TRINIDAD AND TOBAGO

PHARMACEUTICAL COUNTRY PROFILE

REPUBLIC OF TRINIDAD AND TOBAGO
Pharmaceutical Country Profile

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

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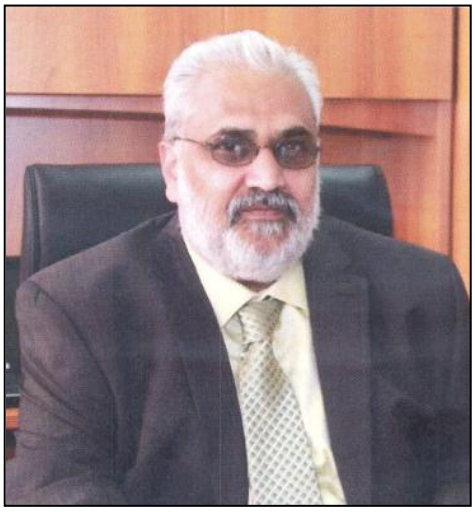
Foreword



The 2012 Pharmaceutical Country Profile for Trinidad and Tobago 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 Trinidad and Tobago. 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 Trinidad and Tobago I would like to express my appreciation to the following people:

Pan American / World Health Organization

Nelly Marin *(Pharmaceutical Policies Advisor for the Americas Region)*
Adriana Ivama *(Medicines and Health Technologies Sub-regional Advisor for the Caribbean)*
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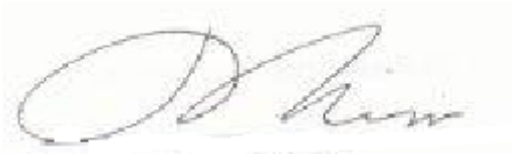
The University of the West Indies

Rian Extavour *(Lecturer)*
Patricia Cumberbatch *(Administrative Assistant)*

National Insurance and Property Development Company (NIPDEC)

Nicholas George *(Pharmacist / Manager)*

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



DR. AKENATH MISIR
Chief Medical Officer of Health
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Acronyms and abbreviations

ADR	Adverse Drug Reaction
API	Active Pharmaceutical Ingredient
CARICOM	Caribbean Community
CMS	Central Medical Store
CFDD	Chemistry Food and Drug Department
CNCD	chronic non-communicable diseases
DID	Drug Inspectorate Division
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
GDPs	Good Distribution Practices
GGHE	General Government Health Expenditure
GMP	Good Manufacturing Practices
GPP	Good Pharmacy Practices
INN	International Non-Proprietary Name
IPR	Intellectual Property Rights
MoH	Ministry of Health
MRA	Medicines Regulatory Authority
NHA	National Health Accounts
NHP	National Health Policy
NIPDEC	National Insurance and Property Development Company
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
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
TTD$	Trinidad and Tobago Dollar
US$	United States Dollars
UWI	University of the West Indies
VAT	Value-added tax
VEN	Vital, Essential and Necessary
WHO	World Health Organization
WTO	World Trade Organization

Introduction

This Pharmaceutical Country Profile provides data on existing socio-economic and health-related conditions, resources, regulatory structures, processes and outcomes relating to the pharmaceutical sector of Trinidad and Tobago. The aim of this document is to compile all relevant, existing information on the pharmaceutical sector and make it available to the public in a user-friendly format.

In 2010, the country profiles project was piloted in 13 countries (http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html). During 2011, the World Health Organization has supported all WHO Member States to develop similar comprehensive pharmaceutical country profiles.

The information is categorized in 8 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Medicines Trade and Production (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical procurement and distribution, and (8) Selection and rational use.

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

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

Data collection in all 193 member states has been conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information. To facilitate the work of national counterparts, the questionnaires were pre-filled at WHO Head Quarter (HQ) using all publicly-available data and before being sent out to each country by the WHO Regional Office, 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 Trinidad and Tobago from Ministry of Health was Dr. Andrea Yearwood (MOH). Data collection was conducted by Ms. Rian Extavour (UWI), with support of Adriana Mitsue Ivama, Guillermo Troya 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.

Comments, suggestions or corrections may be sent to:

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Section 1 - Health and Demographic Data

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

1.1 Demographics and Socioeconomic Indicators

The total population of Trinidad and Tobago in 2010 was 1,317,714[3]. The annual population growth rate in 2008 was 0.4%[1]. The annual Gross Domestic Product (GDP) growth rate is 4.5%[4]. The GDP per capita was US$15,510 in the last year[5].

The population <15 years and ≥60 years, represents the 25.34% and the 10.02% of the total population respectively[3]. The urban population corresponds to the 13% of the total population. In 2008 there were 1.6 births per woman[1].

The adult literacy rate (15+ years) is 99%[1], and the 17% of the total population live below the nationally defined poverty line[6].

1.2 Mortality and Causes of Death

The life expectancy at birth is 66 and 73 years for men and women respectively. The infant mortality rate (i.e. children under one year old) is 31/1,000 live births. For children under the age of five, the mortality rate is 35/1,000 live births. The maternal mortality rate is 45/100,000 live births[1].

The top 10 diseases causing mortality in Trinidad and Tobago in 2006[7] are shown in table 1.

Table 1. Top ten causes of mortality in Trinidad and Tobago

	Disease (International Classification of Diseases[8])
1	Diseases of the heart (I00-I52)
2	Malignant neoplasm (C00-C97)
3	Diabetes mellitus (E10-E14)
4	External causes (V01-Y98)
5	Cerebrovascular disease (I60-I69)
6	Diseases of the respiratory system (J00-J98)
7	Diseases of the digestive system (K00-K92)
8	AIDS/HIV disease (B20-B24)
9	Diseases of the nervous system (G00-G99)
10	Diseases of the genitourinary system (N00-N98)

The top 10 diseases causing morbidity in Trinidad and Tobago in 2007[9] are described in table 2.

Table 2. Top ten causes of morbidity in Trinidad and Tobago

	Disease
1	Injury, poisoning and certain other consequences of external causes
2	Diseases of the genitourinary system
3	Diseases of the heart
4	Symptoms, signs and abnormal clinical and lab findings
5	Diseases of the digestive system
6	Complications of pregnancy
7	Mental illnesses
8	Respiratory disorders
9	Skin disorders
10	Infectious diseases

The adult mortality rate for both sexes (between 15 and 60 years) is 163/1,000 population; and the neonatal mortality rate is 24/1,000 live births[1]. The age-standardized mortality rate by non-communicable diseases is 751/100,000 population[1]; by cardiovascular diseases is 364/100,000 population; and by cancer is 123/100,000 population[2].

The mortality rate for HIV/AIDS and for malaria in 2006 was 22.7 and 0,0 for each 100,000 population respectively[7].

Section 2 - Health Services

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

2.1 Health Expenditures[i]

In Trinidad and Tobago, the total annual expenditure on health (THE) in 2008 was TT$ (Trinidad and Tobago dollars) 7,611 million (1,179.7 million US dollars)[ii]. The total annual health expenditure was 5.7% of the GDP. The total annual expenditure on health per capita was TT$ 5,775.9 (US$ 895.26).

The general government[iii] health expenditure (GGHE) in 2008, as reflected in the national health accounts (NHA) was TT$ 3,720 million (US$ 576.6 million). That is, 48.87% of the total expenditure on health, with a total annual per capita public expenditure on health of TT$ 2,823 (US$ 437.5). The government annual expenditure on health represents 8.8% of the total government budget. Private health expenditure covers the remaining 51.13% of the total health expenditure.

[i] The data in this section were calculated based on the WHO National Health Account for Trinidad and Tobago. Available online: http://www.who.int/nha/country/tto/en/

[ii] The exchange rate used for the calculations was 1 TTD = 0.15 USD

[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.

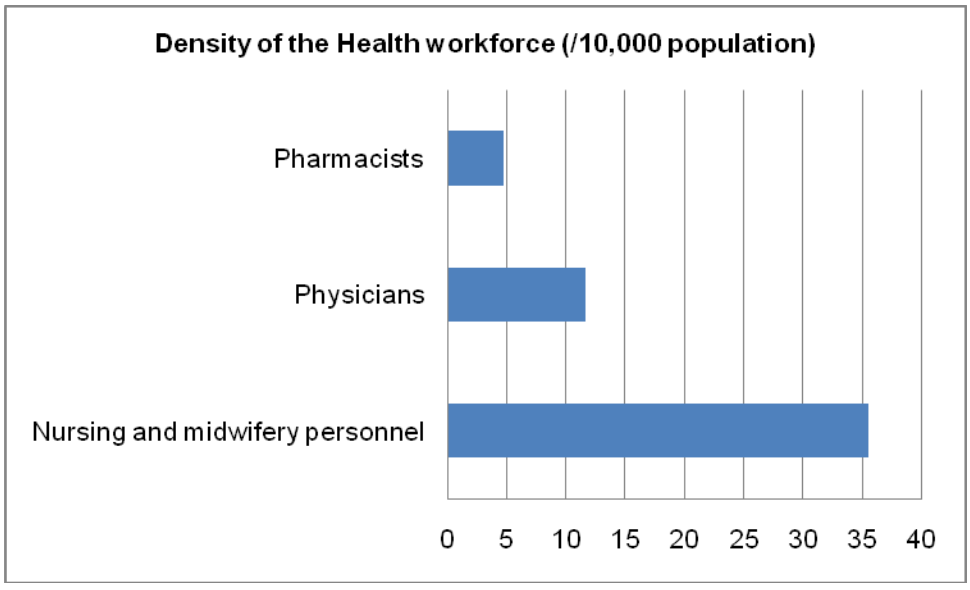
The private out-of-pocket expenditure and the premiums for private prepaid health plans represent the 81.8% and the 14.7% of the Total Private Health Expenditure (TPHE) correspondingly[10].

2.2 Health Personnel and Infrastructure

The health workforce is described in Figure 1. There are 641[11] (4.8/10,000) licensed pharmacists.

There are 1,543 (11.7/10,000) physicians and 4,677[1] (35.5/10,000) nursing and midwifery personnel in Trinidad and Tobago. The ratio of doctors to nurses and midwifery personnel is 1:3.

