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 Statistics¹,²), 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

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Tassia Williams (former Intern on Medicines and Health Technologies, CPC Office)
Guillermo Troya (*former Health Services Administration Advisor for Trinidad and Tobago*)
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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
Ministry of Health, GORTT
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### Acronyms and abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
</tr>
<tr>
<td>API</td>
<td>Active Pharmaceutical Ingredient</td>
</tr>
<tr>
<td>CARICOM</td>
<td>Caribbean Community</td>
</tr>
<tr>
<td>CMS</td>
<td>Central Medical Store</td>
</tr>
<tr>
<td>CFDD</td>
<td>Chemistry Food and Drug Department</td>
</tr>
<tr>
<td>CNCD</td>
<td>chronic non-communicable diseases</td>
</tr>
<tr>
<td>DID</td>
<td>Drug Inspectorate Division</td>
</tr>
<tr>
<td>DTC</td>
<td>Drug and Therapeutics Committee</td>
</tr>
<tr>
<td>EML</td>
<td>Essential Medicines List</td>
</tr>
<tr>
<td>EPA</td>
<td>Economic Partnership Agreement</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Program on Immunization</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practices</td>
</tr>
<tr>
<td>GDP</td>
<td>Gross Domestic Product</td>
</tr>
<tr>
<td>GDPs</td>
<td>Good Distribution Practices</td>
</tr>
<tr>
<td>GGHE</td>
<td>General Government Health Expenditure</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practices</td>
</tr>
<tr>
<td>GPP</td>
<td>Good Pharmacy Practices</td>
</tr>
<tr>
<td>INN</td>
<td>International Non-Proprietary Name</td>
</tr>
<tr>
<td>IPR</td>
<td>Intellectual Property Rights</td>
</tr>
<tr>
<td>MoH</td>
<td>Ministry of Health</td>
</tr>
<tr>
<td>MRA</td>
<td>Medicines Regulatory Authority</td>
</tr>
<tr>
<td>NHA</td>
<td>National Health Accounts</td>
</tr>
<tr>
<td>NHP</td>
<td>National Health Policy</td>
</tr>
<tr>
<td>NIPDEC</td>
<td>National Insurance and Property Development Company</td>
</tr>
<tr>
<td>NMP</td>
<td>National Medicines Policy</td>
</tr>
<tr>
<td>OAS</td>
<td>Organization of American States</td>
</tr>
<tr>
<td>OTC</td>
<td>Over-the-counter</td>
</tr>
</tbody>
</table>
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 online, links have been provided to the source documents so that users can easily access these documents.
The selection of indicators for the profiles has involved all technical units working in the Essential Medicines Department of the World Health Organization (WHO), as well as experts from WHO Regional and Country Offices, Harvard Medical School, Oswaldo Cruz Foundation (known as Fiocruz), University of Utrecht, the Austrian Federal Institute for Health Care and representatives from 13 pilot countries.

Data collection in all 193 member states has been conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information. To facilitate the work of national counterparts, the questionnaires were pre-filled at WHO 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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ivamaadr@cpc.paho.org
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. The annual population growth rate in 2008 was 0.4%. The annual Gross Domestic Product (GDP) growth rate is 4.5%. The GDP per capita was US$15,510 in the last year.

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

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

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.

The top 10 diseases causing mortality in Trinidad and Tobago in 2006 are shown in table 1.
Table 1. Top ten causes of mortality in Trinidad and Tobago

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

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

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

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

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). 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 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.

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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.\textsuperscript{10}

2.2 Health Personnel and Infrastructure

The health workforce is described in Figure 1. There are 641\textsuperscript{11} (4.8/10,000) licensed pharmacists.

There are 1,543 (11.7/10,000) physicians and 4,677\textsuperscript{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.

\textit{Figure 1. Density of the Health workforce in Trinidad and Tobago (all sectors)\textsuperscript{iv}}

\begin{center}
\begin{tikzpicture}
  \begin{axis}[
    ybar, 
    x axis line style={draw=none},
    y axis line style={draw=none},
    enlargelimits=0.15,
    ylabel={Density of the Health workforce (/10,000 population)},
    symbolic x coords={Pharmacists, Physicians, Nursing and midwifery personnel},
    xtick=data,
    nodes near coords,
    nodes near coords align={vertical},
    every node near coord/.append style={/pgf/number format/1000 sep={,}},
  ]
    \addplot coordinates {(Pharmacists, 4.8) (Physicians, 11.7) (Nursing and midwifery personnel, 35.5)};
  \end{axis}
\end{tikzpicture}
\end{center}

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\textsuperscript{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\textsuperscript{vi}. Pharmaceutical policy implementation is not regularly monitored or assessed.

\textsuperscript{vi} Chronic Disease Assistance Program. Available online: http://www.health.gov.tt/sitepages/default.aspx?id=132
Table 3. Items contained in the NMP

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

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\textsuperscript{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)\(^\text{15}\). Legal provisions granting patents to manufacturers exist. These cover pharmaceuticals, laboratory supplies, medical supplies and medical equipment\(^\text{16}\).

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\(^\text{vii}\).

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

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

<table>
<thead>
<tr>
<th>Flexibility and safeguards</th>
<th>Included</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compulsory licensing provisions that can be applied for reasons of public health</td>
<td>Yes</td>
</tr>
<tr>
<td>Bolar exceptions\textsuperscript{viii}</td>
<td>No</td>
</tr>
<tr>
<td>Parallel importing provisions</td>
<td>No</td>
</tr>
</tbody>
</table>

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\textsuperscript{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.

\textsuperscript{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: \texttt{WTO\_OMC\_Fact\_sheet\_TRIPS\_and\_pharmaceutical\_patents}, can be found online at: \texttt{http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf}]
Table 5. Trinidad and Tobago manufacturing capabilities

<table>
<thead>
<tr>
<th>Manufacturing capabilities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and Development for discovering new active substances</td>
<td>No</td>
</tr>
<tr>
<td>Production of pharmaceutical starting materials (APIs)</td>
<td>No</td>
</tr>
<tr>
<td>The production of formulations from pharmaceutical starting material</td>
<td>Yes</td>
</tr>
<tr>
<td>The repackaging of finished dosage forms</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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)\textsuperscript{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

Table 6. Functions of the national MRA

<table>
<thead>
<tr>
<th>Function</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Marketing authorisation / registration</td>
<td>Yes</td>
</tr>
<tr>
<td>Inspection</td>
<td>Yes</td>
</tr>
<tr>
<td>Import control</td>
<td>Yes</td>
</tr>
<tr>
<td>Licensing</td>
<td>Yes</td>
</tr>
<tr>
<td>Market control</td>
<td>Yes</td>
</tr>
<tr>
<td>Quality control</td>
<td>Yes</td>
</tr>
<tr>
<td>Medicines advertising and promotion</td>
<td>Yes</td>
</tr>
<tr>
<td>Clinical trials control</td>
<td>No</td>
</tr>
<tr>
<td>Pharmacovigilance</td>
<td>Yes</td>
</tr>
</tbody>
</table>

As of 2011, there are 17 posts attached to the Drug Inspectorate Division. Eight of these 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. 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.

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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\textsuperscript{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\textsuperscript{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\textsuperscript{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\textsuperscript{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\textsuperscript{14}. By law, potential conflict of interests for experts involved in the assessment and decision-making for registration do not need to be declared\textsuperscript{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\textsuperscript{x} is US$ 123\textsuperscript{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\textsuperscript{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.

\textsuperscript{x} Includes generics and New Chemical Entities (NCE).
Table 7. Local entities inspected in Trinidad and Tobago

<table>
<thead>
<tr>
<th>Entity</th>
<th>Inspection</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local manufacturers</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Private wholesalers</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Retail distributors</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Public pharmacies and stores</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Pharmacies and dispensing points if health facilities</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

5.4 Import Control

Legal provisions exist requiring authorization to import medicines. Laws exist that allow the sampling of imported products for testing\textsuperscript{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\textsuperscript{18, 21}.

5.5 Licensing

In Trinidad and Tobago, legal provisions exist requiring manufacturers, importers, wholesalers and distributors to be licensed\textsuperscript{14}. Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP)\textsuperscript{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**

<table>
<thead>
<tr>
<th>Entity requiring licensing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturers</td>
<td>Yes</td>
</tr>
<tr>
<td>Importers</td>
<td>Yes</td>
</tr>
<tr>
<td>Wholesalers</td>
<td>Yes</td>
</tr>
<tr>
<td>Distributors</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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**

<table>
<thead>
<tr>
<th>Medicines are tested:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>For quality monitoring in the public sector[^xi]</td>
<td>Yes</td>
</tr>
<tr>
<td>For quality monitoring in the private sector[^xii]</td>
<td>Yes</td>
</tr>
<tr>
<td>When there are complaints or problem reports</td>
<td>Yes</td>
</tr>
<tr>
<td>For product registration</td>
<td>Yes</td>
</tr>
<tr>
<td>For public procurement prequalification</td>
<td>Yes</td>
</tr>
<tr>
<td>For public program products prior to acceptance and/or distribution</td>
<td>Yes</td>
</tr>
</tbody>
</table>

[^xi]: Routine sampling in pharmacy stores and health facilities

[^xii]: Routine sampling in retail outlets

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 medicines.
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>
<thead>
<tr>
<th>Convention</th>
<th>Signatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single Convention on Narcotic Drugs, 1961</td>
<td>Yes</td>
</tr>
<tr>
<td>1972 Protocol amending the Single Convention on Narcotic Drugs, 1961</td>
<td>Yes</td>
</tr>
<tr>
<td>Convention on Psychotropic Substances 1971</td>
<td>Yes</td>
</tr>
<tr>
<td>United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Laws exist for the control of narcotic and psychotropic substances, and precursors (Dangerous Drugs Act 1991\(^1\)). The annual consumption of Morphine is 1.29 mg/capita\(^2\).

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

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\(^2\)**

<table>
<thead>
<tr>
<th>Controlled substance</th>
<th>Annual consumption (mg/capita)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morphine</td>
<td>1.298575</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>0.000555</td>
</tr>
<tr>
<td>Pethidine</td>
<td>7.366092</td>
</tr>
<tr>
<td>Oxycodone(^{xiii})</td>
<td>0.000000</td>
</tr>
<tr>
<td>Hydrocodone(^{xiv})</td>
<td>0.000000</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>Unknown</td>
</tr>
<tr>
<td>Methadone(^{xiv})</td>
<td>0.000000</td>
</tr>
</tbody>
</table>

\(^{xiii}\) 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

<table>
<thead>
<tr>
<th>Patient group</th>
<th>Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who cannot afford them</td>
<td>Yes</td>
</tr>
<tr>
<td>Children under 5</td>
<td>Yes</td>
</tr>
<tr>
<td>Pregnant women</td>
<td>Yes</td>
</tr>
<tr>
<td>Elderly persons</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Table 12. Particular conditions for which, medications are provided publicly, at no cost.

