDS
7.02.02	Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	0	2011	BDS
7.02.03	There are national guidelines on Good Distribution Practices (GDP)	Yes ☐ No ☒	2011	BDS
7.02.04	There is a licensing authority that issues GDP licenses	Yes ☐ No ☒	2011	BDS
7.02.04.01	If a licensing authority exists, does it accredit public distribution facilities?	Yes ☐ No ☒		
7.02.05	List of GDP certified warehouses in the public sector exists	Yes ☐ No ☒	2011	BDS
7.02.06	List of GDP certified distributors in the public sector exists	Yes ☐ No ☒	2011	BDS

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	BDS
7.02.08.01S	Forecasting of order quantities	Yes ☐ No ☒		
7.02.08.02S	Requisition/Stock orders	Yes ☐ No ☒		
7.02.08.03S	Preparation of picking/packing slips	Yes ☐ No ☒		
7.02.08.04S	Reports of stock on hand	Yes ☐ No ☒		
7.02.08.05S	Reports of outstanding order lines	Yes ☐ No ☒		
7.02.08.06S	Expiry dates management	Yes ☐ No ☒		
7.02.08.07S	Batch tracking	Yes ☐ No ☒		
7.02.08.08S	Reports of products out of stock	Yes ☐ No ☒		
7.02.09S	Percentage % availability of key medicines at the Central Medical Store	0	2011	BDS
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days	0		
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes ☐ No ☒	2011	BDS
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ☐ No ☒	2011	BDS
7.02.13S	The Public Central Medical Store is ISO certified	Yes ☐ No ☒	2011	BDS
7.02.14S	The second tier public warehouses are GDP certified by a licensing	Yes ☐ No ☒	2011	BDS

	authority			
7.02.15S	The second tier public warehouses are ISO certified	Yes ☐ No ☒	2011	BDS
7.02.16S	Comments and References	No Central Medical Store at public sector.		

7.03 Private Sector Distribution

Core Questions (click here for help)

			Year	Source
7.03.01	Legal provisions exist for licensing wholesalers in the private sector	Yes ☒ No ☐	2011	BDS
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes ☒ No ☐	2011	BDS
7.03.03	List of GDP certified wholesalers in the private sector exists	Yes ☐ No ☒	2011	BDS
7.03.04	List of GDP certified distributors in the private sector exists	Yes ☐ No ☒	2011	BDS
7.03.05	Comments and References	7.03.01-7.03.04 BDS- Barbados Drugs Service 7.03.01 To operate as a pharmaceutical wholesaler under the Health Service Act		

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	Maryam Hinds and Pamela Payne Wilson
8.00.02	Phone number	246 467 9334
8.00.03	Email address	bds@caribsurf.com
8.00.04	Other respondents for filling out this section	Damian Cohall (UWI)

8.01 National Structures

Core Questions (click here for help)

			Year	Source
8.01.01	National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field	Yes ☒ No ☐	2011	BNDF
8.01.01.01	If yes, number of medicines on the EML (no. of INN)	700		
8.01.01.02	If yes, there is a written process for selecting medicines on the EML	Yes ☒ No ☐		
8.01.01.03	If yes, the EML is publicly available	Yes ☒ No ☐		
8.01.01.04	If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG)	Yes ☐ No ☒		
8.01.02	National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field	Yes ☐ No ☒	2011	BDS
8.01.03	STGs specific to Primary care exist. Please use the "year" field to	Yes ☐ No ☒	2011	BDS

	write the year of last update of primary care guidelines			
8.01.04	STGs specific to Secondary care (hospitals) exists. Please use the "year" field to write the year of last update of secondary care STGs.	Yes ☐ No ☒	2011	BDS
8.01.05	STGs specific to Paediatric conditions exist. Please use the "year" field to write the year of last update of paediatric condition STGs	Yes ☐ No ☒	2011	BDS
8.01.06	% of public health facilities with copy of EML (mean)- Survey data	92	2010	WHO Level II (HH and HF Surveys)
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data	55	2010	WHO Level II (HH and HF Surveys)
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes ☒ No ☐	2011	BDS
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes ☒ No ☐	2011	BDS
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes ☒ No ☐	2010	WHO Level II (HH and HF Surveys)
8.01.11	A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes ☐ No ☒	2011	BDS