Figure 1. Density of the Health workforce in Trinidad and Tobago (all sectors)[iv]



[iv] Nursing and Midwifery personnel and Physicians: information related to 2009. Pharmacists: information related to 2007.

In Trinidad and Tobago, there is no strategic plan for pharmaceutical human resource development in place.

There are 21 hospitals (11 public and 10 private)[v] and 27 hospital beds per 10,000 population[1] in the country.

The total number of pharmacists who graduated (first degree) in the past two years in Trinidad and Tobago was 79. There are no specific accreditation requirements for pharmacy schools, but the Pharmacy curriculum is regularly reviewed by the University of the West Indies (UWI) according to the practice-based priorities identified (a review is pending in 2011). Every three years the degree programme is audited by the UWI Quality Assurance Audit Unit. The UWI received institutional accreditation in May 2011 by the Accreditation Council of Trinidad and Tobago[12].

[v] Information provided by Ministry of Health. Office of Drug Inspectorate, 2011.

Section 3 - Policy Issues

This section addresses the main characteristics of the pharmaceutical policy in Trinidad and Tobago. 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 Trinidad and Tobago a Strategic Plan involving the National Health Policy has been developed and is currently under internal review. The public document however, is not yet publicly available.

An official National Medicines Policy (NMP) document exists in the country[13]. It was created in 1998. A NMP implementation plan does not exist. Policies on pharmaceuticals exist at present, and include the NMP and the Chronic Disease Assistance Program[vi]. Pharmaceutical policy implementation is not regularly monitored or assessed.

[vi] Chronic Disease Assistance Program. Available online: http://www.health.gov.tt/sitepages/default.aspx?id=132

Table 3. Items contained in the NMP[13]

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

Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in the constitution or national legislation. There are official written guidelines on medicines donations[14].

There is a National Good Governance policy in Trinidad and Tobago. This Good Governance policy is multi-sectoral and only for the public sector. It was developed in November 2010 and the Pharmacy/Drug Inspectorate is responsible for implementing this policy in the pharmaceutical sector.

A policy is not in place to manage and sanction conflict of interest issues in pharmaceutical affairs. There is, however, a formal code of conduct for public officials. A whistle-blowing mechanism that allows individuals to raise concerns

about wrongdoing occurring in the pharmaceutical sector of Trinidad and Tobago does not exist.

Section 4 – Medicines Trade and Production

This section addresses information about the capacity for manufacturing medicines and regulations regarding intellectual property and patents.

4.1 Intellectual Property Laws and Medicines

Trinidad and Tobago is a member of the World Trade Organization (WTO)[15]. Legal provisions granting patents to manufacturers exist. These cover pharmaceuticals, laboratory supplies, medical supplies and medical equipment[16].

Intellectual Property Rights are managed by the Ministry of Legal Affairs, which is responsible for the law enforcement. The Intellectual Property Office provides information and guidelines for patent applications[vii].

National Legislation has been modified to implement the the trade-related aspects of intellectual property rights (TRIPS) Agreement [14] and contains TRIPS-specific flexibilities and safeguards[17], presented in Table 4.

[vii] Ministry of Legal Affairs, available online at: http://www.legalaffairs.gov.tt and Intellectual Property Office, available online at: http://www.ipo.gov.tt

Table 4. TRIPS flexibilities and safeguards present in the national law[14]

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

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

There are legal provisions for data exclusivity for pharmaceuticals[17], but not for extension of patents.

4.2 Manufacturing

There are 4 licensed pharmaceutical manufacturers in Trinidad and Tobago. Manufacturing capabilities are presented in Table 5 below.

[viii] 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.

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]

Table 5. Trinidad and Tobago manufacturing capabilities[14]

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

There are no multinational pharmaceutical companies manufacturing medicines locally in Trinidad and Tobago.

Section 5 – Medicines Regulation

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

5.1 Regulatory Framework

In Trinidad and Tobago, there are legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA)[18,20,22,23]. The legal framework includes: Food and Drugs Act (Act 8 of 1960), Antibiotics Act (Act 18 of 1948), Dangerous Drugs Act (Act 38 of 1991), Narcotic Control (General Provisions) Regulations & Narcotic Control (Licensing) Regulations and Pharmacy Board Act (Act 7 of 1960).

The MRA functions are performed by the Drug Inspectorate Division (DID) and the Chemistry Food and Drug Department (CFDD), both are part of the Ministry of Health, with a number of functions outlined in Table 6. The MRA has its own website, for which the URL address is http://www.health.gov.tt/sitepages/default.aspx?id=93 .

Table 6. Functions of the national MRA

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

As of 2011, there are 17 posts attached to the Drug Inspectorate Division. Eight of theses posts are currently filled with permanent staff working for the MRA. The MRA receives external technical assistance from the Pan American Health Organization to support its activities. The MRA is involved in harmonization/collaboration initiatives such as: PAHO/WHO, the Pan American Network for Drug Regulatory Harmonization (PANDRH) and the Caribbean Community (CARICOM). Two assessments of the medicines regulatory system have been conducted in the last two years[ix]. Funding for the MRA is provided through the regular government budget. The Regulatory Authority does not retain revenues derived from regulatory activities. The registration of companies in Trinidad and Tobago is not computerized. The registration of Antibiotics & Narcotics is manual, but Drug Inspectorate maintains a computerized database

[ix] In 2009 it was conducted the HERA Regional Assessment on Drug Registration and Regulatory Systems in CARICOM Member States and the Dominican Republic; and in 2011 it was conducted the Ministry of Health/PAHO/WHO Report on Self-Assessment of the National Medicines Regulatory Authority in Trinidad and Tobago.

of all registered products. The Chemistry, Food and Drug Division, however, is not computerized.

5.2 Marketing Authorization (Registration)

In Trinidad and Tobago, legal provisions require marketing authorization (registration) for all pharmaceutical products on the market[18,19], however, there is no legal provision for medicines registration renewal and there is no expiration date of the authorization. There are no mechanisms for exception/waiver of registration[20]. Mutual recognitions mechanisms are not in place. Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products. It is unknown how many pharmaceutical products are registered in the country[20]. There are no legal provisions requiring the MRA to make the list of registered pharmaceutical products publicly available and update it regularly. Medicines are always registered by their INN (International Non-proprietary Names) or Brand name + INN[14]. Legal provisions require a fee to be paid for Medicines Market Authorization (registration) based on applications, except for Antibiotics, Narcotics and Preparations containing narcotics, which registration are free of charge.

Marketing Authorization holders are required by law to provide information about variations to the existing Marketing Authorization. Legally, a Summary of Product Characteristics (SPC) of the medicines that are registered is required to be published. Furthermore, legal provisions requiring the establishment of an expert committee involved in the Marketing Authorization process are in place; and the possession of a Certificate for Pharmaceutical Products (that accords with the WHO Certification scheme) is required as part of the Marketing Authorization

application[14]. By law, potential conflict of interests for experts involved in the assessment and decision-making for registration do not need to be declared[20]. Although the law is not specific about appeals regarding MRA decisions, in practice there is also recourse to the Chief Medical Officer. Additionally if persons are really aggrieved, the law provides for constitutional review by a judge in chambers.

The registration fee (per application) for a pharmaceutical product[x] is US$ 123[18], and the time limit imposed for the assessment of all Marketing Authorization applications is 3 months.

5.3 Regulatory Inspection

As contained in the Food and Drugs Act, the Antibiotics Act and the Dangerous Drugs Act, legal provisions exist allowing for appointment of government pharmaceutical inspectors[18, 19, 21]. Legal provisions exist 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 public and private facilities. Where inspections are legal requirements, these are the same for public and private facilities. Inspections are carried out on a number of entities, outlined in Table 7.

[x] Includes generics and New Chemical Entities (NCE).

Table 7. Local entities inspected in Trinidad and Tobago

Entity	Inspection	Frequency
Local manufacturers	Yes	Annually
Private wholesalers	Yes	
Retail distributors	Yes	
Public pharmacies and stores	Yes	
Pharmacies and dispensing points if health facilities	Yes	

5.4 Import Control

Legal provisions exist requiring authorization to import medicines. Laws exist that allow the sampling of imported products for testing[18, 19, 21].

Legal provisions exist requiring importation of medicines through authorized ports of entry. Regulations or laws exist to allow for inspection of imported pharmaceutical products at authorized ports of entry[18, 21].

5.5 Licensing

In Trinidad and Tobago, legal provisions exist requiring manufacturers, importers, wholesalers and distributors to be licensed[14]. Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP)[18]. Good Manufacturing Practices are not published by the government.

Legal provisions exist requiring wholesalers and distributors to comply with Good Distribution Practices.

Table 8. Legal provisions pertaining to licensing

Entity requiring licensing	
Manufacturers	Yes
Importers	Yes
Wholesalers	Yes
Distributors	Yes

Good Distribution Practices are not published by the government.

The regulation of Pharmacy practice is under the purview of the Pharmacy Board of Trinidad and Tobago. Legal provisions exist requiring pharmacists to be registered[22]. Legal provisions exist requiring public and private pharmacies to be licensed[20]. National Good Pharmacy Practice Guidelines are not published by the government. A list of licensed pharmaceutical establishments is not publicly available or required by the legal provisions.

5.6 Market Control and Quality Control

In Trinidad and Tobago, legal provisions exist for controlling the pharmaceutical market[21]. A laboratory exists in Trinidad and Tobago for Quality Control testing[20]. The laboratory is a functional part of the MRA. However, Trinidad and Tobago is also signatory to the Agreement establishing the Caribbean Regional Drug Testing Laboratory[23].

Existing national laboratory facilities have not been accepted for collaboration with the WHO pre-qualification programme. Medicines are tested for a number of reasons, summarised in Table 9.

Table 9. Reasons for medicines testing

Medicines are tested:	
For quality monitoring in the public sector[xi]	Yes
For quality monitoring in the private sector[xii]	Yes
When there are complaints or problem reports	Yes
For product registration	Yes
For public procurement prequalification	Yes
For public program products prior to acceptance and/or distribution	Yes

Samples are collected by government inspectors for undertaking post-marketing surveillance testing[14]. The results of the analysis are not publicly available.