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>All diseases covered in the EML</td>
<td>Yes</td>
</tr>
<tr>
<td>Any non-communicable diseases</td>
<td>Yes</td>
</tr>
<tr>
<td>Malaria</td>
<td>Yes</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>Yes</td>
</tr>
<tr>
<td>Sexually transmitted diseases</td>
<td>Yes</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>Yes</td>
</tr>
<tr>
<td>Expanded Program on Immunization (EPI) vaccines for children</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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.

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\(^{xv}\) 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\textsuperscript{17}.

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

There is a written public sector procurement policy\textsuperscript{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\textsuperscript{14}. A process exists to ensure the quality of products that are

\textsuperscript{xviii} A password is needed to access the website.

\textsuperscript{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\textsuperscript{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\textsuperscript{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.

\textsuperscript{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 Store25

<table>
<thead>
<tr>
<th>Process</th>
<th>Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Forecasting of order quantities</td>
<td>Yes</td>
</tr>
<tr>
<td>Requisition/Stock orders</td>
<td>Yes</td>
</tr>
<tr>
<td>Preparation of picking/packing slips</td>
<td>Yes</td>
</tr>
<tr>
<td>Reports of stock on hand</td>
<td>Yes</td>
</tr>
<tr>
<td>Reports of outstanding order lines</td>
<td>Yes</td>
</tr>
<tr>
<td>Expiry dates management</td>
<td>Yes</td>
</tr>
<tr>
<td>Batch tracking</td>
<td>Yes</td>
</tr>
<tr>
<td>Reports of products out of stock</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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 sector20. 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, 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. 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.

A written National Strategy for containing antimicrobial resistance does not exist in Trinidad and Tobago\textsuperscript{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.

\textbf{8.2 Prescribing}

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

There are no regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs)\textsuperscript{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\textsuperscript{14}. 
Prescribing by INN name is obligatory in the public sector only.\textsuperscript{14}

A professional association code of conduct exists governing professional behaviour of doctors.\textsuperscript{26}

### 8.3 Dispensing

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

<table>
<thead>
<tr>
<th>Curriculum</th>
<th>Covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>The concept of EML</td>
<td>Yes</td>
</tr>
<tr>
<td>Use of STGs</td>
<td>Yes</td>
</tr>
<tr>
<td>Drug information</td>
<td>Yes</td>
</tr>
<tr>
<td>Clinical pharmacology</td>
<td>Yes</td>
</tr>
<tr>
<td>Medicines supply management</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Mandatory continuing education that includes rational use of medicines is not required for pharmacists.\textsuperscript{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.\textsuperscript{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\textsuperscript{14}. 
References


9 Ministry of Health, Government Republic of Trinidad and Tobago. Annual Hospital Utilization Reports: Hospital Discharge Reports, 2007.

10 World Health Organization (WHO), National Health Account for Trinidad and Tobago. Available online: http://www.who.int/nha/country/tto/en/


12 University of the West Indies (UWI), School of Pharmacy Administration, 2011.

13 Ministry of Health, Government of the Republic of Trinidad and Tobago, Trinidad and Tobago National Drug Policy, 1998.


18 Ministry of Legal Affairs, Government of the Republic of Trinidad and Tobago, **Food and Drugs Act (Act 8 of 1960)** and its corresponding amendments.

19 Ministry of Legal Affairs, Government of the Republic of Trinidad and Tobago, **Antibiotics Act (Act 18 of 1948)** and its corresponding amendments.

20 Health Research for Action (HERA), **Regional Assessment on Drug Registration and Regulatory Systems in CARICOM Member States and the Dominican Republic. Volume II. Belgium 2009.**

21 Ministry of Legal Affairs, Government of the Republic of Trinidad and Tobago, **Dangerous Drugs Act (Act 38 of 1991)** and its corresponding amendments.

22 Ministry of Legal Affairs, Government of the Republic of Trinidad and Tobago, **Pharmacy Board Act (Act 7 of 1960)** and its corresponding amendments.


26 Medical Board of Trinidad and Tobago, **A code of ethics in the practice of Medicine, 1990.** Available online: [http://www.mbtt.org/adobe/ethics.pdf](http://www.mbtt.org/adobe/ethics.pdf)
REPUBLIC OF TRINIDAD AND TOBAGO

Pharmaceutical Country Profile

ANNEX

Survey Data

(Fragment of the questionnaire)

2011
<table>
<thead>
<tr>
<th>0.01.01</th>
<th>Country (precoded)</th>
<th>Trinidad and Tobago</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01.02</td>
<td>Name coordinator</td>
<td>Dr Andrea Yearwood</td>
</tr>
<tr>
<td>0.01.03</td>
<td>Address (Street, City)</td>
<td>63 Park Street, Port of Spain, Trinidad and Tobago</td>
</tr>
<tr>
<td>0.01.04</td>
<td>Phone number</td>
<td>(868)-627-0010/12/14</td>
</tr>
<tr>
<td>0.01.05</td>
<td>Email address</td>
<td><a href="mailto:andrea.yearwood@health.gov.tt">andrea.yearwood@health.gov.tt</a></td>
</tr>
<tr>
<td>0.01.06</td>
<td>Web address</td>
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</tr>
<tr>
<td>0.01.07</td>
<td>Institution</td>
<td>Ministry of Health</td>
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### Section 1 Health and Demographic data

#### 1.00 Respondent Information Section 1

<table>
<thead>
<tr>
<th>1.00.01</th>
<th>Name of person responsible for filling out Survey section 1</th>
<th>Carla Ruiz (Health Policy, Research and Planning)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.00.02</td>
<td>Phone number</td>
<td>627-0010 Ext 504</td>
</tr>
<tr>
<td>1.00.03</td>
<td>Email address</td>
<td><a href="mailto:carla.ruiz@health.gov.tt">carla.ruiz@health.gov.tt</a></td>
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<tr>
<td>1.00.04</td>
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</tbody>
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#### 1.01 Demographic and Socioeconomic Indicators

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

<table>
<thead>
<tr>
<th>1.01.01</th>
<th><strong>Population</strong>, total (,000)</th>
<th>1,317.714</th>
<th>2010</th>
<th>TRT. Central Statistical Office</th>
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<tr>
<td>1.01.02</td>
<td>Population growth rate (Annual %)</td>
<td>0.4</td>
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<td>1.01.03</td>
<td>Total <strong>Gross Domestic Product</strong> (GDP) (millions US$)</td>
<td>20,433</td>
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<td>Ministry of Finance</td>
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<td>1.01.04</td>
<td>GDP growth (Annual %)</td>
<td>4.5</td>
<td>2010</td>
<td>Review of the Economy 2010</td>
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<tr>
<td>1.01.05C</td>
<td><strong>GDP</strong> per capita (US$ current exchange rate)</td>
<td>PREFILL CALC</td>
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**Comments and References**


**Supplementary questions** ([click here for help](#))
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<tr>
<td>1.01.07S</td>
<td>Population &lt; 15 years (% of total population)</td>
<td>25.34</td>
<td>2010 TRT. Central Statistical Office</td>
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<td>1.01.08S</td>
<td>Population &gt; 60 years (% of total population)</td>
<td>10.02</td>
<td>2010 TRT. Central Statistical Office</td>
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<td>1.01.09S</td>
<td>Urban population (% of total population)</td>
<td>13</td>
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<td>1.01.10S</td>
<td>Fertility rate, total (Births per woman)</td>
<td>1.6</td>
<td>2008 WHS 2010</td>
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<td>1.01.11S</td>
<td>Population living with less than $1.25/day (international PPP) (%)</td>
<td>17</td>
<td>2007 World Fact Book - CIA</td>
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<td>1.01.12S</td>
<td>Population living below nationally defined poverty line (%)</td>
<td>17</td>
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<td>1.01.13S</td>
<td>Income share held by lowest 20% of the population (% of national income)</td>
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<td>1.01.14S</td>
<td>Adult literacy rate, 15+ years (% of relevant population)</td>
<td>99</td>
<td>2007 WHS 2010</td>
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**Comments and References**


Please note data presented in 1.01.08S including population with 60 year and older


---

**1.02 Mortality and Causes of Death**

**Core questions** ([click here for help](#))
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<tr>
<td>1.02.01</td>
<td>Life expectancy at birth for men (Years)</td>
<td>66</td>
<td>2008</td>
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<tr>
<td>1.02.02</td>
<td>Life expectancy at birth for women (Years)</td>
<td>73</td>
<td>2008</td>
<td>WHS 2010</td>
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<tr>
<td>1.02.03</td>
<td>Infant mortality rate, between birth and age 1 (/1,000 live births)</td>
<td>31</td>
<td>2008</td>
<td>WHS 2010</td>
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<td>1.02.04</td>
<td>Under 5 mortality rate (/1,000 live births)</td>
<td>35</td>
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<td>WHS 2010</td>
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<td>1.02.05</td>
<td>Maternal mortality ratio (/100,000 live births)</td>
<td>45</td>
<td>2005</td>
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<td>1.02.06</td>
<td>Please provide a list of top 10 diseases causing mortality</td>
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<tr>
<td>1.02.06.01</td>
<td>Disease 1</td>
<td>Diseases of the Heart (I00-I52)</td>
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<tr>
<td>1.02.06.02</td>
<td>Disease 2</td>
<td>Malignant Neoplasm (C00-C97)</td>
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<td>1.02.06.03</td>
<td>Disease 3</td>
<td>Diabetes Mellitus (E10-E14)</td>
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<td>1.02.06.04</td>
<td>Disease 4</td>
<td>External Causes (V01-Y98)</td>
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<td>1.02.06.05</td>
<td>Disease 5</td>
<td>Cerebrovascular Disease (I60-I69)</td>
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<td>Disease 6</td>
<td>Diseases of the Respiratory System (J00-J98)</td>
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<td>1.02.06.07</td>
<td>Disease 7</td>
<td>Diseases of the Digestive System (K00-K92)</td>
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<td>1.02.06.08</td>
<td>Disease 8</td>
<td>AIDS/HIV Disease (B20-B24)</td>
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<td>1.02.06.09</td>
<td>Disease 9</td>
<td>Diseases of the Nervous System (G00-G99)</td>
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<td>1.02.06.10</td>
<td>Disease 10</td>
<td>Diseases of the Genitourinary System (N00-N98)</td>
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Please provide a list of top 10 diseases causing morbidity 2007 Hospital Discharges; Annual Hospital Utilization Reports
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<th>Disease Code</th>
<th>Disease Category</th>
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<tbody>
<tr>
<td>1.02.07.01</td>
<td>Injury, Poisoning and Certain Other Consequences of External Causes</td>
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<td>1.02.07.02</td>
<td>Diseases of the Genitourinary System</td>
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<td>1.02.07.03</td>
<td>Diseases of the Heart</td>
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<td>1.02.07.04</td>
<td>Symptoms, Signs and Abnormal Clinical and Lab Findings</td>
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<td>Diseases of the Digestive System</td>
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<tr>
<td>1.02.07.06</td>
<td>Complications of Pregnancy</td>
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<tr>
<td>1.02.07.07</td>
<td>Mental Illnesses</td>
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<tr>
<td>1.02.07.08</td>
<td>Respiratory Disorders</td>
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<td>1.02.07.09</td>
<td>Skin Disorders</td>
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<tr>
<td>1.02.07.10</td>
<td>Infectious Diseases</td>
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</table>