8.01.12	A written National strategy exists to contain antimicrobial resistance. If yes, please write year of last update of the strategy in the "year" field	Yes ☐ No ☒	2011	BDS
8.01.13	Comments and References	The BNDF is the National EML and selection is conducted by the National Formulary Committee. Standard Treatment Guidelines from Caribbean are used for HV/AIDS, Asthma, Diabetes, Hypertension (?) and other international STG. 8.01.05. The same existing STGs for specific diseases are followed for paediatrics when applicable. 8.01.09. Public Campaigns are conducted every quarter. 8.01.12. There is no written guidelines or strategies. The Infection Control Committee - QEH provide guidances on the matter.		
Supplementary questions (click here for help)				
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes ☒ No ☐	2011	BDS
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes ☒ No ☐	2011	BDS
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes ☒ No ☐	1980	Drug Service Act
8.01.16.01S	If yes, conflict of interest declarations are required from members of national EML committee	Yes ☐ No ☒		
8.01.17S	National medicines formulary exists	Yes ☒ No ☐	2011	BNDF 30th Edition 2011/2012

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 ☒	2011	MOH (CMO)
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☐ No ☒	2011	MOH (CMO)
8.01.20S	Comments and References	8.01.15S. there is a form for application and the selection is conducted by the national formulary committee. 8.01.16S. The Drug Service Act was last amended in 1990. 8.01.18S. There is no national funded intersectoral task force. Nevertheless, Ministry of Health has an Infection Control Nurse who does check on such matters in the Geriatric and District Hospitals and Queen Elizabeth Hospital (QEH) has an Infection Control Committee and designated officers. 8.01.19S. The Public Health Laboratories do not have that mandate, but they have the capacity to do testing.		

8.02 Prescribing

Core Questions (click here for help)

			Year	Source
8.02.01	Legal provisions exist to govern the licensing and prescribing practices of prescriber	Yes ☒ No ☐	2011	Medical Registration Act
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes ☐ No ☒	2011	BDS
8.02.03	Do prescribers in the private sector dispense medicines?	Yes ☒ No ☐	2011	BDS
8.02.04	Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes ☒ No ☐	2011	QEH

8.02.05	Do more than half of referral hospitals have a DTC?	Yes ☒ No ☐ Unknown ☐	2011	BDS
8.02.06	Do more than half of general hospitals have a DTC?	Yes ☐ No ☐ Unknown ☒	2011	BDS
8.02.07	Do more than half of regions/provinces have a DTC?	Yes ☐ No ☒ Unknown ☐	2011	BDS
8.02.08	The core medical training curriculum includes components on:		2011	UWI
8.02.08.01	Concept of EML	Yes ☐ No ☒		
8.02.08.02	Use of STGs	Yes ☒ No ☐		
8.02.08.03	Pharmacovigilance	Yes ☐ No ☒		
8.02.08.04	Problem based pharmacotherapy	Yes ☒ No ☐		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see physician)	Yes ☒ No ☐	2011	Medical Professional Act Section 18 Subsection 2(a) and (b)
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes ☐ No ☒		
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes ☐ No ☒		
8.02.12	Prescribing by INN name is obligatory in:		2011	BDS
8.02.12.01	Public sector	Yes ☐ No ☒		
8.02.12.02	Private sector	Yes ☐ No ☒		
8.02.13	Average number of medicines prescribed per patient contact in			

	public health facilities (mean)			
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	99	2010	WHO Level II (HH and HF Surveys)
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	36	2010	WHO Level II (HH and HF Surveys)
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)	23	2010	WHO Level II (HH and HF Surveys)
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)	7	2010	WHO Level II (HH and HF Surveys)
8.02.18	% of prescribed drugs dispensed to patients (mean)	99	2010	WHO Level II (HH and HF Surveys)
8.02.19	% of medicines adequately labelled in public health facilities (mean)	100	2010	WHO Level II (HH and HF Surveys)
8.02.20	Comments and References	8.02.05. QEH is the referral hospital and has a DTC. 8.02.06. The general hospital is private with its own pharmacy 8.02.08.EML and Pharmacovigilance are not covered. STG and Problem Based Pharmacovigilance are covered and are emphasised/stressed. UWI - University of the West Indies		
Supplementary questions (click here for help)				
			Year	Source
8.02.21S	A professional association code of conduct exists governing	Yes ☒ No ☐	2011	Medical Profession

	professional behaviour of doctors			al Act Section 23
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes ☒ No ☐		
8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)	40	2011	WHO Level II (HH and HF Surveys)
8.02.24S	Comments and References	8.02.22S International Council of Nursing		