5.7 Medicines Advertising and Promotion

In Trinidad and Tobago, legal provisions exist to control the promotion and/or advertising of prescription medicines. Legal provisions prohibit direct advertising of prescription medicines to the public, but pre-approval for medicines advertisements and promotional materials is not required. Guidelines and Regulations do not exist for advertising and promotion of non-prescription

[xi] Routine sampling in pharmacy stores and health facilities

[xii] Routine sampling in retail outlets

medicines[14]. There is no national code of conduct concerning advertising and promotion of medicines by marketing authorization holders.

5.8 Clinical Trials

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

Legal provisions exist for GMP compliance of investigational products. Sponsors are not legally required to comply with Good Clinical Practices (GCP). National GCP regulations are not published by the Government and legal provisions do not permit the inspection of facilities where clinical trials are performed.

5.9 Controlled Medicines

Trinidad and Tobago is a signatory to the following international conventions:

Table 10. International Conventions to which Trinidad and Tobago 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 (Dangerous Drugs Act 1991[21]). The annual consumption of Morphine is 1.29 mg/capita[24].

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

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

Table 10S. Annual consumption of selected controlled substances in Trinidad and Tobago[24]

Controlled substance	Annual consumption (mg/capita)
Morphine	1.298575
Fentanyl	0.000555
Pethidine	7.366092
Oxycodone[xiii]	0.000000
Hydrocodone[xiv]	0.000000
Phenobarbital	Unknown
Methadone[xiv]	0.000000

[xiii] Oxycodone and Methadone are not used in Trinidad and Tobago.

[xiv] Hydroxycodone is used as a laboratory control and for forensic analysis only.

5.10 Pharmacovigilance

In Trinidad and Tobago, there are legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate**.** Legal provisions also exist requiring the Marketing Authorization holders to continuously monitor the safety of their products and report to the MRA. Laws regarding the monitoring of Adverse Drug Reactions (ADR) exist in the country. A national pharmacovigilance centre linked to the MRA does not exist.

An official standardized form for reporting ADRs is used in Trinidad and Tobago. Although the forms are available, medical personnel do not report. There is no national ADR computerized database. Information is therefore not available to be sent to the WHO collaborating centre in Uppsala.

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/communication. A clear communication strategy for routine communication and crises communication does not exist.

ADRs are not monitored in any specific public health program (TB, HIV, or AIDS).

There is, however, a risk management plan presented as part of product dossier submitted by manufacturers for Marketing Authorization.

There are no training courses in pharmacovigilance offered by the MRA and, at present, there is no documented governmental plan for improving the pharmacovigilance system.

Section 6 - Medicines Financing

In this section, information is provided on the medicines financing mechanism in Trinidad and Tobago, 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 Trinidad and Tobago, patients who access the public health sector are treated free of charge for all disease states (see Table 12). There are provisions for the groups in Table 11 to receive medicines free of charge.

Table 11. Particular population groups provided with medicines free of charge[14]

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

Table 12. Particular conditions for which, medications are provided publicly, at no cost.

Conditions	Covered
All diseases covered in the EML	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

Patients attending private services are entitled to receive medicines for certain conditions, such as Chronic and Non-Communicable Diseases at private pharmacies.

Private health insurance schemes provide coverage for medicines (depending on the plan subscribed to).

6.2 Patients Fees and Copayments

There is no fee or co-payment for consultation in public sector. Co-payments or fee requirements for consultations are levied at the point of delivery in the private sector only, where persons with insurance plans may access some treatments in designated private sector establishments. They may pay only a percentage of the cost with the insurance company being billed for the balance.

There are no co-payments or fee requirements imposed for medicines in the public sector. Fee or co-payment also occurs with medication in the private sector at designated private pharmacies linked to insurance programmes.

Revenue from fees or from the sale of medicines is not used to pay the salaries or supplement the income of public health personnel in the same facility[14, xv].

6.3 Pricing Regulation for the Private Sector[xvi]

In Trinidad and Tobago, there are legal or regulatory provisions affecting pricing of medicines. These provisions are aimed at the level of manufacturers, wholesalers and retailers[14].

The government does not run an active national medicines price monitoring system for retail prices[14]. Regulations do not exist mandating that retail medicine price information should be publicly accessible.

6.4 Prices, Availability and Affordability of Key Medicines

A national or international study on medicines prices, availability and affordability has not been conducted in the last 5 years.

[xv] Information refers to the public sector only.

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

6.5 Price Components and Affordability

Currently, a survey of medicines price components is being conducted by the government.

6.6 Duties and Taxes on Pharmaceuticals (Market)

Trinidad and Tobago imposes a 15% duty on imported active pharmaceutical ingredients (APIs) and on imported finished products. Provisions for tax exceptions or waivers for pharmaceuticals and health products are in place. There is a waiver of duty from 15% to 5% if the items imported are manufactured in the region.

If the importer declares the items as “supplements” VAT (value-added-tax) will be charged, however, if the items are declared as “drugs” no VAT will be imposed.

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 Trinidad and Tobago.

7.1 Public Sector Procurement

Public sector procurement in Trinidad and Tobago is centralized and under the responsibility of a procurement agency (NIPDEC) which is semi-autonomous[17].

Public sector requests for tender documents are publicly available and public sector tender awards are also publicly available[25,xviii]. Procurement is based on the prequalification of suppliers[13, xix].

There is a written public sector procurement policy[13]. This policy was approved in 1998. Legal provisions do not exist to give priority to locally produced goods in public procurement.

The key functions of the procurement unit and those of the tender committee are clearly separated[14]. A process exists to ensure the quality of products that are

[xviii] A password is needed to access the website.

[xix] The company must be registered in Trinidad and Tobago. Prequalification must be sought through the Chemistry Food & Drug division and Drug Inspectorate Department in keeping with the Antibiotics Act and the Dangerous Drugs Act.

publicly procured. The quality assurance process includes the prequalification of products and suppliers[xx]. A list of prequalified suppliers and products is available.

A list of samples tested during the procurement process and the results of quality testing are not available. The tender methods employed in public sector procurement include international competitive tenders[14].

7.2 Public Sector Distribution

The government supply system department in Trinidad and Tobago has a Central Medical Store (CMS) at National Level (NIPDEC). There are no public warehouses in the secondary tier of the public sector distribution. There are no national guidelines on Good Distribution Practices (GDPs). A licensing authority that issues GDPs licenses does not exist.

A number of processes are in place at the Central Medical Store (CMS) as detailed in Table 13.

[xx] Prequalification is based on business registration and medicine registration by the Chemistry Food and Drug Division (CFDD). At NIPDEC, random product sampling is done on inventory. The samples are sent to the CFDD for testing.

Table 13. Processes employed by the Central Medical Store[25]

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

Routine procedure to track the expiry dates of medicines at the CMS exist. The public CMS is not GDPs certified by any licensing authority.

7.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector[20]. A list of GDPs certified wholesalers or distributors however, does not exist in this sector.

Section 8 - Selection and rational use of medicines

This section outlines the structures and policies governing the selection of essential medicines and promotion of rational drug use in Trinidad and Tobago.

8.1 National Structures

A National Essential Medicines List (EML) exists[xxi], In Trinidad it is called Vital, Essential and Necessary (VEN) List. The EML was lastly updated in 2011 and is publicly available.

Selection of medicines for the EML is undertaken through a written process. A mechanism aligning the EML with the Standard Treatment Guidelines (STGs) is in place.

There is no public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers[14]. Public education campaigns on rational medicine use topics have not been conducted in the last two years. A survey on rational use of medicines has not been conducted in the previous two years. There is a national programme or committee, involving government, civil society, and professional bodies, to monitor and promote rational use of medicines.

[xxi] V.E.N. List: Divided into Vital, Essential and Necessary. Ministry of Health – Pharmaceutical V.E.N. Listing, 2011 GORTT. Available online: http://www.health.gov.tt/downloads/DownloadItem.aspx?id=194

A written National Strategy for containing antimicrobial resistance does not exist in Trinidad and Tobago[14].

The Essential Medicines List includes formulations specifically for children. Criteria for the selection of medicines to the EML are explicitly documented. There is a formal committee for the selection of products to the EML. Potential conflict of interest declarations are required from members of national EML committee. A national medicines formulary exists.

A funded national inter-sectoral task force to coordinate the promotion of the appropriate use of antimicrobials and prevention of the spread of infection does not exist.

A national reference laboratory does not have responsibility for coordinating epidemiological surveillance of antimicrobial resistance.

8.2 Prescribing

Legal provisions exist to govern the licensing and prescribing practices of prescribers[14]. Furthermore, legal provisions restricting dispensing by prescribers exist[18]. Prescribers in the private sector dispense medicines[14].

There are no regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs)[14]. However, more than half of the referral hospitals have one.

Mandatory continuing education that includes pharmaceutical issues is not required for doctors or paramedical staff[14].

Prescribing by INN name is obligatory in the public sector only[14].

A professional association code of conduct exists governing professional behaviour of doctors[26].

8.3 Dispensing

Legal provisions in Trinidad and Tobago exist to govern dispensing practices of pharmaceutical personnel[18, 22]. The basic pharmacist training curriculum includes a spectrum of components as outlined in Table 14.

Table 14. Core aspects of the pharmacist training curriculum[12]

Curriculum	Covered
The concept of EML	Yes
Use of STGs	Yes
Drug information	Yes
Clinical pharmacology	Yes
Medicines supply management	Yes

Mandatory continuing education that includes rational use of medicines is not required for pharmacists[14].

Substitution of generic equivalents at the point of dispensing is allowed in public sector facilities only if prescription is written with the International Non-Proprietary Name (INN)/generic name but not in private points of delivery. Sometimes antibiotics are sold over-the-counter without a prescription. Sometimes injectable medicines are sold over-the-counter without a prescription[14].

As reported by the Pharmacy Board of Trinidad and Tobago, a professional code of conduct exists governing professional behaviour of pharmacists.

In practice, sometimes nurses prescribe prescription-only medicines at the primary care level in the public sector[14].