**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)*

<table>
<thead>
<tr>
<th>Supplementary Question</th>
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<tr>
<td>1.02.09S Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)</td>
<td>163</td>
<td>2008 WHS 2010</td>
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<tr>
<td>1.02.10S Neonatal mortality rate (/1,000 live births)</td>
<td>24</td>
<td>2008 WHS 2010</td>
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<td>1.02.11S Age-standardized mortality rate by non-communicable diseases (/100,000 population)</td>
<td>751</td>
<td>2004 WHS 2010</td>
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<tr>
<td>1.02.12S Age-standardized mortality rate by cardiovascular diseases (/100,000 population)</td>
<td>364</td>
<td>2004 WHS 2009</td>
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Pharmaceutical Sector Country Profile Questionnaire.
<table>
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<td>1.02.13S</td>
<td>Age-standardized mortality rate by cancer (/100,000 population)</td>
<td>123</td>
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<td>1.02.14S</td>
<td><strong>Mortality rate</strong> for HIV/AIDS (/100,000 population)</td>
<td>22.7</td>
<td>2006</td>
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<td>1.02.15S</td>
<td>Mortality rate for tuberculosis (/100,000 population)</td>
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<td>1.02.16S</td>
<td>Mortality rate for Malaria (/100,000 population)</td>
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<td>1.02.17S</td>
<td>Comments and References</td>
<td>1.02.14S, 1.02.16S from Ministry of Planning and Development, Central Statistical Office, 2006.</td>
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## Section 2 Health Services

### 2.00 Respondent Information Section 2

<table>
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<th>Carla Ruiz, Research Officer, Health Policy, Research and Planning, Ministry of Health</th>
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<tbody>
<tr>
<td>2.00.02</td>
<td>Phone number</td>
<td>627-0010</td>
</tr>
<tr>
<td>2.00.03</td>
<td>Email address</td>
<td><a href="mailto:carla.ruiz@health.gov.tt">carla.ruiz@health.gov.tt</a></td>
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<tr>
<td>2.00.04</td>
<td>Other respondents for filling out this section</td>
<td>Rian Extavour, Lecturer (UWI, School of Pharmacy)</td>
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### 2.01 Health Expenditures

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

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<tr>
<th>2.01.01.01</th>
<th>Total annual expenditure on health (millions NCU)</th>
<th>7,611</th>
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<tbody>
<tr>
<td>2.01.01.02</td>
<td>Total annual expenditure on health (millions US$ average exchange rate)</td>
<td>1,179.7</td>
<td>2008</td>
<td>Calculated based on National Health Account - WHO</td>
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<tr>
<td>2.01.02C</td>
<td>Total health expenditure as % of Gross Domestic Product</td>
<td>5.00</td>
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<tr>
<td>2.01.03.01C</td>
<td>Total annual expenditure on health per capita (NCU)</td>
<td>5,691.30</td>
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<tr>
<td>2.01.03.02C</td>
<td>Total annual expenditure on health per capita (US$ average exchange rate)</td>
<td>904.82</td>
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<td>2.01.04.01</td>
<td>General government annual expenditure on health (millions NCU)</td>
<td>3,720</td>
<td>2008</td>
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Pharmaceutical Sector Country Profile Questionnaire.
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<th>Source</th>
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<td>2.01.04</td>
<td>General government annual expenditure on health (millions US$ average exchange rate)</td>
<td>576.6</td>
<td>2008</td>
<td>Calculated based on National Health Account - WHO</td>
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<td>2.01.05</td>
<td>Government annual expenditure on health as percentage of total government budget (% of total</td>
<td>8.8</td>
<td>2008</td>
<td>National Health Account - WHO</td>
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<tr>
<td></td>
<td>government budget)</td>
<td></td>
<td></td>
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<tr>
<td>2.01.06C</td>
<td>Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)</td>
<td>56.68</td>
<td>2008</td>
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<td>2.01.07.01C</td>
<td>Annual per capita government expenditure on health (NCU)</td>
<td>3,225.81</td>
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<td>2.01.07.02C</td>
<td>Annual per capita government expenditure on health (US$ average exchange rate)</td>
<td>512.85</td>
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<td>2.01.08C</td>
<td>Private health expenditure as % of total health expenditure (% of total expenditure on health)</td>
<td>43.32</td>
<td>2008</td>
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<td>2.01.09</td>
<td>Population covered by a public health service or public health insurance or social health insurance, or other sickness funds of total population</td>
<td>?</td>
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<tr>
<td>2.01.10</td>
<td>Population covered by private health insurance (% of total population)</td>
<td>?</td>
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<tr>
<td>2.01.11.01</td>
<td>Total pharmaceutical expenditure (millions NCU)</td>
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Pharmaceutical Sector Country Profile Questionnaire.
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<td>2.01.11.02</td>
<td>Total pharmaceutical expenditure (millions US$ current exchange rate)</td>
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<tr>
<td>2.01.12.01C</td>
<td>Total pharmaceutical expenditure per capita (NCU)</td>
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<tr>
<td>2.01.12.02C</td>
<td>Total pharmaceutical expenditure per capita (US$ current exchange rate)</td>
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<tr>
<td>2.01.13C</td>
<td>Pharmaceutical expenditure as a % of GDP (% of GDP)</td>
</tr>
<tr>
<td>2.01.14C</td>
<td>Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)</td>
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<tr>
<td>2.01.15.01</td>
<td>Total public expenditure on pharmaceuticals (millions NCU)</td>
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<td>2.01.15.02</td>
<td>Total public expenditure on pharmaceuticals (millions US$ current exchange rate)</td>
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<tr>
<td>2.01.16C</td>
<td>Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)</td>
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<tr>
<td>2.01.17.01C</td>
<td>Total public expenditure on pharmaceuticals per capita (NCU)</td>
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<td>2.01.17.02C</td>
<td>Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)</td>
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<td>2.01.18.01</td>
<td>Total private expenditure on pharmaceuticals (millions NCU)</td>
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<tr>
<td>2.01.18.02</td>
<td>Total private expenditure on pharmaceuticals (millions US$ current exchange rate)</td>
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Pharmaceutical Sector Country Profile Questionnaire.
## Supplementary questions (click for help)

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<th>Source</th>
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<td>2.01.20S</td>
<td>Social security expenditure as % of government expenditure on health (%)</td>
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<td>2.01.21S</td>
<td>Market share of generic pharmaceuticals [branded and INN] by value (%)</td>
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<tr>
<td>2.01.22S</td>
<td>Annual growth rate of total pharmaceuticals market value (%)</td>
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<tr>
<td>2.01.23S</td>
<td>Annual growth rate of generic pharmaceuticals market value (%)</td>
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<tr>
<td>2.01.24S</td>
<td>Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)</td>
<td>81.8</td>
<td>2008 National Health Account - WHO</td>
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<tr>
<td>2.01.25S</td>
<td>Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)</td>
<td>14.7</td>
<td>2008 National Health Account - WHO</td>
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## 2.02 Health Personnel and Infrastructure

### Core questions (click for help)

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<td>2.02.01</td>
<td>Total number of pharmacists licensed/registered to practice in your country</td>
<td>641</td>
<td>2007 Global Health Atlas</td>
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<tr>
<td>2.02.02C</td>
<td>Pharmacists per 10,000 population</td>
<td>4.8</td>
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<td>Question</td>
<td>Answer</td>
<td>Year</td>
<td>Source</td>
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<tr>
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<tr>
<td>2.02.03 Total number of pharmacists working in the public sector</td>
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<tr>
<td>2.02.04 Total number of <em>pharmaceutical technicians and assistants</em></td>
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<tr>
<td>2.02.05 A strategic plan for pharmaceutical human resource development is in place in your country?</td>
<td>Yes ☐ No ☒</td>
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<td>MOH</td>
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<td>2.02.06 Total number of physicians</td>
<td>1,543</td>
<td>2009</td>
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<tr>
<td>2.02.07C Physicians per 10,000 pop</td>
<td>11.6</td>
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<td>2.02.08 Total number of <em>nursing and midwifery personnel</em></td>
<td>4,677</td>
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<tr>
<td>2.02.09C Nurses and midwives per 10,000 pop</td>
<td>35.1</td>
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<td>2.02.10 Total number of hospitals</td>
<td>21</td>
<td>2011</td>
<td>Drug Inspectorate/Ministry of Health</td>
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<tr>
<td>2.02.11 Number of hospital beds per 10,000 pop</td>
<td>27</td>
<td>2009</td>
<td>WHS 2010</td>
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<tr>
<td>2.02.12 Total number of primary health care units and centers</td>
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<tr>
<td>2.02.13 Total number of licensed pharmacies</td>
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<td>2.02.14 Comments and References</td>
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**Supplementary questions (click here for help)**

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<tr>
<th>Question</th>
<th>Year</th>
<th>Source</th>
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<tbody>
<tr>
<td>2.02.15S Starting annual salary for a newly registered <em>pharmacist</em></td>
<td></td>
<td>2.02.01. Global Health Atlas - Country Data - Trinidad and Tobago. Available at: <a href="http://apps.who.int/globalatlas/dataQuery/default.asp">http://apps.who.int/globalatlas/dataQuery/default.asp</a> 2.02.10. Information provided by Drug Inspectorate/Ministry of Health (2011): 11 public and 10 private hospitals.</td>
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<tr>
<td>2.02.16S</td>
<td>Total number of pharmacists who graduated (first degree) in the past 2 years in your country</td>
<td>79</td>
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<td>---</td>
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<tr>
<td>2.02.17S</td>
<td>Are there accreditation requirements for pharmacy schools?</td>
<td>Yes ☑ No ☐</td>
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<tr>
<td>2.02.18S</td>
<td>Is the Pharmacy Curriculum regularly reviewed?</td>
<td>Yes ☑ No ☐</td>
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</tbody>
</table>
| 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.  