8.03 Dispensing

Core Questions (click here for help)

			Year	Source
8.03.01	Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes ☒ No ☐	1993	Pharmacy Act Section 27, 30 Pharmacy Act The Pharmacy(Compounding and dispensing of drugs and poisons) (Amendement) Regulations,1993 Pharmacy Act The Pharmacy(Compounding and dispensing of drugs and poisons)

				(Amendement) Regulations,1986 Section 3 subsection 7
8.03.02	The basic pharmacist training curriculum includes components on:		2011	BDS
8.03.02.01	Concept of EML	Yes ☐ No ☒		
8.03.02.02	Use of STGs	Yes ☐ No ☒		
8.03.02.03	Drug Information	Yes ☐ No ☒		
8.03.02.04	Clinical pharmacology	Yes ☒ No ☐		
8.03.02.05	Medicines supply management	Yes ☐ No ☒		
8.03.03	Mandatory continuing education that includes rational use of medicines is required for pharmacists	Yes ☐ No ☒	2011	BDS
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes ☒ No ☐	1986	Pharmacy Act The Pharmacy(Compounding and dispensing of drugs and poisons) (Amendement) Regulations,1986 Section 3 subsection 7
8.03.05	Generic substitution at the point of dispensing in private sector	Yes ☒ No ☐	1986	Pharmacy Act The

	facilities is allowed			Pharmacy(Compounding and dispensing of drugs and poisons) (Amendement) Regulations,1993 Section 3 subsection 7
8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-the-counter without any prescription?	Yes ☒ No ☐ Unknown ☐	2011	BDS
8.03.07	In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription?	Yes ☐ No ☒ Unknown ☐	2011	BDS
8.03.08	Comments and References	8.03.03. No mandatory Education is required.		
Supplementary questions (click here for help)				
			Year	Source
8.03.09S	A professional association code of conduct exists governing professional behaviour of pharmacists	Yes ☒ No ☐	2011	BDS
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	BDS
8.03.10.01S	Nurses	Yes ☐ No ☒ Unknown ☐		

8.03.10.02S	Pharmacists	Yes ☐ No ☒ Unknown ☐
8.03.10.03S	Paramedics	Yes ☐ No ☒ Unknown ☐
8.03.10.04S	Personnel with less than one month training	Yes ☐ No ☒ Unknown ☐
8.03.11S	Comments and References	8.03.09S. The professional legislation is the pharmacy act and there is a pharmacy council.

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	Maryam Hinds
9.00.02	Phone number	246 467 9334
9.00.03	Email address	bds@caribsurf.com
9.00.04	Other respondents for filling out this section	

9.01 Data from Household Surveys

Core Questions (click here for help)

			Year	Source
9.01.01	What household surveys have been undertaken in the past 5 years to assess access to medicines?	WHO Level II Pharmaceutical Survey: Household Survey (2010)		
9.01.02	Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)		2010	WHO Level II (HH and HF Surveys)
9.01.03	Adults with acute conditions not taking all medicines because they cannot afford them (%)	6	2010	WHO Level II (HH and HF Surveys)
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 (%)	1	2010	WHO Level II (HH and HF Surveys)

9.01.06	Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)	72	2010	WHO Level II (HH and HF Surveys)
9.01.07	Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)	0	2010	WHO Level II (HH and HF Surveys)
9.01.08	Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)	68	2010	WHO Level II (HH and HF Surveys)
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 (%)	44	2010	WHO Level II (HH and HF Surveys)
9.01.10	Percentage of people who obtained the medicines prescribed in the 15 days before the interview (%)			
9.01.11	People who obtained prescribed medicines for free in the 15 days before the interview (%)	78	2010	WHO Level II (HH and HF Surveys)
9.01.12	Comments and References	9.01.02 very severe -100%, moderately severe- 43%, not severe - 18%		
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 (%)	0	2010	WHO Level II (HH and HF Surveys)
9.01.14S	Adults with chronic conditions not taking all medicines because they cannot afford them (%)	1	2010	WHO Level II (HH and HF Surveys)

9.01.15S	Adults with chronic conditions not taking all medicines because the medicines were not available (%)	0	2010	WHO Level II (HH and HF Surveys)
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			