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REPUBLIC OF TRINIDAD AND TOBAGO

Pharmaceutical Country Profile

ANNEX

Survey Data

(Fragment of the questionnaire)

2011

Section 0 General Info

0.01 Contact Info

0.01.01	Country (precoded)	Trinidad and Tobago
0.01.02	Name coordinator	Dr Andrea Yearwood
0.01.03	Address (Street, City)	63 Park Street, Port of Spain, Trinidad and Tobago
0.01.04	Phone number	(868)-627-0010/12/14
0.01.05	Email address	andrea.yearwood@health.gov.tt
0.01.06	Web address	
0.01.07	Institution	Ministry of Health

Section 1 Health and Demographic data

1.00 Respondent Information Section 1

1.00.01	Name of person responsible for filling out Survey section 1	Carla Ruiz (Health Policy, Research and Planning)
1.00.02	Phone number	627-0010 Ext 504
1.00.03	Email address	carla.ruiz@health.gov.tt
1.00.04	Other respondents for filling out this section	

1.01 Demographic and Socioeconomic Indicators

Core questions (click here for help)

			Year	Source
1.01.01	Population, total (,000)	1,317.714	2010	TRT. Central Statistical Office
1.01.02	Population growth rate (Annual %)	0.4	2008	WHS 2010
1.01.03	Total Gross Domestic Product (GDP) (millions US$)	20,433	2010	Ministry of Finance
1.01.04	GDP growth (Annual %)	4.5	2010	Review of the Economy 2010
1.01.05C	GDP per capita (US$ current exchange rate)	PREFILL CALC		
1.01.06	Comments and References	1.01.01. Data related to Population of Trinidad and Tobago: Ministry of Planning and Development. Central Statistical Office Midyear Population Estimates 2000-2010; GORTT 2010. Available at: http://www.cso.gov.tt/Pages/default.aspx 1.01.04. Minstry of Finance. Review of the Economy - Facing the Issues, Turning the Economy Around 2010. GORTT, 2010. Available at http://www.finance.gov.tt/. Copy attached.		

Supplementary questions (click here for help)

			Year	Source
1.01.07S	Population < 15 years (% of total population)	25.34	2010	TRT. Central Statistical Office
1.01.08S	Population > 60 years (% of total population)	10.02	2010	TRT. Central Statistical Office
1.01.09S	Urban population (% of total population)	13	2008	WHS 2010
1.01.10S	Fertility rate, total (Births per woman)	1.6	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 (%)	17	2007	World Fact Book -CIA
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)	99	2007	WHS 2010
1.01.15S	Comments and References	1.01.07S and 1.01.08S. Ministry of Planning and Development, Central Statistical Office Midyear Population Estimates 2000-2010. GORTT 2010. Available at: http://www.cso.gov.tt/statistics/Statistics/MIDYEARPOP2000-2010.xls consulted in 26/05/2011 Please note data presented in 1.01.08S including population with 60 year and older 1.01.12S: Central Intelligence Agency. World Fact Book - Trinidad and Tobago; July 2011. Available at https://www.cia.gov/library/publications/the-world-factbook/geos/td.html		

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)	66	2008	WHS 2010
1.02.02	Life expectancy at birth for women (Years)	73	2008	WHS 2010
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)	31	2008	WHS 2010
1.02.04	Under 5 mortality rate (/1,000 live births)	35	2008	WHS 2010
1.02.05	Maternal mortality ratio (/100,000 live births)	45	2005	WHS 2010
1.02.06	Please provide a list of top 10 diseases causing mortality		2006	CSO
1.02.06.01	Disease 1	Diseases of the Heart (I00-I52)		
1.02.06.02	Disease 2	Malignant Neoplasm (C00-C97)		
1.02.06.03	Disease 3	Diabetes Mellitus (E10-E14)		
1.02.06.04	Disease 4	External Causes (V01-Y98)		
1.02.06.05	Disease 5	Cerebrovascular Disease (I60-I69)		
1.02.06.06	Disease 6	Diseases of the Respiratory System (J00-J98)		
1.02.06.07	Disease 7	Diseases of the Digestive System (K00-K92)		
1.02.06.08	Disease 8	AIDS/HIV Disease (B20-B24)		
1.02.06.09	Disease 9	Diseases of the Nervous System (G00-G99)		
1.02.06.10	Disease 10	Diseases of the Genitourinary System (N00-N98)		
1.02.07	Please provide a list of top 10 diseases causing morbidity		2007	Hospital Discharges ; Annual Hospital Utilization Reports

1.02.07.01	Disease 1	Injury, Poisoning and Certain Other Consequences of External Causes
1.02.07.02	Disease 2	Diseases of the Genitourinary System
1.02.07.03	Disease 3	Diseases of the Heart
1.02.07.04	Disease 4	Symptoms, Signs and Abnormal Clinical and Lab Findings
1.02.07.05	Disease 5	Diseases of the Digestive System
1.02.07.06	Disease 6	Complications of Pregnancy
1.02.07.07	Disease 7	Mental Illnesses
1.02.07.08	Disease 8	Respiratory Disorders
1.02.07.09	Disease 9	Skin Disorders
1.02.07.10	Disease 10	Infectious Diseases
1.02.08	Comments and References	Ministry of Health. Hospital Discharge Reports, 2007. GORTT. Ministry of Health. Annual Hospital Utilization Reports, 2007. GORTT. 1.02.05. At the TRT Health System Profile published in 2008, the maternal mortality ration is 37.75/100.000 related to the period of 2000-2003

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)	163	2008	WHS 2010
1.02.10S	Neonatal mortality rate (/1,000 live births)	24	2008	WHS 2010
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	751	2004	WHS 2010
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	364	2004	WHS 2009

1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	123	2004	WHS 2009
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	22.7	2006	CSO
1.02.15S	Mortality rate for tuberculosis (/100,000 population)			
1.02.16S	Mortality rate for Malaria (/100,000 population)	0	2006	CSO
1.02.17S	Comments and References	1.02.14S, 1.02.16S from Ministry of Planning and Development, Central Statistical Office, 2006.		

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	Carla Ruiz, Research Officer, Health Policy, Research and Planning, Ministry of Health
2.00.02	Phone number	627-0010
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2.00.04	Other respondents for filling out this section	Rian Extavour, Lecturer (UWI, School of Pharmacy)

2.01 Health Expenditures

Core questions (click here for help)

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)	7,611	2008	National Health Account - WHO
2.01.01.02	Total annual expenditure on health (millions US$ average exchange rate)	1,179.7	2008	Calculated based on National Health Account - WHO
2.01.02C	Total health expenditure as % of Gross Domestic Product	5.00		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	5,691.30		
2.01.03.02C	Total annual expenditure on health per capita (US$ average exchange rate)	904.82		
2.01.04.01	General government annual expenditure on health (millions NCU)	3,720	2008	National Health Account - WHO

2.01.04.02	General government annual expenditure on health (millions US$ average exchange rate)	576.6	2008	Calculated based on National Health Account - WHO
2.01.05	Government annual expenditure on health as percentage of total government budget (% of total government budget)	8.8	2008	National Health Account - WHO
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	56.68	2008	Calculated based on National Health Account - WHO
2.01.07.01C	Annual per capita government expenditure on health (NCU)	3,225.81		
2.01.07.02C	Annual per capita government expenditure on health (US$ average exchange rate)	512.85		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	43.32	2008	Calculated based on National Health Account - WHO
2.01.09	Population covered by a public health service or public health insurance or social health insurance, or other sickness funds of total population)			
2.01.10	Population covered by private health insurance (% of total population)			
2.01.11.01	Total pharmaceutical expenditure (millions NCU)			

2.01.11.02	Total pharmaceutical expenditure (millions US$ current exchange rate)			
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	PREFILL CALC		
2.01.12.02C	Total pharmaceutical expenditure per capita (US$ current exchange rate)	PREFILL CALC		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	PREFILL CALC		
2.01.14C	Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	PREFILL CALC		
2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)			
2.01.15.02	Total public expenditure on pharmaceuticals (millions US$ current exchange rate)			
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	PREFILL CALC		
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	PREFILL CALC		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	PREFILL CALC		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)			
2.01.18.02	Total private expenditure on pharmaceuticals (millions US$ current exchange rate)			
2.01.19	Comments and References	Trinidad and Tobago - WHO National Health Account 2008. Available at: http://apps.who.int/nha/database/StandardReport.aspx?ID=REP_WEB_MINI_TEMPLATE_WEB_VERSION&COUNTRYKEY=84040		

Supplementary questions (click for help)				
			Year	Source
2.01.20S	Social security expenditure as % of government expenditure on health (% of government expenditure on health)			
2.01.21S	Market share of generic pharmaceuticals [branded and INN] by value (%)			
2.01.22S	Annual growth rate of total pharmaceuticals market value (%)			
2.01.23S	Annual growth rate of generic pharmaceuticals market value (%)			
2.01.24S	Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)	81.8	2008	National Health Account - WHO
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	14.7	2008	National Health Account - WHO
2.01.26S	Comments and References	Trinidad and Tobago - WHO National Health Account 2008. Available at: http://apps.who.int/nha/database/StandardReport.aspx?ID=REP_WEB_MINI_TEMPLATE_WEB_VERSION&COUNTRYKEY=84040		

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	641	2007	Global Health Atlas
2.02.02C	Pharmacists per 10,000 population	4.8		

2.02.03	Total number of pharmacists working in the public sector			
2.02.04	Total number of pharmaceutical technicians and assistants			
2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes ☐ No ☒	2011	MOH
2.02.06	Total number of physicians	1,543	2009	WHS 2010
2.02.07C	Physicians per 10,000 pop	11.6		
2.02.08	Total number of nursing and midwifery personnel	4,677	2009	WHS 2010
2.02.09C	Nurses and midwives per 10,000 pop	35.1		
2.02.10	Total number of hospitals	21	2011	Drug Inspectorate/Ministry of Health
2.02.11	Number of hospital beds per 10,000 pop	27	2009	WHS 2010
2.02.12	Total number of primary health care units and centers			
2.02.13	Total number of licensed pharmacies			
2.02.14	Comments and References	2.02.01. Global Health Atlas - Country Data - Trinidad and Tobago. Available at: http://apps.who.int/globalatlas/dataQuery/default.asp 2.02.10. Information provided by Drug Inspectorate/Ministry of Health (2011): 11 public and 10 private hospitals.		
Supplementary questions (click here for help)				
			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist			

	in the public sector (NCU)			
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country	79	2010	School of Pharmacy Administration - University of the West Indies
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes ☐ No☒	2011	School of Pharmacy Administration - University of the West Indies
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes ☒ No ☐	2011	School of Pharmacy Administration - University of the West Indies
2.02.19S	Comments and References	2.02.16S Interview with Pat Cumberbatch, Administrative Assistant, School of Pharmacy, Faculty of Medical Sciences, the University of the West Indies on 11th July 2011. 2.02.17S The University of the West Indies received institutional accreditation in May 2011. Accrediation Council of Trinidad and Tobago website. Available at http://www.actt.org.tt/services/article.aspx?CategoryID=1896&id=4484 and at http://sta.uwi.edu/accreditation/faqs.asp. The Caribbean Authority for Accreditation of Medicine and Health Professionals does not have standards for accreditation for pharmacy education as yet. 2.02.18S The curriculum is reviewed according to the practice-based priorities identified by faculty and practitioners. A review is pending in 2011. Every three years, the degree programme is audited by the UWI Quality Assurance Audit Unit. An overview is available at http://sta.uwi.edu/accreditation/faqs.asp		