2.02.18S 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](http://sta.uwi.edu/accreditation/faqs.asp) |
### Section 3 Policy issues

#### 3.00 Respondent Information Section 4

<table>
<thead>
<tr>
<th>3.00.01</th>
<th>Name of person responsible for filling out this section of the instrument</th>
<th>Carla Ruiz, Research Officer, Health Policy, Research and Planning</th>
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<tbody>
<tr>
<td>3.00.02</td>
<td>Phone number</td>
<td>627-0010</td>
</tr>
<tr>
<td>3.00.03</td>
<td>Email address</td>
<td><a href="mailto:carla.ruiz@health.gov.tt">carla.ruiz@health.gov.tt</a></td>
</tr>
<tr>
<td>3.00.04</td>
<td>Other respondents for filling out this section</td>
<td></td>
</tr>
</tbody>
</table>

#### 3.01 Policy Framework

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

<table>
<thead>
<tr>
<th>3.01.01</th>
<th>National Health Policy exists. If yes, please write year of the most recent document in the &quot;year&quot; field.</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.01.02</td>
<td>National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the &quot;year&quot;</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3.01.03</td>
<td>Please provide comments on the Health policy and its implementation plan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.04</td>
<td>National Medicines Policy official document exists. If yes, please write the year of the most recent document in the &quot;year&quot; field.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3.01.05</td>
<td>Group of policies addressing pharmaceuticals exist.</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3.01.06</td>
<td>National Medicines Policy covers the following components:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Response</th>
<th>Year</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.01.06.01</td>
<td>Selection of <strong>Essential Medicines</strong></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.02</td>
<td>Medicines Financing</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.03</td>
<td>Medicines Pricing</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.04</td>
<td>Medicines <strong>Procurement</strong></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.05</td>
<td>Medicines <strong>Distribution</strong></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.06</td>
<td>Medicines <strong>Regulation</strong></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.07</td>
<td>Pharmacovigilance</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.08</td>
<td>Rational Use of Medicines</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.09</td>
<td>Human Resource Development</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.10</td>
<td>Research</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.11</td>
<td>Monitoring and Evaluation</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.12</td>
<td><strong>Traditional Medicine</strong></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Code</th>
<th>Question</th>
<th>Response</th>
<th>Year</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.01.07</td>
<td>National medicines policy implementation plan exists. If yes, please write year of the most recent document.</td>
<td>Yes</td>
<td>2011</td>
<td>MOH MRA</td>
</tr>
<tr>
<td>3.01.08</td>
<td>Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in the &quot;year&quot; field</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.09</td>
<td>National clinical laboratory policy implementation plan exists. If yes, please write year of the most recent document in the &quot;year&quot; field</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.10</td>
<td>Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?</td>
<td>Yes</td>
<td>2011</td>
<td>MOH</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes/No</th>
<th>Date</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.01.11 There are official written guidelines on medicines donations.</td>
<td>Yes</td>
<td>2007</td>
<td>WHO level I</td>
</tr>
<tr>
<td>3.01.12 Is pharmaceutical policy implementation being regularly monitored/assessed?</td>
<td>☑ No</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>3.01.12.01 Who is responsible for pharmaceutical policy monitoring?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>The Pharmacy/Drug Inspectorate at the Ministry of Health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.13 Is there a national good governance policy?</td>
<td>Yes</td>
<td>2011</td>
<td>MoH</td>
</tr>
<tr>
<td>3.01.13.01 Multisectoral</td>
<td>☑ Yes</td>
<td>2011</td>
<td>MoH</td>
</tr>
<tr>
<td>3.01.13.02 For the pharmaceutical sector</td>
<td>☑ Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.13.03 Which agencies are responsible?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pharmacy/Drug Inspectorate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.14 A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.</td>
<td>☑ No</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>3.01.15 There is a formal code of conduct for public officials.</td>
<td>Yes</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>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)?</td>
<td>☑ No</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>3.01.16.01 Please describe:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.17 Comments and References</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.04 Ministry of Health. Trinidad and Tobago National Drug Policy 1998; GORTT (attached)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.05 Policies on pharmaceuticals include National Drug Policy and Chronic Disease Assistance Program; available at <a href="http://www.health.gov.tt/sitepages/default.aspx?id=132">http://www.health.gov.tt/sitepages/default.aspx?id=132</a></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.01.06.12 The term used in the policy is Herbal/Complementary</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
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

<table>
<thead>
<tr>
<th>4.00.01</th>
<th>Name of person responsible for filling out this section of the instrument</th>
<th>Junia Walcott</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.00.02</td>
<td>Phone number</td>
<td>627-0046</td>
</tr>
<tr>
<td>4.00.03</td>
<td>Email address</td>
<td><a href="mailto:junia.walcott@health.gov.tt">junia.walcott@health.gov.tt</a></td>
</tr>
<tr>
<td>4.00.04</td>
<td>Other respondents for filling out this section</td>
<td>Carla Ruiz</td>
</tr>
</tbody>
</table>

#### 4.01 Intellectual Property Laws and Medicines

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

<table>
<thead>
<tr>
<th>4.01.01</th>
<th>Country is a member of the World Trade Organization</th>
<th>Yes ☑️ No ☐</th>
<th>1995</th>
<th>WTO</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.01.02</td>
<td>Legal provisions provide for granting of Patents on:</td>
<td>Yes ☑️ No ☐</td>
<td>1996</td>
<td>Patents Act</td>
</tr>
<tr>
<td>4.01.02.01</td>
<td>Pharmaceuticals</td>
<td>Yes ☑️ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.01.02.02</td>
<td>Laboratory supplies</td>
<td>Yes ☑️ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.01.02.03</td>
<td>Medical supplies</td>
<td>Yes ☑️ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.01.02.04</td>
<td>Medical equipment</td>
<td>Yes ☑️ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.01.03.01</td>
<td>Please provide name and address of the institution responsible for managing and enforcing intellectual property rights</td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.01.03.02</td>
<td>Please provide URL</td>
<td><a href="http://www.legalaffairs.gov.tt">www.legalaffairs.gov.tt</a> and <a href="http://www.ipo.gov.tt">www.ipo.gov.tt</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.01.04</td>
<td>National Legislation has been modified to implement the TRIPS Agreement</td>
<td>Yes ☑️ No ☐</td>
<td>2007</td>
<td>WHO level I</td>
</tr>
<tr>
<td>4.01.05</td>
<td>Current laws contain (TRIPS) flexibilities and safeguards</td>
<td>Yes ☑️ No ☐</td>
<td>2009</td>
<td>Hera Report -</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Question Number</th>
<th>Description</th>
<th>Yes/No Answer</th>
<th>Year</th>
<th>Additional Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.01.06</td>
<td>Country is eligible for the transitional period to 2016</td>
<td>Yes ☑ No ☐</td>
<td></td>
<td>Patents</td>
</tr>
<tr>
<td>4.01.07</td>
<td>Which of the following (TRIPS) flexibilities and safeguards are present in the national law?</td>
<td>2007 WHO level I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.01.07.01</td>
<td>Compulsory licensing provisions that can be applied for reasons of public health</td>
<td>Yes ☑ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.01.08</td>
<td>Are parallel importing provisions present in the national law?</td>
<td>Yes ☑ No ☐</td>
<td>2007 WHO Level 1</td>
<td></td>
</tr>
<tr>
<td>4.01.09</td>
<td>The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health</td>
<td>Yes ☑ No ☐</td>
<td>2011 MOH</td>
<td></td>
</tr>
<tr>
<td>4.01.10</td>
<td>Are there legal provisions for data exclusivity for pharmaceuticals</td>
<td>Yes ☑ No ☐</td>
<td>2009 Hera Report - Patents</td>
<td></td>
</tr>
<tr>
<td>4.01.11</td>
<td>Legal provisions exist for patent extension</td>
<td>Yes ☑ No ☐</td>
<td>2011 MOH</td>
<td></td>
</tr>
<tr>
<td>4.01.12</td>
<td>Legal provisions exist for linkage between patent status and Marketing Authorization</td>
<td>Yes ☑ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.01.13</td>
<td>Comments and References</td>
<td>4.01.01. World Trade Organization - Members and Observers. Available at: <a href="http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm">http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm</a></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### 4.02 Manufacturing

**Core questions** *(click here for help)*

<table>
<thead>
<tr>
<th>4.02.01</th>
<th>Number of licensed pharmaceutical manufacturers in the country</th>
<th>4</th>
<th>2011</th>
<th>MOH, MRAA</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.02.02</td>
<td>Country has manufacturing capacity</td>
<td></td>
<td>2007</td>
<td>WHO level I</td>
</tr>
<tr>
<td>4.02.02.01</td>
<td>R&amp;D to discover new active substances</td>
<td>Yes [ ] No [x] Unknown [ ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.02.02.02</td>
<td>Production of pharmaceutical starting materials (APIs)</td>
<td>Yes [ ] No [x] Unknown [ ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.02.02.03</td>
<td>Production of formulations from pharmaceutical starting material</td>
<td>Yes [ ] No [x] Unknown [ ]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.02.02.04</td>
<td>Repackaging of finished dosage forms</td>
<td>Yes [ ] No [x] Unknown [ ]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 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)*

| 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

<table>
<thead>
<tr>
<th>5.00.01</th>
<th>Name of person responsible for filling out this section of the instrument</th>
<th>Junia Walcott</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.00.02</td>
<td>Phone number</td>
<td>627-0046</td>
</tr>
<tr>
<td>5.00.03</td>
<td>Email address</td>
<td><a href="mailto:junia.walcott@health.gov.tt">junia.walcott@health.gov.tt</a></td>
</tr>
<tr>
<td>5.00.04</td>
<td>Other respondents for filling out this section</td>
<td></td>
</tr>
</tbody>
</table>

#### 5.01 Regulatory Framework

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

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

Pharmaceutical Sector Country Profile Questionnaire.
5.01.05 What are the functions of the National Medicines Regulatory Authority?