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	Carla Ruiz, Research Officer, Health Policy, Research and Planning		
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3.00.04	Other respondents for filling out this section			

3.01 Policy Framework

Core questions (click here for help)

			Year	Source
3.01.01	National Health Policy exists. If yes, please write year of the most recent document in the "year" field.	Yes ☐ No ☐		
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 ☐		
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 ☐	1998	TRT National Drug Policy
3.01.05	Group of policies addressing pharmaceuticals exist.	Yes ☒ No ☐	1998	National Drug Policy, CDAP Program
3.01.06	National Medicines Policy covers the following components:	—		

3.01.06.01	Selection of Essential Medicines	☒Yes		
3.01.06.02	Medicines Financing	☒Yes		
3.01.06.03	Medicines Pricing	☐Yes		
3.01.06.04	Medicines Procurement	☒Yes		
3.01.06.05	Medicines Distribution	☒Yes		
3.01.06.06	Medicines Regulation	☒Yes		
3.01.06.07	Pharmacovigilance	☐Yes		
3.01.06.08	Rational Use of Medicines	☒Yes		
3.01.06.09	Human Resource Development	☒Yes		
3.01.06.10	Research	☒Yes		
3.01.06.11	Monitoring and Evaluation	☒Yes		
3.01.06.12	Traditional Medicine	☒Yes		
3.01.07	National medicines policy implementation plan exists. If yes, please write year of the most recent document.	Yes ☐ No ☒	2011	MOH MRA
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 ☐		
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 national legislation?	Yes ☒ No ☐	2011	MOH

3.01.11	There are official written guidelines on medicines donations.	Yes ☒ No ☐	2007	WHO level I
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes ☐ No ☒	2011	MOH
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?	The Pharmacy/Drug Inspectorate at the Ministry of Health		
3.01.13	Is there a national good governance policy?	Yes ☒ No ☐	2011	MoH
3.01.13.01	Multisectoral	☒Yes	2011	MoH
3.01.13.02	For the pharmaceutical sector	☐Yes		
3.01.13.03	Which agencies are responsible?	Pharmacy/Drug Inspectorate		
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes ☐ No ☒	2011	MOH
3.01.15	There is a formal code of conduct for public officials.	Yes ☒ No ☐	2011	MOH
3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes ☐ No ☒	2011	MOH
3.01.16.01	Please describe:			
3.01.17	Comments and References	3.01.01 There is a strategic plan involving the national health policy has been developed and is currently under internal review. The public document is not yet available. 3.01.04 Ministry of Health. Trinidad and Tobago National Drug Policy 1998; GORTT (attached) 3.01.05 Policies on pharmaceuticals include National Drug Policy and Chronic Disease Assistance Program; available at http://www.health.gov.tt/sitepages/default.aspx?id=132 3.01.06.12 The term used in the policy is Herbal/Complementary		

		Medicine. 3.01.13. The policy was developed in November 2010 and is for the Public Sector only

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	Junia Walcott
4.00.02	Phone number	627-0046
4.00.03	Email address	junia.walcott@health.gov.tt
4.00.04	Other respondents for filling out this section	Carla Ruiz

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:		1996	Patents Act
4.01.02.01	Pharmaceuticals	Yes ☒ No☐		
4.01.02.02	Laboratory supplies	Yes ☒ No ☐		
4.01.02.03	Medical supplies	Yes ☒ No ☐		
4.01.02.04	Medical equipment	Yes ☒ No ☐		
4.01.03.01	Please provide name and address of the institution responsible for managing and enforcing intellectual property rights	Ministry of Legal Affairs, 72-74 South Quay, Port of Spain for law enforcement. The Intellectual Property Office provides information and guidelines for patent applications.		
4.01.03.02	Please provide URL	www.legalaffairs.gov.tt and www.ipo.gov.tt		
4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes ☒ No ☐	2007	WHO level I
4.01.05	Current laws contain (TRIPS) flexibilities and safeguards	Yes ☒ No☐	2009	Hera Report -

				Patents
4.01.06	Country is eligible for the transitional period to 2016	Yes ☐ No☐		
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2007	WHO level I
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 ☒	2007	WHO Level 1
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	MOH
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes ☒ No ☐	2009	Hera Report - Patents
4.01.11	Legal provisions exist for patent extension	Yes ☐ No ☒	2011	MOH
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes ☐ No ☐		
4.01.13	Comments and References	4.01.01. World Trade Organization - Members and Observers. Available at: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm 4.01.02-04 Ministry of Legal Affairs, Government of the Republic of Trinidad and Tobago. The Patents Act 1996 (Act No. 21 of 1996) - based on list of exemptions. 4.01.05-6; 4.01.10; 4.01.12 HERA Regional Assessment of Patent and Related Issues and Access to Medicines, Vol 2 2009 (attached)		

4.02 Manufacturing

Core questions (click here for help)

			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country	4	2011	MOH. MRAA
4.02.02	Country has manufacturing capacity		2007	WHO level I
4.02.02.01	R&D to discover new active substances	Yes ☐ No ☒ Unknown ☐		
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes ☐ No ☒ Unknown ☐		
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes ☒ No ☐ Unknown ☐		
4.02.02.04	Repackaging of finished dosage forms	Yes ☒ No ☐ Unknown ☐		
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)			
4.02.04	Comments and References			

Supplementary questions (click here for help)

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

Section 5 Medicines Regulation

5.00 Respondent Information Section 4

5.00.01	Name of person responsible for filling out this section of the instrument	Junia Walcott
5.00.02	Phone number	627-0046
5.00.03	Email address	junia.walcott@health.gov.tt
5.00.04	Other respondents for filling out this section	

5.01 Regulatory Framework

Core questions (click here for help)

			Year	Source
5.01.01	Are there legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA)?	Yes ☒ No ☐	1960	Food and Drug Act. See comments for more legislation
5.01.02	There is a Medicines Regulatory Authority	Yes ☒ No ☐	2011	MOH.MRAA
5.01.03	If yes, please provide name and address of the Medicines regulatory authority	Ministry of Health: Drug Inspectorate Department, Park and Edward Streets, Port of Spain Chemistry Food and Drug Department, 92 Frederick Street, Port of Spain		
5.01.04	The Medicines Regulatory Authority is:		2011	MOH.MRAA
5.01.04.01	Part of MoH	☒Yes		
5.01.04.02	Semi autonomous agency	☐Yes		
5.01.04.03	Other (please specify)			

5.01.05	What are the functions of the National Medicines Regulatory Authority?		2011	MOH. MRAA
5.01.05.01	Marketing authorization / registration	Yes ☒ No ☐		
5.01.05.02	Inspection	Yes ☒ No ☐		
5.01.05.03	Import control	Yes ☒ No ☐		
5.01.05.04	Licensing	Yes ☒ No ☐		
5.01.05.05	Market control	Yes ☒ No ☐		
5.01.05.06	Quality control	Yes ☒ No ☐		
5.01.05.07	Medicines advertising and promotion	Yes ☒ No ☐		
5.01.05.08	Clinical trials control	Yes ☐ No ☒		
5.01.05.09	Pharmacovigilance	Yes ☒ No ☐		
5.01.05.10	Other: (please explain)			
5.01.06	Number of the MRA permanent staff	8	2011	Drug Inspectorate Division
5.01.06.01	Date of response	13/07/2011		
5.01.07	The MRA has its own website	Yes ☒ No ☐	2011	MOH.MRAA
5.01.07.01	- If yes, please provide MRA Web site address (URL)	http://www.health.gov.tt/sitepages/default.aspx?id=93		
5.01.08	The MRA receives external technical assistance	Yes ☒ No ☐	2011	MOH.MRAA
5.01.08.01	If yes, please describe:	PAHO/WHO		
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes ☒ No ☐	2011	MOH. MRA
5.01.09.01	- If yes, please specify	Pan American Network for Drug Regulatory Harmonization		

		(PANDRH), PAHO/WHO, CARICOM		
5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes ☒ No ☐	2011	MOH.MRAA
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the government.	Yes ☒ No ☐	2011	MOH. MRA
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☐ No ☒	2011	MOH. MRA
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ☐ No ☒	2011	MOH.MRA
5.01.13.01	- If yes, please specify			
5.01.14	Revenues derived from regulatory activities are kept with the Regulatory Authority	Yes ☐ No ☒	2011	MOH/MRAA
5.01.15	The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes ☐ No ☒	2011	MOH/MRAA
5.01.16	Comments and References	5.01.01. The legal framework includes: • Ministry of Legal Affairs. Food and Drugs Act Chapter 30:01,Act 8 of 1965, GORTT with its corresponding Amendments; GORTT (attached) • Ministry of Legal Affairs. Antibiotics Act Chapter 30:02, Act 18 of 1948, GORTT 1948 with its corresponding Amendments and Cap 30-02, Antibiotics (Conditions for Use) Order; Cap 30-02 Approved Pharmaceutical Firms Order; • Ministry of Legal Affairs. Dangerous Drugs Act Chapter 11:25, Act 38 of 1991; GORTT, with its corresponding Amendments;		

		• Ministry of Legal Affairs. Pharmacy Board Act, Chapter 29:52, Act 7 of 1960, GORTT with its corresponding Amendments and Schedules (attached) 5.01.06 No information from Chemistry Food and Drug Division available. 5.1.10. in 2009 it was conducted the HERA/CARICOM. Assessmento on Drug Regulatory Authorities in the Caribbean countries and Dominican Republic. Country Report is available at Volume II (attached report) In 2011 was conducted the Medicines Regulatory Authority Assessment (self assessment), supported by PAHO/WHO. Reference as follows: TRINIDAD AND TOBAGO. Ministry of Health; PAHO/WHO. Report on Self-Assessment of the National Medicines Regulatory Authority in Trinidad and Tobago, 2011. 5.01.12 All fees go to the Consolidated Fund. 5.01.13. Fees for services. Resources don't remain at MA 5.01.15 The registration of companies in Trinidad and Tobago is not computerized. The registration of Antibiotics & Narcotics is manual, but Dr.In. computerizes regs.

5.02 Marketing Authorization (Registration)

Core questions (click here for help)

			Year	Source
5.02.01	Legal provisions require a Marketing Authorization (registration) for all pharmaceutical products on the market	Yes ☒ No ☐	1965	Food and Drugs Act*
5.02.02	Are there any mechanism for exception/waiver of registration?	Yes ☐ No ☒	2009	CARICOM DRA HERA REPORT Volume II
5.02.03	Are there mechanisms for recognition of registration done by other	Yes ☐ No ☒	2011	MOH / MRAA

	countries			
5.02.03.01	If yes, please explain:			
5.02.04	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes ☒ No ☐	2011	MOH/MRA A
5.02.05	Information from the prequalification programme managed by WHO is used for product registration	Yes ☐ No ☒	2009	CARICOM DRA HERA Report Volume II
5.02.06	Number of pharmaceutical products registered in your country			
5.02.07	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes ☐ No ☒	2007	WHO level I
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 ☐	2007	WHO level I
5.02.09	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes ☒ No ☐	2011	MOH/MRA A
5.02.10	Comments and References	5.01.01. Also: Narcotic Control (General Provisions) Regulations & Narcotic Control (Licensing) Regulations 5.02.01. it is also complemented by Food and Drugs Regulations with corresponding Amendments; Antibiotics Act No. 14, 1948 with its corresponding Amendments and Cap 30-02, Antibiotics (Conditions for Use) Order; Cap 30-02 Approved Pharmaceutical Firms Order; Dangerous Drugs Act of 1991 with its corresponding Amendments; Please note that in Trinidad and Tobago there is no legal provision		

		for medicines registration renewal and there is not an expiration date of registration. 5.02.02; 5.02.05 HERA Assessment of Drug Regulatory Systems 2009, Vol 2 (attached) 5.02.06. The CARICOM DRA Report says the number is unknown. 5.02.09. Except for Antibiotics, Narcotics and Preparations containing narcotics, which registration are free of charge.		
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	MOH/MRA A
5.02.12S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes ☒ No ☐	2011	MOH/MRA A
5.02.13S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☒ No ☐	2007	WHO level I
5.02.14S	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes ☒ No ☐	2007	WHO level I
5.02.15S	Legal provisions require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	Yes ☐ No ☒	2009	HERA Report DRA
5.02.16S	Legal provisions allow applicants to appeal against MRAs decisions	Yes ☐ No ☒	2011	MOH/MRA
5.02.17S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US$)	123	1965	Food and Drug Act Form Dand E page 123

5.02.18S	Registration fee - the Amount per application for a generic pharmaceutical product (US$)			
5.02.19S	Time limit for the assessment of a Marketing Authorization application (months)	3	2011	MOH. MRAA
5.02.20S	Comments & References	5.02.15S. HERA Assessment of Drug Regulatory Systems 2009, Vol 2 (attached) 5.02.16S. Although the law is not specific about appeals regarding MRA decisions, in practice there is also recourse to the Chief Medical Officer. Additionally if persons are really aggrieved, the law provides for constitutional review by a judge in chambers. 5.01.17S Ministry of Legal Affairs - Food and Drugs Act of 1965; Forms (2007)		

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 ☐	1965	Food and Drug Act Section 25 Page10 Section 17 Page 208 Antibiotics act Section 12:(1) Dangerous Drug Act Section 12:(1)
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are	Yes ☒ No ☐	2011	MOH.MRAA

	performed			
5.03.02.01	If yes, legal provisions exist requiring inspections to be performed	Yes ☒ No ☐		
5.03.03	Inspection is a pre-requisite for licensing of:		2011	MOH. MRAA
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	MOH/MRA
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes ☒ No ☐	2007	MOH/MRA A WHO level I
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	Annually		
5.03.06	Comments and References	5.03.01; 5.03.05.04-05: Dangerous Drugs Act 1991 (attached); Ministry of Legal Affairs. Food and Drugs Act 1965 (attached); Ministry of Legal Affairs. Antibiotics Act 1948 (attached)		

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 ☐	1965	Food and Drug Act Division 3 New Drugs Antibiotics Act Section 17 Dangerous Drug Act Section 11 Subsection 1-3 page 20 Section 13, 14 Page 22 Section 15, 17 subsection 1-3 Page 23
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes ☒ No ☐	1965	Food and Drug Act Adminstration and enforcement Section 22 page 13 Section 8 page 29
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes ☒ No ☐	1991	Dangerous Drug Act Section 4 subsection (c)
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes ☒ No ☐	1965	Food and Drug Act Adminstration and enforcement Section

				22 page 13
5.04.05	Comments and References	5.04.01-04 Dangerous Drugs Act 1991 (attached); Ministry of Legal Affairs . Food and Drugs Act 1965 (attached); Ministry of Legal Affairs. Antibiotics Act 1948 (attached)		
5.05 Licensing				
			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes ☒ No ☐	2007	WHO level I
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes ☒ No ☐	2011	MOH/MRA A Food and Drug Act Section 32 Adminstration and Enforcement Section 32
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by the government.	Yes ☐ No ☒	2011	MOH/Durg Inspectorate
5.05.04	Legal provisions exist requiring importers to be licensed	Yes ☒ No ☐	2007	MOH /MRA
5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ☒ No ☐	2007	MOH /MRA
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices **When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)**	Yes ☒ No ☐	2011	MOH /MRA

5.05.07	National Good Distribution Practice requirements are published by the government	Yes ☐ No ☒	2011	MOH/MRA
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes ☒ No ☐	1960	Pharmacy Board Act Section 18D page 18
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes ☒ No ☐	2009	CARICOM DRA HERA REPORT Volume II
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes ☒ No ☐	2009	CARICOM DRA HERA REPORT Volume II
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes ☐ No ☒	2011	MOH
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes ☐ No ☒	2011	MOH/MRA
5.05.13	Comments and References	5.05.08, Regulation of Pharmacy Practice is under the purview of the Pharmacy Board of Trinidad and Tobago. Pharmacy Board Act 1960 attached 5.05.09-10, HERA Assessment of Drug Regulatory Systems Vol 2 (attached) 5.05.12. A list of licensed pharmaceutical establishments is not publicly available or required by legal provisions.		

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 ☐	1991	Dangerous Drug Act

5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes ☒ No ☐	2009	CARICOM DRA Hera 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	Trinidad and Tobago is also signatory to the Agreement establishing the Caribbean Regional Drug Testing Laboratory. CARICOM DRA HERA REPORT 2009 Volume II		
5.06.03	Is there any national laboratory accepted for collaboration with WHO prequalification Programme? Please describe.	No		
5.06.04	Medicines are tested:		2011	MOH/MRA
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	Yes ☒ No ☐	2007	WHO level I

	surveillance testing			
5.06.06	How many Quality Control samples were taken for testing in the last two years?			
5.06.07	Total number of samples tested in the last two years that failed to meet quality standards			
5.06.08	Results of quality testing in past two years are publicly available	Yes ☐ No ☒	2011	MOH/MRA
5.06.09	Comments and References	5.06.01 Dangerous Drugs Act 1991 (attached) 5.06.02 HERA Assessment of Drug Regulatory Systems Vol 2 2009 (attached)		

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 ☐	2007	WHO level I
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 ☐	2007	WHO level I
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional materials	Yes ☐ No ☒	2007	WHO level I
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes ☐ No ☒	2007	WHO level I

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

5.08 Clinical trials

Core Questions (click here for help)

			Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes ☐ No ☒	2011	MOH/MRA
5.08.02	Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes ☐ No ☒	2011	MOH/MRA
5.08.03	Legal provisions exist requiring registration of the clinical trials into	Yes ☐ No ☒	2011	MOH/MRA

	international/national/regional registry			
5.08.04	Comments and References			
Supplementary questions (click here for help)				
			Year	Source
5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes ☒ No ☐	2011	MOH/MRA
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes ☐ No ☒	2011	MOH/MRA
5.08.07S	National GCP regulations are published by the Government.	Yes ☐ No ☒	2011	MOH/MRA
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☐ No ☒	2011	MOH/MRA
5.08.09S	Comments and References			
5.09 Controlled Medicines				
Core Questions (click here for help)				
			Date	Source
5.09.01	The country has adopted the following conventions:			
5.09.01.01	Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1964	International Narcotics Control Board, 2010
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1979	International Narcotics Control Board, 2010
5.09.01.03	Convention on Psychotropic	Yes ☒ No ☐	1971	International Narcotics

	Substances 1971			Control Board, 2010
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes ☒ No ☐	1989	International Narcotics Control Board, 2010
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes ☒ No ☐	2007	Dangerous Drug Act Chapter 11:25
5.09.03	Annual consumption of Morphine (mg/capita)	1.298575	2009	International Narcotics Control Board, 2010
5.09.04	Comments and References	5.09.02. Dangerous Drugs Act. 1991. International Narcotics Control Board is accessible via http://incb.org/		

Supplementary questions (click here for help)

			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Yes ☐ No ☒ Unknown ☐	2011	MOH/MRAA
5.09.05.01S	If yes, year of review	.		
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.000555	2009	International Narcotics Control Board, 2010
5.09.07S	Annual consumption of Pethidine	7.366092	2009	Internation

	(mg/capita)			al Narcotics Control Board, 2010
5.09.08S	Annual consumption of Oxycodone (mg/capita)	0	2009	International Narcotics Control Board, 2010
5.09.09S	Annual consumption of Hydrocodone (mg/capita)	0	2009	International Narcotics Control Board, 2010
5.09.10S	Annual consumption of Phenobarbital (mg/capita)			
5.09.11S	Annual consumption of Methadone (mg/capita)	0	2009	International Narcotics Control Board, 2010
5.09.12S	Comments and References	5.09.08S Oxycodone is not used in Trinidad and Tobago. 5.09.09S Hydroxycodone is used as a laboratory control and for forensic analysis. 5.09.11S Methadone is not used in Trinidad and Tobago International Narcotics Control Board is accessible via http://incb.org/.		