| 5.01.05.01 | Marketing authorization / registration | Yes ☒ No ☐ |
| 5.01.05.02 | Inspection | Yes ☒ No ☐ |
| 5.01.05.03 | Import control | Yes ☒ No ☐ |
| 5.01.05.04 | Licensing | Yes ☒ No ☐ |
| 5.01.05.05 | Market control | Yes ☒ No ☐ |
| 5.01.05.06 | Quality control | Yes ☒ No ☐ |
| 5.01.05.07 | Medicines advertising and promotion | Yes ☒ No ☐ |
| 5.01.05.08 | Clinical trials control | Yes ☐ No ☒ |
| 5.01.05.09 | Pharmacovigilance | Yes ☒ No ☐ |
| 5.01.05.10 | Other: (please explain) | |

5.01.06 Number of the MRA permanent staff 8

5.01.06.01 Date of response 13/07/2011

5.01.07 The MRA has its own website Yes ☒ No ☐

5.01.07.01 If yes, please provide MRA website address (URL) http://www.health.gov.tt/sitepages/default.aspx?id=93

5.01.08 The MRA receives external technical assistance Yes ☒ No ☐

5.01.08.01 If yes, please describe: PAHO/WHO

5.01.09 The MRA is involved in harmonization/collaboration initiatives Yes ☒ No ☐

5.01.09.01 If yes, please specify Pan American Network for Drug Regulatory Harmonization
### 5.01.10
An assessment of the medicines regulatory system has been conducted in the last five years.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

2011 MOH.MRA

### 5.01.11
Medicines Regulatory Authority gets funds from regular budget of the government.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

2011 MOH. MRA

### 5.01.12
Medicines Regulatory Authority is funded from fees for services provided.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

2011 MOH. MRA

### 5.01.13
Medicines Regulatory Authority receives funds/support from other sources

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>✗</th>
</tr>
</thead>
</table>

2011 MOH/MRA

### 5.01.15
The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>✗</th>
</tr>
</thead>
</table>

2011 MOH/MRA

### 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;
5.01.06 No information from Chemistry Food and Drug Division available.

5.1.10. in 2009 it was conducted the HERA/CARICOM, Assessment 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)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1965</td>
<td>Food and Drugs Act*</td>
</tr>
<tr>
<td>2009</td>
<td>CARICOM DRA HERA REPORT Volume II</td>
</tr>
<tr>
<td>2011</td>
<td>MOH / MRAA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5.02.01 Legal provisions require a <strong>Marketing Authorization</strong> (registration) for all pharmaceutical products on the market</th>
<th>Yes ☒ No ☐</th>
<th>1965</th>
<th>Food and Drugs Act*</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.02.02 Are there any mechanism for exception/waiver of registration?</td>
<td>Yes ☐ No ☒</td>
<td>2009</td>
<td>CARICOM DRA HERA REPORT Volume II</td>
</tr>
<tr>
<td>5.02.03 Are there mechanisms for recognition of registration done by other</td>
<td>Yes ☐ No ☒</td>
<td>2011</td>
<td>MOH / MRAA</td>
</tr>
<tr>
<td>Question</td>
<td>Yes/No</td>
<td>Year</td>
<td>Source</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------</td>
<td>------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>5.02.04 Explicit and publicly available criteria exist for assessing</td>
<td>Yes ☑</td>
<td>2011</td>
<td>MOH/MRA</td>
</tr>
<tr>
<td>Marketing Authorization of pharmaceutical products</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.02.05 Information from the prequalification programme managed by</td>
<td>Yes ☑</td>
<td>2009</td>
<td>CARICOM DRA HERA Report Volume II</td>
</tr>
<tr>
<td>WHO is used for product registration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.02.06 Number of pharmaceutical products registered in your country</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.02.07 Legal provisions require the MRA to make the list of registered</td>
<td>Yes ☑</td>
<td>2007</td>
<td>WHO level I</td>
</tr>
<tr>
<td>pharmaceuticals with defined periodicity publicly available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.02.07.01 If yes, how frequently updated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.02.07.02 If yes, please provide updated list or URL</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>5.02.08 Medicines registration always includes the INN (International</td>
<td>Yes ☑</td>
<td>2007</td>
<td>WHO level I</td>
</tr>
<tr>
<td>Non-proprietary Names)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.02.09 Legal provisions require the payment of a fee for Medicines</td>
<td>Yes ☑</td>
<td>2011</td>
<td>MOH/MRA</td>
</tr>
<tr>
<td>Marketing Authorization (registration) applications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.02.10 Comments and References</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.01.01. Also: Narcotic Control (General Provisions) Regulations &amp;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Narcotic Control (Licensing) Regulations</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.02.01. it is also complemented by Food and Drugs Regulations with</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>corresponding Amendments; Antibiotics Act No. 14, 1948 with its</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>corresponding Amendments and Cap 30-02, Antibiotics (Conditions for Use)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Order; Cap 30-02 Approved Pharmaceutical Firms Order; Dangerous</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drugs Act of 1991 with its corresponding Amendments;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Please note that in Trinidad and Tobago there is no legal provision</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
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)

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legal provisions require Marketing Authorization holders to provide</td>
<td>Yes ☑</td>
<td>2011</td>
<td>MOH/MRA A</td>
</tr>
<tr>
<td>information about variations to the existing Marketing Authorization</td>
<td>No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legal provisions require publication of a <strong>Summary of Product</strong></td>
<td>Yes ☑</td>
<td>2011</td>
<td>MOH/MRA A</td>
</tr>
<tr>
<td><strong>Characteristics (SPCs)</strong> of the medicines registered</td>
<td>No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legal provisions require the establishment of an expert committee</td>
<td>Yes ☑</td>
<td>2007</td>
<td>WHO level I</td>
</tr>
<tr>
<td>involved in the marketing authorization process</td>
<td>No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Certificate for Pharmaceutical Products</strong> in accordance with the</td>
<td>Yes ☑</td>
<td>2007</td>
<td>WHO level I</td>
</tr>
<tr>
<td>WHO Certification scheme is required as part of the Marketing</td>
<td>No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Authorization application</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legal provisions require declaration of potential **conflict of</td>
<td>Yes ☑</td>
<td>2009</td>
<td>HERA Report DRA</td>
</tr>
<tr>
<td>interests** for the experts involved in the assessment and</td>
<td>No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>decision-making for registration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legal provisions allow applicants to appeal against MRAs decisions</td>
<td>Yes ☑</td>
<td>2011</td>
<td>MOH/MRA A</td>
</tr>
<tr>
<td>Registration fee - the amount per application for pharmaceutical</td>
<td>123</td>
<td>1965</td>
<td>Food and Drug</td>
</tr>
<tr>
<td>product containing <strong>New Chemical Entity (NCE)</strong> (US$)</td>
<td></td>
<td></td>
<td>Act Form Dand</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>E page 123</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
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])

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
</table>
| 1965 | Section 17 Page 208.
| 1965 | Antibiotics act Section 12:(1).
| 2011 | Dangerous Drug Act Section 12:(1). |

5.03.01 Legal provisions exist allowing for appointment of government pharmaceutical inspectors

Yes ☒ No ☐

5.03.02 Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are

Yes ☒ No ☐

5.01.17S Ministry of Legal Affairs - Food and Drugs Act of 1965; Forms (2007)
<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.03.02.01</td>
<td>If yes, legal provisions exist requiring inspections to be performed</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5.03.03</td>
<td>Inspection is a pre-requisite for licensing of:</td>
<td>2011</td>
<td>MOH, MRAA</td>
</tr>
<tr>
<td>5.03.03.01</td>
<td>Public facilities</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5.03.03.02</td>
<td>Private facilities</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5.03.04</td>
<td>Inspection requirements are the same for public and private facilities</td>
<td>2011</td>
<td>MOH/MRA</td>
</tr>
<tr>
<td>5.03.05.01</td>
<td>Local manufactures are inspected for GMP compliance</td>
<td>2007</td>
<td>MOH/MRA, WHO level I</td>
</tr>
<tr>
<td>5.03.05.02</td>
<td>Private wholesalers are inspected</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5.03.05.03</td>
<td>Retail distributors are inspected</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5.03.05.04</td>
<td>Public pharmacies and stores are inspected</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5.03.05.05</td>
<td>Pharmacies and dispensing points of health facilities are inspected</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>5.03.05.06</td>
<td>Please provide details on frequency of inspections for the different categories of facilities</td>
<td>Annually</td>
<td></td>
</tr>
<tr>
<td>5.03.06</td>
<td>Comments and References</td>
<td>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)</td>
<td></td>
</tr>
</tbody>
</table>

5.04 Import Control

Core Questions ([click here for help](#))
<table>
<thead>
<tr>
<th>Code</th>
<th>Question</th>
<th>Yes/No</th>
<th>Year</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.04.01</td>
<td>Legal provisions exist requiring authorization to import medicines</td>
<td>Yes ☒ No ☐</td>
<td>1965</td>
<td>Food and Drug Act Division 3 New Drugs Act Section 17</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dangerous Drug Act Section 11 Subsection 1-3 page 20</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Section 13, 14 Page 22</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Section 15, 17 subsection 1-3 Page 23</td>
</tr>
<tr>
<td>5.04.02</td>
<td>Legal provisions exist allowing the sampling of imported products for testing</td>
<td>Yes ☒ No ☐</td>
<td>1965</td>
<td>Food and Drug Act Administration and enforcement Section 22 page 13</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Section 8 page 29</td>
</tr>
<tr>
<td>5.04.03</td>
<td>Legal provisions exist requiring importation of medicines through authorized ports of entry</td>
<td>Yes ☒ No ☐</td>
<td>1991</td>
<td>Dangerous Drug Act Section 4 subsection (c)</td>
</tr>
<tr>
<td>5.04.04</td>
<td>Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry</td>
<td>Yes ☒ No ☐</td>
<td>1965</td>
<td>Food and Drug Act Administration and enforcement Section</td>
</tr>
</tbody>
</table>
5.05 Licensing

| 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 |
| 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 | Yes ☒ No ☐ | 2011 | MOH /MRA |

When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)
| 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 exist 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)*

| 5.06.01 | Legal Provisions for regulating the pharmaceutical market exist | Yes ☒ No ☐ | 1991 | Dangerous Drug Act |