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	MOH/MRA

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	MOH/MRA
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes ☒ No ☐	2011	MOH/MRA
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes ☐ No ☒	2011	MOH/MRA
5.10.04.01	If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time			
5.10.04.02	If a national pharmacovigilance center exists in your country, an analysis report has been published in the last two years.	Yes ☐ No ☐		
5.10.04.03	If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes ☐ No ☐		
5.10.05	An official standardized form for reporting ADRs is used in your country	Yes ☒ No ☐	2011	MOH/MRA
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes ☐ No ☒	2011	MOH/MRA
5.10.07	How many ADR reports are in the database?			
5.10.08	How many reports have been submitted in the last two years?			
5.10.09	Are ADR reports sent to the WHO database in Uppsala?	Yes ☐ No ☒	2011	MOH/MRA
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?	☒	2011	MOH/MRA
5.10.11	Is there a clear communication strategy for routine communication and crises communication?	Yes ☐ No ☒		
5.10.12	In the absence of a national pharmacovigilance system, ADRs are monitored in at least one public health program (for example TB, HIV, AIDS)?	Yes ☐ No ☒		
5.10.13	Please describe how you intend to enhance the Pharmacovigilance system	There is no documented plan for improving the pharmacovigilance system.		
5.10.14	Comments and References			
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 ☐	2011	MOH/MRA
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 ☐	2011	MOH/MRA
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 data in the last 2 years?	Yes ☐ No ☐		
5.10.22S	Are there training courses in pharmacovigilance?	Yes ☐ No ☒	2011	MOH MRA
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	Junia Walcott
6.00.02	Phone number	627-0046
6.00.03	Email address	junia.walcott@health.gov.tt
6.00.04	Other respondents for this sections	

6.01 Medicines Coverage and Exemptions

Core Questions (click here for help)

			Year	Source
6.01.01	Do the followings receive medicines free of charge:		2011	MOH
6.01.01.01	Patients who cannot afford them	Yes ☒ No☐		
6.01.01.02	Children under 5	Yes ☒ No☐		
6.01.01.03	Pregnant women	Yes ☒ No☐		
6.01.01.04	Elderly persons	Yes ☒ No☐		
6.01.01.05	Please describe/explain your yes answers for questions above	All medicines are free in the Public Sector for any patients attending public clinics. Patients attending private services are entitled to receive medicines for certain conditions, such as Chronic and Non-Communicable Diseases at private pharmacies.		
6.01.02	Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for :		2011	MOH
6.01.02.01	All medicines included in the EML	Yes ☒ No ☐		
6.01.02.02	Any non-communicable diseases	Yes ☒ No ☐		
6.01.02.03	Malaria medicines	Yes ☒ No ☐		
6.01.02.04	Tuberculosis medicines	Yes ☒ No ☐		

6.01.02.05	Sexually transmitted diseases medicines	Yes ☒ No ☐		
6.01.02.06	HIV/AIDS medicines	Yes ☒ No ☐		
6.01.02.07	Expanded Program on Immunization (EPI) vaccines	Yes ☒ No ☐		
6.01.02.08	If others, please specify			
6.01.02.09	Please describe/explain your yes answers for questions above	All disease states are treated free of charge in the Public Health Sector.		
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?	Yes ☐ No ☒	2011	MOH
6.01.03.01	Does it provide coverage for medicines that are on the EML for inpatients	Yes ☐ No ☒		
6.01.03.02	Does it provide coverage for medicines that are on the EML for outpatients	Yes ☐ No ☒		
6.01.03.03	Please describe the medicines benefit of public/social insurance schemes			
6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes ☒ No ☐	2011	MOH
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the EML?	Yes ☐ No ☐		
6.01.05	Comments and References	6.01.04.01. Coverage is linked to the plan subscribed to.		

6.02 Patients Fees and Copayments

Core Questions (click here for help)

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

	consultations			
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes ☐ No ☒	2011	MOH
6.02.03	In practice, (even though this may be contrary to regulations) is revenue from fees or sales of medicines sometimes used to pay the salaries or supplement the income of public health personnel in the same facility?	Yes ☐ No ☒	2011	MOH
6.02.03.01	Please describe the patient fees and copayments system			
6.02.04	Comments and References	6.02.01. In public sector, there is no fee. There are fees for consultation in the private sector only, where persons with insurance plans may access some treatyments in designated private sector establishments. They may pay only a percentage of the cost with the insurance company being billed for the balance. This also occurs with medication in the private sector at designated private pharmacies linked to insurance programmes. 6.02.02, 6.02.03 Answers refer to public sector only.		
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 ☐	2007	MOH
6.03.01.01	If yes, are the provisions aimed at Manufacturers	Yes ☒ No ☐		
6.03.01.02	If yes, are the provisions aimed at Wholesalers	Yes ☒ No ☐		
6.03.01.03	If yes, are the provisions aimed at Retailers	Yes ☒ No ☐		
6.03.01.04	Please explain the positive answers above: (explain scope of provisions	Markup is in categories and not in generics versus originator. mark		

	i.e generics vs. originator or subsets of medicines, EML etc.)	up depends on subsets of medicines: 10% -Wholesaler Retail - 25% - Antibiotics and Narcotics; 30% - Ethicals; 35% - OTC Items		
6.03.02	Government runs an active national medicines price monitoring system for retail prices	Yes ☐ No ☒	2007	MOH
6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes ☐ No ☒	2011	MOH
6.03.03.01	-if yes, please explain how the information is made publically available			
6.03.04	Comments and References			

6.04 Prices, Availability and Affordability

Core Questions (click here for help)

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

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

			LPG		6.04.01.02	6.04.01.04	
		Median (%)	**Orig**		6.04.02.01	6.04.02.03	
			LPG		6.04.02.02	6.04.02.04	
	Price	**Median Price Ratio**	**Orig**	6.04.03.01	6.04.03.03	6.04.03.05	
			LPG	6.04.03.02	6.04.03.04	6.04.03.06	
	Affordability Days' wages of the lowest paid govt worker for standard treatment with co-trimoxazole for a child respiratory infection	**Number of days' wages**	**Orig**		6.04.04.01	6.04.04.03	
			LPG		6.04.04.02	6.04.04.04	
6.04.05	Comments and References						

6.05 Price Components and Affordability

Core Questions (click here for help)

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

6.05.03	Median cumulative percentage mark-up between MSP/CIF price and final medicine price for a basket of key medicines in the private sector (Median % contribution)	
6.05.04	Comment and References	6.05.01 This survey is under development.
Supplementary questions (click here for help)		
6.05.05S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)	
6.05.06S	Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution)	
6.05.07S	Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%)	
6.05.08S	Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%)	
6.05.09S	Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)	
6.05.10S	Median percentage contribution of the wholesale mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)	
6.05.11S	Median percentage contribution of the retail mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)	
6.05.12S	Comment and References	

6.06 Duties and Taxes on Pharmaceuticals (Market)

Core Questions (click here for help)

			Year	Source
6.06.01	There are duties on imported active pharmaceutical ingredients (APIs)	Yes ☒ No ☐	2011	MOH/MRA
6.06.02	There are duties on imported finished products	Yes ☒ No ☐	2011	MOH
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes ☐ No ☐		
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes ☒ No ☐	2011	MOH
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist	If the importer declares the items as supplements, he has to pay VAT, it the items are declared as drugs, no VAT is charged. There is a waiver of duty from 15% to 5% if the items imported are manufactured in the region.		
6.06.06	Comments and References			

Supplementary questions (click here for help)

			Year	Source
6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)	15	2011	MOH
6.06.08S	Duty on imported finished products (%)	15	2011	MOH
6.06.09S	VAT on pharmaceutical products (%)	0	2011	MOH
6.06.10S	Comments and References			

Section 7 Pharmaceutical procurement and distribution

7.00 Respondent Information Section 6

7.00.01	Name of person responsible for filling out this section of the instrument	Mr. Nicholas George, Pharmacist/Manager
7.00.02	Phone number	634-4506
7.00.03	Email address	ngeorge@nipdec.com
7.00.04	Other respondents for filling out this section	

7.01 Public Sector Procurement

Core Questions (click here for help)

			Date	Source
7.01.01	Public sector procurement is:		2009	CARICOM IP HERA REPORT Volume II
7.01.01.01	Decentralized	☐Yes		
7.01.01.02	Centralized and decentralized	☐Yes		
7.01.01.03	Please describe	Procurement of pharmaceutical supplies for the public sector is centralized		
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:		2009	CARICOM IP HERA Report Volume II
7.01.02.01	Part of MoH	Yes ☐ No ☒		

7.01.02.02	Semi-Autonomous	Yes ☒ No ☐		
7.01.02.03	Autonomous	Yes ☐ No ☒		
7.01.02.04	A government procurement agency which procures all public goods	Yes ☐ No ☒		
7.01.03	Public sector requests for tender documents are publicly available	Yes ☒ No ☐	2011	NIPDEC
7.01.04	Public sector tender awards are publicly available	Yes ☒ No ☐	2011	NIPDEC
7.01.05	Procurement is based on prequalification of suppliers	Yes ☒ No ☐	1998	TRT National Drug Policy
7.01.05.01	If yes, please describe how it works	The company must be registered in Trinidad and Tobago. Prequalification has to be sought through the CF&D and Drug Inspectorate Division in keeping with the Antibiotic Act and the Dangerous Drugs Act.		
7.01.06	Comments and References	7.01.03.-04.A password is needed to access the tender information in the website. Interview with Mr. Nicholas George of National Insurance Property Development Co. Ltd. NIPDEC Central Medical Stores on Thursday 15th June 2011. 7.01.02.02 There is a contractor: NIPDEC who is responsible for procurement and distribution on behalf of Ministry of Health. The board is appointed by the government. Website: www.nipdec.com/pharm_div/ 7.01.01-02 HERA Assessment of Drug Regulatory Systems Vol2 2009 (attached) 7.01.05 National Drug Policy 1998 (attached)		
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 ☐	1998	TRT National Drug Policy
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local	Yes ☐ No ☒	2011	MOH

	manufacturers?			
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes ☒ No ☐	2011	MOH
7.01.10S	A process exists to ensure the quality of products procured	Yes ☒ No ☐	2011	MOH
7.01.10.01S	If yes, the quality assurance process includes pre-qualification 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	MOH
7.01.12S	Which of the following tender methods are used in public sector procurement:		2011	MOH
7.01.12.01S	National competitive tenders	Yes ☐ No ☒		
7.01.12.02S	International competitive tenders	Yes ☒ No ☐		
7.01.12.03S	Direct purchasing	Yes ☐ No ☒		
7.01.13S	Comments and References	7.01.10.01S - prequalification is based on business registration and medicine registration by Food and Drug Division. At NIPDEC, random product sampling is done on inventory. The samples are sent to Chemistry, Food and Drug Division for testing. 7.01.07S. Procurement policy as a part of the National Drug Policy 1998 (attached)		

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	NIPDEC
7.02.02	Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	0	2011	MOH
7.02.03	There are national guidelines on Good Distribution Practices (GDP)	Yes ☐ No ☒	2011	MOH MRA
7.02.04	There is a licensing authority that issues GDP licenses	Yes ☐ No ☒	2011	MOH/MRA
7.02.04.01	If a licensing authority exists, does it accredit public distribution facilities?	Yes ☐ No ☒		
7.02.05	List of GDP certified warehouses in the public sector exists	Yes ☐ No ☒	2011	MOH
7.02.06	List of GDP certified distributors in the public sector exists	Yes ☐ No ☒	2011	MOH
7.02.07	Comments and References	7.02.01. National Central Medical Store: NIPDEC. Visit conducted in June 2011; interview with Nicholas George, Manager/Senior Pharmacist		
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	NIPDEC
7.02.08.01S	Forecasting of order quantities	Yes ☒ No ☐		
7.02.08.02S	Requisition/Stock orders	Yes ☒ No ☐		

7.02.08.03S	Preparation of picking/packing slips	Yes ☒ No ☐		
7.02.08.04S	Reports of stock on hand	Yes ☒ No ☐		
7.02.08.05S	Reports of outstanding order lines	Yes ☒ No ☐		
7.02.08.06S	Expiry dates management	Yes ☒ No ☐		
7.02.08.07S	Batch tracking	Yes ☒ No ☐		
7.02.08.08S	Reports of products out of stock	Yes ☒ No ☐		
7.02.09S	Percentage % availability of key medicines at the Central Medical Store			
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days			
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes ☒ No ☐	2011	NIPDEC
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ☐ No ☒	2011	NIPDEC
7.02.13S	The Public Central Medical Store is ISO certified	Yes ☐ No ☒	2011	NIPDEC
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes ☐ No ☐		
7.02.15S	The second tier public warehouses are ISO certified	Yes ☐ No ☐		
7.02.16S	Comments and References	7.02.14S; 7.02.15S: There are no second tier public warehouses.		

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 ☐	2009	CARICOM DRA HERA Report Volume II
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes ☒ No ☐	2009	CARICOM DRA HERA Report Volume II
7.03.03	List of GDP certified wholesalers in the private sector exists	Yes ☐ No ☒	2011	MOH
7.03.04	List of GDP certified distributors in the private sector exists	Yes ☐ No ☒	2011	MOH
7.03.05	Comments and References	7.03.01-02 HERA Assessment of Drug Regulatory Systems Vol2 2009 (attached)		

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	Junia Walcott
8.00.02	Phone number	627-0046
8.00.03	Email address	junia.walcott@health.gov.tt
8.00.04	Other respondents for filling out this section	Rian Extavour, Lecturer, School of Pharmacy

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	MOH
8.01.01.01	If yes, number of medicines on the EML (no. of INN)			
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 ☐		
8.01.03	STGs specific to Primary care exist. Please use the "year" field to	Yes ☐ No ☐		

	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 ☐		
8.01.05	STGs specific to Paediatric conditions exist. Please use the "year" field to write the year of last update of paediatric condition STGs	Yes ☐ No ☐		
8.01.06	% of public health facilities with copy of EML (mean)- Survey data			
8.01.07	% of public health facilities with copy of STGs (mean)- Survey data			
8.01.08	A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	Yes ☐ No ☒	2007	WHO level I
8.01.09	Public education campaigns on rational medicine use topics have been conducted in the previous two years	Yes ☐ No ☒	2011	MOH
8.01.10	A survey on rational medicine use has been conducted in the previous two years	Yes ☐ No ☒	2011	MOH
8.01.11	A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	Yes ☒ No ☐	2011	MOH
8.01.12	A written National strategy exists to contain antimicrobial resistance. If yes, please write year of last update of the strategy in the "year" field	Yes ☐ No ☒	2011	MOH

8.01.13	Comments and References	8.01.01. The EML list is considered a V.E.N. Listing (divided into Vital, Essential and Necessary). Ministry of Health Pharmaceutical V.E.N. Listing 2011, GORTT. Available at www.health.gov.tt/downloads/DownloadItem.aspx?id=12. 8.01.06. Every Health Centre is supposed to have a copy of the EML		
Supplementary questions (click here for help)				
			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes ☒ No ☐	2011	MOH
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes ☒ No ☐	2011	MOH
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes ☒ No ☐	2011	MOH
8.01.16.01S	If yes, conflict of interest declarations are required from members of national EML committee	Yes ☐ No ☒		
8.01.17S	National medicines formulary exists	Yes ☒ No ☐	2011	MOH
8.01.18S	Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection?	Yes ☐ No ☒	2011	MOH
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☐ No ☒	2011	MOH
8.01.20S	Comments and References			

8.02 Prescribing

Core Questions (click here for help)				
			Year	Source
8.02.01	Legal provisions exist to govern the licensing and prescribing practices of prescriber	Yes ☒ No ☐	2011	MOH
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes ☒ No ☐	2007	Food and Drug Act Section 13 subsection b page 105
8.02.03	Do prescribers in the private sector dispense medicines?	Yes ☒ No ☐	2011	MOH
8.02.04	Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes ☐ No ☒	2011	MOH
8.02.05	Do more than half of referral hospitals have a DTC?	Yes ☒ No ☐ Unknown ☐	2011	MOH
8.02.06	Do more than half of general hospitals have a DTC?	Yes ☐ No ☒ Unknown ☐	2011	MOH
8.02.07	Do more than half of regions/provinces have a DTC?	Yes ☐ No ☐ Unknown ☒	2011	MOH
8.02.08	The core medical training curriculum includes components on:			
8.02.08.01	Concept of EML	Yes ☐ No ☐		
8.02.08.02	Use of STGs	Yes ☐ No ☐		
8.02.08.03	Pharmacovigilance	Yes ☐ No ☐		
8.02.08.04	Problem based pharmacotherapy	Yes ☐ No ☐		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see physician)	Yes ☐ No ☒	2011	MOH
8.02.10	Mandatory continuing education	Yes ☐ No ☐		

	that includes pharmaceutical issues is required for nurses			
8.02.11	Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff	Yes ☐ No ☒	2011	MOH
8.02.12	Prescribing by INN name is obligatory in:		2011	MOH
8.02.12.01	Public sector	Yes ☒ No ☐		
8.02.12.02	Private sector	Yes ☐ No ☒		
8.02.13	Average number of medicines prescribed per patient contact in public health facilities (mean)			
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)			
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)			
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)			
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)			
8.02.18	% of prescribed drugs dispensed to patients (mean)			
8.02.19	% of medicines adequately labelled in public health facilities (mean)			
8.02.20	Comments and References	8.02.02 Food and Drugs Act 1965 (attached) 8.02.13 to 8.02.20 Level II Survey of Health Facilities is incomplete.		
Supplementary questions (click here for help)				

			Year	Source
8.02.21S	A professional association code of conduct exists governing professional behaviour of doctors	Yes ☒ No ☐	1990	Medical Board of T&T
8.02.22S	A professional association code of conduct exists governing professional behaviour of nurses	Yes ☐ No ☐		
8.02.23S	Diarrhoea in children treated with Oral Rehydration Solution (ORS) (%)			
8.02.24S	Comments and References	8.02.21S Medical Board of Trinidad and Tobago. A Code of Ethics in the Practice of Medicine, 1990. Available at http://www.mbtt.org/adobe/ethics.pdf		

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 ☐	1960	Food and Drug Act Section 13 Subsection b page 105; and 1961. Pharmacy Board Act
8.03.02	The basic pharmacist training curriculum includes components on:		2010	School of Pharmacy, UWI
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 ☒	2007	WHO level I
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes ☒ No ☐	2007	WHO level I
8.03.05	Generic substitution at the point of dispensing in private sector facilities is allowed	Yes ☐ No ☒	2007	WHO level I
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 ☐	2007	WHO Level 1
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 ☐	2007	WHO Level 1
8.03.08	Comments and References	8.03.01. Ministry of Legal Affairs. Food and Drugs Act 1960 8.03.02 School of Pharmacy. The University of the West Indies. 8.03.02.01-04: Components are incorporated in various Pharmacy Practice and Pharmacy Administration courses. 8.03.03 Continuing pharmacy education is not mandatory in T&T. 8.03.04 Substitution is permitted only if prescriptions are written using INN/generic name and the generics or brand available in public sector is dispensed.		

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	Pharmacy Board of TRT
8.03.10S	In practice, (even though this may		2007	WHO level I and MOH

	be contrary to regulations) do the following groups of staff *sometimes* prescribe prescription-only medicines at the primary care level in the public sector?	☐Yes
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	

Section 9 Household data/access

9.00 Respondent Information section 8

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

9.01 Data from Household Surveys

Core Questions (click here for help)

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

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

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