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.06.02</td>
<td>Does a laboratory exist in the country for Quality Control testing?</td>
<td>Yes</td>
<td>No</td>
<td>2009</td>
<td>CARICOM DRA Hera Report Volume II</td>
</tr>
<tr>
<td>5.06.02.01</td>
<td>If yes, is the laboratory part of the MRA?</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.06.02.02</td>
<td>Does the regulatory authority contract services elsewhere?</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.06.02.03</td>
<td>If yes, please describe</td>
<td></td>
<td></td>
<td></td>
<td>Trinidad and Tobago is also signatory to the Agreement establishing the Caribbean Regional Drug Testing Laboratory.</td>
</tr>
<tr>
<td>5.06.03</td>
<td>Is there any national laboratory accepted for collaboration with WHO prequalification Programme? Please describe.</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.06.04</td>
<td>Medicines are tested:</td>
<td></td>
<td></td>
<td>2011</td>
<td>MOH/MRA</td>
</tr>
<tr>
<td>5.06.04.01</td>
<td>For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities)</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.06.04.02</td>
<td>For quality monitoring in private sector (routine sampling in retail outlets)</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.06.04.03</td>
<td>When there are complaints or problem reports</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.06.04.04</td>
<td>For product registration</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.06.04.05</td>
<td>For public procurement prequalification</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.06.04.06</td>
<td>For public program products prior to acceptance and/or distribution</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.06.05</td>
<td>Samples are collected by government inspectors for undertaking post-marketing</td>
<td>Yes</td>
<td>No</td>
<td>2007</td>
<td>WHO level I</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
| 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](#))

<table>
<thead>
<tr>
<th>Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.07.01</td>
<td>Legal provisions exist to control the promotion and/or advertising of prescription medicines</td>
<td>Yes ☒ No ☐ 2007 WHO level I</td>
</tr>
<tr>
<td>5.07.02</td>
<td>Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:</td>
<td></td>
</tr>
<tr>
<td>5.07.03</td>
<td>Legal provisions prohibit direct advertising of prescription medicines to the public</td>
<td>Yes ☒ No ☐ 2007 WHO level I</td>
</tr>
<tr>
<td>5.07.04</td>
<td>Legal provisions require a pre-approval for medicines advertisements and promotional materials</td>
<td>Yes ☐ No ☒ 2007 WHO level I</td>
</tr>
<tr>
<td>5.07.05</td>
<td>Guidelines/Regulations exist for advertising and promotion of non-prescription medicines</td>
<td>Yes ☒ No ☐ 2007 WHO level I</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
### 5.07.06
A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available

<table>
<thead>
<tr>
<th>5.07.06.01</th>
<th>If yes, the code of conduct applies to domestic manufacturers only, multinational manufacturers only, or both</th>
</tr>
</thead>
<tbody>
<tr>
<td>Domestic only</td>
<td>Yes [ ] No [X]</td>
</tr>
<tr>
<td>Multinational only</td>
<td>Yes [ ] No [ ]</td>
</tr>
<tr>
<td>Both</td>
<td>Yes [ ] No [ ]</td>
</tr>
</tbody>
</table>

### 5.07.06.02
If yes, adherence to the code is voluntary

<table>
<thead>
<tr>
<th>5.07.06.03</th>
<th>If yes, the code contains a formal process for complaints and sanctions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes [ ] No [ ]</td>
<td></td>
</tr>
</tbody>
</table>

### 5.07.06.04
If yes, list of complaints and sanctions for the last two years is publicly available

| 5.07.07 | Comments and References |

### 5.08 Clinical trials
**Core Questions** *(click here for help)*

<table>
<thead>
<tr>
<th>5.08.01</th>
<th>Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes [ ] No [X]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5.08.02</th>
<th>Legal provisions exist requiring the agreement by an ethics committee/institutional review board of the Clinical Trials to be performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes [ ] No [X]</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5.08.03</th>
<th>Legal provisions exist requiring registration of the clinical trials into</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes [ ] No [X]</td>
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</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
### Supplementary questions (click here for help)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.08.04 Comments and References</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>5.08.05S</strong> Legal provisions exist for GMP compliance of investigational products</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH/MRA</td>
</tr>
<tr>
<td><strong>5.08.06S</strong> Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH/MRA</td>
</tr>
<tr>
<td><strong>5.08.07S</strong> National GCP regulations are published by the Government</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH/MRA</td>
</tr>
<tr>
<td><strong>5.08.08S</strong> Legal provisions permit inspection of facilities where clinical trials are performed</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH/MRA</td>
</tr>
<tr>
<td><strong>5.08.09S</strong> Comments and References</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 5.09 Controlled Medicines

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.09.01 The country has adopted the following conventions:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>5.09.01.01</strong> Single Convention on Narcotic Drugs, 1961</td>
<td>Yes</td>
<td>No</td>
<td>1964</td>
<td>International Narcotics Control Board, 2010</td>
</tr>
<tr>
<td><strong>5.09.01.02</strong> The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961</td>
<td>Yes</td>
<td>No</td>
<td>1979</td>
<td>International Narcotics Control Board, 2010</td>
</tr>
<tr>
<td><strong>5.09.01.03</strong> Convention on Psychotropic</td>
<td>Yes</td>
<td>No</td>
<td>1971</td>
<td>International Narcotics Control Board, 2010</td>
</tr>
<tr>
<td>Substances</td>
<td>1971</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>------</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 5.09.01.04

**United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988**

- Yes [ ] No [ ]
- Year: 1989
- Source: International Narcotics Control Board, 2010

### 5.09.02

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

- Yes [ ] No [ ]
- Year: 2007
- Source: Dangerous Drug Act Chapter 11:25

### 5.09.03

**Annual consumption of Morphine (mg/capita)**

- 1.298575
- Year: 2009
- Source: International Narcotics Control Board, 2010

### 5.09.04

**Comments and References**

- International Narcotics Control Board is accessible via [http://incb.org/](http://incb.org/)

### Supplementary questions (click here for help)

<table>
<thead>
<tr>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOH/MRA</td>
</tr>
</tbody>
</table>

---

**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 [ ]
- Year: 2011
- Source: MOH/MRA

**5.09.06S**

- **Annual consumption of Fentanyl (mg/capita)**

- 0.000555
- Year: 2009
- Source: International Narcotics Control Board, 2010

**5.09.07S**

- **Annual consumption of Pethidine**

- 7.366092
- Year: 2009
- Source: International Narcotics Control Board, 2010

---

Pharmaceutical Sector Country Profile Questionnaire.
### 5.09.08S
**Annual consumption of Oxycodone (mg/capita)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>International Narcotics Control Board, 2010</td>
<td>0</td>
</tr>
</tbody>
</table>

Oxycodone is not used in Trinidad and Tobago.

### 5.09.09S
**Annual consumption of Hydrocodone (mg/capita)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>International Narcotics Control Board, 2010</td>
<td>0</td>
</tr>
</tbody>
</table>

Hydroxycodone is used as a laboratory control and for forensic analysis.

### 5.09.10S
**Annual consumption of Phenobarbital (mg/capita)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>International Narcotics Control Board, 2010</td>
<td>—</td>
</tr>
</tbody>
</table>

### 5.09.11S
**Annual consumption of Methadone (mg/capita)**

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>International Narcotics Control Board, 2010</td>
<td>0</td>
</tr>
</tbody>
</table>

Methadone is not used in Trinidad and Tobago.

### 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](#))

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>MOH/MRA</td>
<td>Yes ☑ No ☐</td>
</tr>
</tbody>
</table>

There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate.
| 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 | | | |

Pharmaceutical Sector Country Profile Questionnaire.
| 5.10.10 | Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication? | Yes □ No ☒ | 2011 | 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)**

<p>| 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? | |</p>
<table>
<thead>
<tr>
<th>5.10.20.01S</th>
<th>Doctors</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.10.20.02S</td>
<td>Nurses</td>
<td>Yes</td>
</tr>
<tr>
<td>5.10.20.03S</td>
<td>Pharmacists</td>
<td>Yes</td>
</tr>
<tr>
<td>5.10.20.04S</td>
<td>Consumers</td>
<td>Yes</td>
</tr>
<tr>
<td>5.10.20.05S</td>
<td>Pharmaceutical Companies</td>
<td>Yes</td>
</tr>
<tr>
<td>5.10.20.06S</td>
<td>Others, please specify whom</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5.10.21S</th>
<th>Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?</th>
<th>Yes ☐ No ☐</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>5.10.22S</th>
<th>Are there training courses in pharmacovigilance?</th>
<th>Yes ☐ No ☒</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>5.10.22.01S</th>
<th>If yes, how many people have been trained in the last two years?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.10.23S</td>
<td>Comments and References</td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
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 section

---

6.01 Medicines Coverage and Exemptions

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.01.01</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>6.01.01.01</td>
<td>Patients who cannot afford them</td>
<td>Yes ☒ No ☐</td>
</tr>
<tr>
<td>6.01.01.02</td>
<td>Children under 5</td>
<td>Yes ☒ No ☐</td>
</tr>
<tr>
<td>6.01.01.03</td>
<td>Pregnant women</td>
<td>Yes ☒ No ☐</td>
</tr>
<tr>
<td>6.01.01.04</td>
<td>Elderly persons</td>
<td>Yes ☒ No ☐</td>
</tr>
<tr>
<td>6.01.01.05</td>
<td>Please describe/explain your yes answers for questions above</td>
<td>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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.01.02</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>6.01.02.01</td>
<td>All medicines included in the EML</td>
<td>Yes ☒ No ☐</td>
</tr>
<tr>
<td>6.01.02.02</td>
<td>Any non-communicable diseases</td>
<td>Yes ☒ No ☐</td>
</tr>
<tr>
<td>6.01.02.03</td>
<td>Malaria medicines</td>
<td>Yes ☒ No ☐</td>
</tr>
<tr>
<td>6.01.02.04</td>
<td>Tuberculosis medicines</td>
<td>Yes ☒ No ☐</td>
</tr>
<tr>
<td>Question</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-----</td>
<td>----</td>
</tr>
<tr>
<td>6.02.01.05 Sexually transmitted diseases medicines</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.02.01.06 HIV/AIDS medicines</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.02.01.07 Expanded Program on Immunization (EPI) vaccines</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.02.01.08 If others, please specify</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.02.01.09 Please describe/explain your yes answers for questions above</td>
<td>All disease states are treated free of charge in the Public Health Sector.</td>
<td></td>
</tr>
<tr>
<td>6.02.01.10 Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.02.01.11 Does it provide coverage for medicines that are on the EML for inpatients</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.02.01.12 Does it provide coverage for medicines that are on the EML for outpatients</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.02.01.13 Please describe the medicines benefit of public/social insurance schemes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.02.01.14 Do private health insurance schemes provide any medicines coverage?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.02.01.15 If yes, is it required to provide coverage for medicines that are on the EML?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>6.02.01.16 Comments and References</td>
<td>6.02.01.01. Coverage is linked to the plan subscribed to.</td>
<td></td>
</tr>
</tbody>
</table>

**6.02 Patients Fees and Copayments**

**Core Questions (click here for help)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.02.01 In your health system, at the point of delivery, are there any co-payment/fee requirements for</td>
<td>Yes</td>
<td>No</td>
<td>2011 MOH</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
**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

**6.02.04** 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 treatments 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]

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>MOH</td>
</tr>
</tbody>
</table>

**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

Pharmaceutical Sector Country Profile Questionnaire.

53
| 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 |
| 6.04.01-04 | 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

<table>
<thead>
<tr>
<th>Availability (one or both of)</th>
<th>Mean (%)</th>
<th>Orig</th>
<th>Public procurement</th>
<th>Public patient</th>
<th>Private patient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>6.04.01.01</td>
<td>6.04.01.03</td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
## 6.05 Price Components and Affordability

### Core Questions (click here for help)

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

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.05.03</td>
<td>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)</td>
</tr>
<tr>
<td>6.05.04</td>
<td>Comment and References</td>
</tr>
</tbody>
</table>

**6.05.01** This survey is under development.

**Supplementary questions (click here for help)**

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.05.05S</td>
<td>Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the public sector (Median % contribution)</td>
</tr>
<tr>
<td>6.05.06S</td>
<td>Median percentage contribution of MSP/CIF to final medicine price for a basket of key medicines in the private sector (Median % contribution)</td>
</tr>
<tr>
<td>6.05.07S</td>
<td>Median manufacturer selling price (CIF) as percent of final medicine price for a basket of key medicines (%)</td>
</tr>
<tr>
<td>6.05.08S</td>
<td>Median wholesaler selling price as percent of final medicine price for a basket of key medicines (%)</td>
</tr>
<tr>
<td>6.05.09S</td>
<td>Median pharmacist mark-up or dispensing fee as percent of retail price for a basket of key medicines (%)</td>
</tr>
<tr>
<td>6.05.10S</td>
<td>Median percentage contribution of the wholesale mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)</td>
</tr>
<tr>
<td>6.05.11S</td>
<td>Median percentage contribution of the retail mark-up to final medicine price for a basket of key medicines (in the public and private sectors) (%)</td>
</tr>
<tr>
<td>6.05.12S</td>
<td>Comment and References</td>
</tr>
</tbody>
</table>
## 6.06 Duties and Taxes on Pharmaceuticals (Market)

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

<table>
<thead>
<tr>
<th>Core Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are <strong>duties</strong> on imported active pharmaceutical ingredients (APIs)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are duties on imported <strong>finished products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>VAT</strong> (value-added tax) or any other tax is levied on finished pharmaceuticals products</td>
<td></td>
<td></td>
</tr>
<tr>
<td>There are provisions for tax exceptions or waivers for pharmaceuticals and health products</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Supplementary Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duty on imported active pharmaceutical ingredients, APIs (%)</td>
<td>15</td>
<td>MOH</td>
</tr>
<tr>
<td>Duty on imported finished products (%)</td>
<td>15</td>
<td>MOH</td>
</tr>
<tr>
<td><strong>VAT</strong> on pharmaceutical products (%)</td>
<td>0</td>
<td>MOH</td>
</tr>
</tbody>
</table>

If the importer declares the items as supplements, he has to pay VAT, if 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.
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)

<table>
<thead>
<tr>
<th>Question</th>
<th>Date</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.01.01.01 Decentralized</td>
<td>Yes</td>
<td>2009 CARICOM IP HERA REPORT Volume II</td>
</tr>
<tr>
<td>7.01.01.02 Centralized and decentralized</td>
<td>Yes</td>
<td>2009 CARICOM IP HERA Report Volume II</td>
</tr>
<tr>
<td>7.01.01.03 Please describe Procurement of pharmaceutical supplies for the public sector is centralized</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.01.02.01 Part of MoH</td>
<td>Yes</td>
<td>2009 CARICOM IP HERA REPORT Volume II</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
| 7.01.02.02 | Semi-Autonomous | Yes ☒ No ☐ |
| 7.01.02.03 | Autonomous | Yes ☐ No ☒ |
| 7.01.02.04 | A government procurement agency which procures all public goods | Yes ☐ No ☒ |
| 7.01.03 | Public sector requests for tender documents are publicly available | Yes ☒ No ☐ |
| 7.01.04 | Public sector tender awards are publicly available | Yes ☒ No ☐ |
| 7.01.05 | Procurement is based on prequalification of suppliers | Yes ☒ No ☐ |
| 7.01.05.01 | If yes, please describe how it works | 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)

| 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 |

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Q</th>
<th>Question</th>
<th>Answer</th>
<th>Year</th>
<th>Authority</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.01.09S</td>
<td>The key functions of the procurement unit and those of the tender committee are clearly separated</td>
<td>Yes</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>7.01.10S</td>
<td>A process exists to ensure the quality of products procured</td>
<td>Yes</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>7.01.10.01S</td>
<td>If yes, the quality assurance process includes pre-qualification of products and suppliers</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.01.10.02S</td>
<td>If yes, explicit criteria and procedures exist for pre-qualification of suppliers</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.01.10.03S</td>
<td>If yes, a list of pre-qualified suppliers and products is publicly available</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.01.11S</td>
<td>List of samples tested during the procurement process and results of quality testing are available</td>
<td>Yes</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>7.01.12S</td>
<td>Which of the following tender methods are used in public sector procurement:</td>
<td></td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>7.01.12.01S</td>
<td>National competitive tenders</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.01.12.02S</td>
<td>International competitive tenders</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.01.12.03S</td>
<td>Direct purchasing</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.01.13S</td>
<td>Comments and References</td>
<td>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)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**7.02 Public Sector Distribution**

Pharmaceutical Sector Country Profile Questionnaire.
### Core Questions (click here for help)

<table>
<thead>
<tr>
<th>Core Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.02.01 The government supply system department has a Central Medical Store at National Level</td>
<td></td>
<td>NIPDEC 2011</td>
</tr>
<tr>
<td>7.02.02 Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)</td>
<td></td>
<td>MOH 2011</td>
</tr>
<tr>
<td>7.02.03 There are national guidelines on Good Distribution Practices (GDP)</td>
<td></td>
<td>MOH MRA 2011</td>
</tr>
<tr>
<td>7.02.04 There is a licensing authority that issues GDP licenses</td>
<td></td>
<td>MOH/MRA 2011</td>
</tr>
<tr>
<td>7.02.05 List of GDP certified warehouses in the public sector exists</td>
<td></td>
<td>MOH 2011</td>
</tr>
<tr>
<td>7.02.06 List of GDP certified distributors in the public sector exists</td>
<td></td>
<td>MOH 2011</td>
</tr>
<tr>
<td>7.02.07 Comments and References</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.02.01. National Central Medical Store: NIPDEC. Visit conducted in June 2011; interview with Nicholas George, Manager/Senior Pharmacist</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Supplementary questions (click here for help)

<table>
<thead>
<tr>
<th>Supplementary Question</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.02.08S Which of the following processes is in place at the Central Medical Store:</td>
<td></td>
<td>NIPDEC</td>
</tr>
<tr>
<td>7.02.08S.01S Forecasting of order quantities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.02.08S.02S Requisition/Stock orders</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Question ID</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.02.08.03S</td>
<td>Preparation of picking/packing slips</td>
</tr>
<tr>
<td>7.02.08.04S</td>
<td>Reports of stock on hand</td>
</tr>
<tr>
<td>7.02.08.05S</td>
<td>Reports of outstanding order lines</td>
</tr>
<tr>
<td>7.02.08.06S</td>
<td>Expiry dates management</td>
</tr>
<tr>
<td>7.02.08.07S</td>
<td>Batch tracking</td>
</tr>
<tr>
<td>7.02.08.08S</td>
<td>Reports of products out of stock</td>
</tr>
<tr>
<td>7.02.09S</td>
<td>Percentage % availability of key medicines at the Central Medical Store</td>
</tr>
<tr>
<td>7.02.10S</td>
<td>Average stock-out duration for a basket of medicines at the Central Medical Store, in days</td>
</tr>
<tr>
<td>7.02.11S</td>
<td>Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store</td>
</tr>
<tr>
<td>7.02.12S</td>
<td>The Public Central Medical Store is GDP certified by a licensing authority</td>
</tr>
<tr>
<td>7.02.13S</td>
<td>The Public Central Medical Store is ISO certified</td>
</tr>
<tr>
<td>7.02.14S</td>
<td>The second tier public warehouses are GDP certified by a licensing authority</td>
</tr>
<tr>
<td>7.02.15S</td>
<td>The second tier public warehouses are ISO certified</td>
</tr>
<tr>
<td>7.02.16S</td>
<td>Comments and References</td>
</tr>
</tbody>
</table>

### 7.03 Private Sector Distribution

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NIPDEC</td>
</tr>
</tbody>
</table>

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>7.03.01</th>
<th>Legal provisions exist for licensing wholesalers in the private sector</th>
<th>Yes ✗ No ☐</th>
<th>2009</th>
<th>CARICOM DRA HERA Report Volume II</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.03.02</td>
<td>Legal provisions exist for licensing distributors in the private sector</td>
<td>Yes ✗ No ☐</td>
<td>2009</td>
<td>CARICOM DRA HERA Report Volume II</td>
</tr>
<tr>
<td>7.03.03</td>
<td>List of GDP certified wholesalers in the private sector exists</td>
<td>Yes ☐ No ✗</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>7.03.04</td>
<td>List of GDP certified distributors in the private sector exists</td>
<td>Yes ☐ No ✗</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>7.03.05</td>
<td>Comments and References</td>
<td>7.03.01-02 HERA Assessment of Drug Regulatory Systems Vol2 2009 (attached)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Section 8 Selection and rational use

#### 8.00 Respondent Information Section 7

<table>
<thead>
<tr>
<th>Section 8.00.01</th>
<th>Name of person responsible for filling out this section of the instrument</th>
<th>Junia Walcott</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 8.00.02</td>
<td>Phone number</td>
<td>627-0046</td>
</tr>
<tr>
<td>Section 8.00.03</td>
<td>Email address</td>
<td><a href="mailto:junia.walcott@health.gov.tt">junia.walcott@health.gov.tt</a></td>
</tr>
<tr>
<td>Section 8.00.04</td>
<td>Other respondents for filling out this section</td>
<td>Rian Extavour, Lecturer, School of Pharmacy</td>
</tr>
</tbody>
</table>

#### 8.01 National Structures

**Core Questions** ([Click here for help](#))

<table>
<thead>
<tr>
<th>Section 8.01.01</th>
<th>National essential medicines list (EML) exists. If yes, please write year of last update of EML in the &quot;year&quot; field</th>
<th>Yes ☒ No ☐</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 8.01.01.01</td>
<td>If yes, number of medicines on the EML (no. of INN)</td>
<td></td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>Section 8.01.01.02</td>
<td>If yes, there is a written process for selecting medicines on the EML</td>
<td>Yes ☒ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Section 8.01.01.03</td>
<td>If yes, the EML is publicly available</td>
<td>Yes ☒ No ☐</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Section 8.01.01.04</td>
<td>If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG)</td>
<td>Yes ☒ No ☐</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Section 8.01.02</th>
<th>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 &quot;year&quot; field</th>
<th>Yes ☐ No ☐</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 8.01.03</td>
<td>STGs specific to Primary care exist. Please use the &quot;year&quot; field to</td>
<td>Yes ☐ No ☐</td>
</tr>
</tbody>
</table>

---

Pharmaceutical Sector Country Profile Questionnaire.
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Yes</th>
<th>No</th>
<th>Year</th>
<th>Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.01.04</td>
<td>STGs specific to Secondary care (hospitals) exists. Please use the &quot;year&quot; field to write the year of last update of secondary care STGs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.05</td>
<td>STGs specific to Paediatric conditions exist. Please use the &quot;year&quot; field to write the year of last update of paediatric condition STGs</td>
<td>Y</td>
<td>N</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.06</td>
<td>% of public health facilities with copy of EML (mean)- Survey data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.07</td>
<td>% of public health facilities with copy of STGs (mean)- Survey data</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.08</td>
<td>A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.09</td>
<td>Public education campaigns on <a href="https://www.who.int/rationaluse">rational medicine use</a> topics have been conducted in the previous two years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.10</td>
<td>A survey on rational medicine use has been conducted in the previous two years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.11</td>
<td>A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.12</td>
<td>A written National strategy exists to contain <a href="https://www.who.int/rationaluse">antimicrobial resistance</a>. If yes, please write year of last update of the strategy in the &quot;year&quot; field</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8.01.13 Comments and References


8.01.06. Every Health Centre is supposed to have a copy of the EML

### Supplementary questions (click here for help)

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.01.14S The Essential Medicines List (EML) includes formulations specific for children</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>8.01.15S There are explicitly documented criteria for the selection of medicines in the EML</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>8.01.16S There is a formal committee or other equivalent structure for the selection of products on the National EML</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>8.01.16.01S If yes, conflict of interest declarations are required from members of national EML committee</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.01.17S National medicines formulary exists</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>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?</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>8.01.19S A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>8.01.20S Comments and References</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8.02 Prescribing

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

Pharmaceutical Sector Country Profile Questionnaire.
that includes pharmaceutical issues is required for **nurses**.

<table>
<thead>
<tr>
<th>Question ID</th>
<th>Question Description</th>
<th>Yes</th>
<th>No</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.02.11</td>
<td>Mandatory continuing education that includes pharmaceutical issues is required for paramedical staff</td>
<td>Yes</td>
<td>No</td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>8.02.12</td>
<td>Prescribing by <strong>INN</strong> name is obligatory in:</td>
<td></td>
<td></td>
<td>2011</td>
<td>MOH</td>
</tr>
<tr>
<td>8.02.12.01</td>
<td>Public sector</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.02.12.02</td>
<td>Private sector</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.02.13</td>
<td>Average number of medicines prescribed per patient contact in public health facilities (mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.02.14</td>
<td>% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.02.15</td>
<td>% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.02.16</td>
<td>% of patients in outpatient public health care facilities receiving antibiotics (mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.02.17</td>
<td>% of patients in outpatient public health care facilities receiving injections (mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.02.18</td>
<td>% of prescribed drugs dispensed to patients (mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.02.19</td>
<td>% of medicines adequately labelled in public health facilities (mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.02.20</td>
<td>Comments and References</td>
<td></td>
<td></td>
<td></td>
<td>8.02.02 Food and Drugs Act 1965 (attached) 8.02.13 to 8.02.20 Level II Survey of Health Facilities is incomplete.</td>
</tr>
</tbody>
</table>

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

---

Pharmaceutical Sector Country Profile Questionnaire.
### 8.02.21S
A professional association code of conduct exists governing professional behaviour of doctors
- Yes □ No □
- Year: 1990
- Source: 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](#))

#### 8.03.01
Legal provisions exist to govern dispensing practices of pharmaceutical personnel
- Yes □ No □
- Year: 1960
- Source: 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:

<table>
<thead>
<tr>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>School of Pharmacy, UWI</td>
</tr>
</tbody>
</table>

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 □
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
<th>Year</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.03.03 Mandatory continuing education that includes rational use of medicines is required for pharmacists</td>
<td>Yes [ ] No [x]</td>
<td>2007</td>
<td>WHO level I</td>
</tr>
<tr>
<td>8.03.04 <strong>Generic substitution</strong> at the point of dispensing in public sector facilities is allowed</td>
<td>Yes [ ] No [ ]</td>
<td>2007</td>
<td>WHO level I</td>
</tr>
<tr>
<td>8.03.05 <strong>Generic substitution</strong> at the point of dispensing in private sector facilities is allowed</td>
<td>Yes [ ] No [ ]</td>
<td>2007</td>
<td>WHO level I</td>
</tr>
<tr>
<td>8.03.06 In practice, (even though this may be contrary to regulations) are antibiotics sometimes <strong>sold over-the-counter</strong> without any prescription?</td>
<td>Yes [ ] No [ ] Unknown [ ]</td>
<td>2007</td>
<td>WHO Level 1</td>
</tr>
<tr>
<td>8.03.07 In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription?</td>
<td>Yes [ ] No [ ] Unknown [ ]</td>
<td>2007</td>
<td>WHO Level 1</td>
</tr>
<tr>
<td>8.03.08 Comments and References</td>
<td>8.03.01 Ministry of Legal Affairs. Food and Drugs Act 1960</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>8.03.02 School of Pharmacy. The University of the West Indies.</td>
<td></td>
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<tr>
<td></td>
<td>8.03.02.01-04: Components are incorporated in various Pharmacy Practice and Pharmacy Administration courses.</td>
<td></td>
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<tr>
<td></td>
<td>8.03.03 Continuing pharmacy education is not mandatory in T&amp;T.</td>
<td></td>
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<tr>
<td></td>
<td>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.</td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer Options</th>
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</tr>
</thead>
<tbody>
<tr>
<td>8.03.09S A professional association <strong>code of conduct</strong> exists governing professional behaviour of pharmacists</td>
<td>Yes [ ] No [ ]</td>
<td>2011</td>
<td>Pharmacy Board of TRT</td>
</tr>
<tr>
<td>8.03.10S In practice, (even though this may be contrary to regulations) are <strong>sold over-the-counter</strong> without any prescription?</td>
<td>Yes [ ] No [ ]</td>
<td>2007</td>
<td>WHO level I and MOH</td>
</tr>
</tbody>
</table>
be contrary to regulations) do the following groups of staff *sometimes* prescribe *prescription-only medicines* at the primary care level in the public sector?

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

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>9.00.01</td>
<td>Name of person responsible for filling out this section of the instrument</td>
</tr>
<tr>
<td>9.00.02</td>
<td>Phone number</td>
</tr>
<tr>
<td>9.00.03</td>
<td>Email address</td>
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<tr>
<td>9.00.04</td>
<td>Other respondents for filling out this section</td>
</tr>
</tbody>
</table>

#### 9.01 Data from Household Surveys

<table>
<thead>
<tr>
<th>Core Questions (<a href="#">click here for help</a>)</th>
<th>Year</th>
<th>Source</th>
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<tbody>
<tr>
<td>9.01.01 What household surveys have been undertaken in the past 5 years to assess access to medicines?</td>
<td></td>
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<tr>
<td>9.01.02 Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)</td>
<td></td>
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<tr>
<td>9.01.03 Adults with acute conditions not taking all medicines because they cannot afford them (%)</td>
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<tr>
<td>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 (%)</td>
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<tr>
<td>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 (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td></td>
</tr>
<tr>
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<td>-----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>9.01.06</td>
<td>Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)</td>
<td></td>
</tr>
<tr>
<td>9.01.07</td>
<td>Adults (from poor households) with chronic conditions not taking all medicines because they cannot afford them (%)</td>
<td></td>
</tr>
<tr>
<td>9.01.08</td>
<td>Adults (from poor households) with chronic conditions who usually take all medicines prescribed by an authorized prescriber (%)</td>
<td></td>
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<tr>
<td>9.01.09</td>
<td>Children (from poor households) with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)</td>
<td></td>
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<tr>
<td>9.01.10</td>
<td>Percentage of people who obtained the medicines prescribed in the 15 days before the interview (%)</td>
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<tr>
<td>9.01.11</td>
<td>People who obtained prescribed medicines for free in the 15 days before the interview (%)</td>
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<tr>
<td>9.01.12</td>
<td>Comments and References</td>
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</tr>
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**Supplementary questions** ([click here for help](#))

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<tr>
<td>9.01.13S</td>
<td>Adults with acute conditions not taking all medicines because the medicines were not available (%)</td>
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<tr>
<td>9.01.14S</td>
<td>Adults with chronic conditions not taking all medicines because they cannot afford them (%)</td>
</tr>
<tr>
<td>9.01.15S</td>
<td>Adults with chronic conditions not taking all medicines because the medicines were not available (%)</td>
</tr>
<tr>
<td>9.01.16S</td>
<td>Children with acute conditions taking all medicines prescribed by</td>
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<td>9.01.17S</td>
<td>Children with acute conditions not taking all medicines because they cannot afford them (%)</td>
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<tr>
<td>9.01.18S</td>
<td>Children with acute conditions not taking all medicines because the medicines were not available (%)</td>
</tr>
<tr>
<td>9.01.19S</td>
<td>Children (from poor households) with acute conditions not taking all medicines because they cannot afford them (%)</td>
</tr>
<tr>
<td>9.01.20S</td>
<td>Comments and References</td>
</tr>
</tbody>
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