SAINT KITTS AND NEVIS

PHARMACEUTICAL COUNTRY PROFILE

FEDERATION OF SAINT KITTS AND NEVIS

Pharmaceutical Country Profile

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Foreword

The 2012 Pharmaceutical Country Profile for St. Kitts and Nevis 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 St. Kitts and Nevis. The compiled data comes from international sources (e.g. the World Health Statistics), surveys conducted in the previous years and country level information collected in 2011. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

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

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Beverly Harris *(Director of Statistics and Economic Planning)*

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

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Acronyms and abbreviations

ADR	Adverse Drug Reaction
API	Active Pharmaceutical Ingredient
CARICOM	Caribbean Community
CCH3	Caribbean Cooperation in Health Phase 3
CMS	Central Medical Store
COHSOD	CARICOM Council for Social and Human Development
CPC	Caribbean Program Coordination
DTC	Drug and Therapeutics Committee
EC$	East Caribbean dollar
ECC	Eastern Caribbean Countries
ECDS	Eastern Caribbean Drug Service
EML	Essential Medicines List
EPI	Expanded Program on Immunization
FIOCRUZ	Oswaldo Cruz Foundation
GCP	Good Clinical Practices
GDP	Good Distribution Practices
GGHE	General Government Health Expenditure
GMP	Good Manufacturing Practices
GPP	Good Pharmacy Practices
HAI	Health Action International
HERA	Health Research for Action
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
HQ	Headquarter
INCB	International Narcotics Control Board
INN	International Nonproprietary Name
IPO	Intellectual Property Office
IPR	Intellectual Property Rights
ISO	International Organization for Standardization
ME	Medication Errors
MRA	Medicines Regulatory Authority
NHA	National Health Account
NHP	National Health Policy
NMP	National Medicines Policy
OECS	Organisation of Eastern Caribbean States
ORS	Oral Rehydration Solution
PAHO	Pan American Health Organization
PPS	Pharmaceutical Procurement Service (OECS)
RUM	Rational Use of Medicines
STD	Sexually Transmitted Disease

STG	Standard Treatment Guidelines
TB	Tuberculosis
THE	Total Health Expenditure
TRIPS	Trade Related aspects of Intellectual Property Rights
US$	United States dollar
USAID	United States Agency for International Development
VAT	Value Added Tax
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 St. Kitts and Nevis. 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 eight sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Medicines Trade and Production (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical procurement and distribution, and (8) Selection and rational use. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). This narrative profile is based on data derived from both the core and supplementary indicators. The tables in the annexes also present all data collected for each of the indicators in the original survey form. For each piece of information, the year and source of the data are indicated; these have been used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links have been provided to the source documents so that users can easily access these documents.

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

Data collection in all 193 member states has been conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information. To facilitate the work of national counterparts, the questionnaires were pre-filled at WHO Headquarter (HQ) using all publicly-available data and before being sent out to each country by the WHO Regional Office (which, in this case, corresponds to the Pan American Health Organization). A coordinator was nominated for each of the member states. The coordinator for St. Kitts and Nevis was Erickson France, with support from Adriana Mitsue Ivama and the PAHO/WHO team.

The completed questionnaires were then used to generate individual country profiles. In order to do this in a structured and efficient manner, a text template was developed. Experts from member states took part in the development of the template 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 WHO web site.

This profile will be regularly updated by the Pan American Health Organization in partnership with the national counterparts. Comments, suggestions or corrections may be sent to:

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Section 1 - Health and Demographic Data

This section gives an overview of the demographics and health status of St. Kitts and Nevis.

1.1 Demographics and Socioeconomic Indicators

The total population of St. Kitts and Nevis in 2010 was 52,000[1] with an annual population growth rate of 1.3% (2008)[2]. The annual Gross Domestic Product (GDP) growth rate was -2.4% in 2010[3]. The GDP per capita was US$ 10,115 in the same year (exchange rate US$ 1 = EC$ 2.69).

In 2008, 27% of the population was under 15 years of age[2], and 12% was over 60 years of age[2]. The urban population stood at 32% of the total population[2]. The fertility rate was 1.8 births per woman[2]. 22% of the population was living below the nationally defined poverty line[4]. The adult literacy rate for the population over 15 years was 98%[4].

1.2 Mortality and Causes of Death

In 2010, the life expectancy at birth was 70 and 76 years for men and women respectively. The infant mortality rate was 18/1,000 live births in the same year[5]. For children under the age of 5, the mortality rate was 21/1,000 live births[5]. The maternal mortality was 152/100,000 live births[5].

The top five diseases causing mortality in St. Kitts and Nevis[6] are listed in Table 1.

Table 1. Top five diseases causing mortality in the country (2010)

	Disease
1	Cerebrovascular disease
2	Ischemic heart disease
3	Cancer
4	Diabetes mellitus
5	Homicide

The top five diseases causing morbidity in St. Kitts and Nevis[6] are listed in Table 2.

Table 2. Top five diseases causing morbidity in the country (2010)

	Disease
1	Respiratory tract infections / Asthma
2	Gastroenteritis
3	Hypertension
4	Diabetes Mellitus
5	Substance abuse disorders

The adult mortality rate for both sexes between 15 and 60 years was 138/1,000 population in 2008[2], and the neonatal mortality rate was 12.2/1,000 live births[5]. The age-standardized mortality rate by non-communicable diseases was 691/100,000 population [7] ; 424/100,000 by cardiovascular diseases[7]; and 108/100,000 by cancer[7].

The mortality rate for HIV/AIDS was 2/100,000 population[6]; and 0/100,000 for tuberculosis[2] and malaria[6].

Section 2 - Health Services

This section provides information regarding health expenditures and human resources for health in St. Kitts and Nevis. The contribution of the public and private sector to overall health expenditure is also presented.

2.1 Health Expenditures

In St. Kitts and Nevis, the total annual expenditure on health (THE) in 2010 was 98 million East Caribbean dollars (37 million dollars)[6]. The THE was 7% of the GDP. The THE per capita was EC$ 1,884.6 (US$ 711.5).

The general government[i] health expenditure (GGHE) in 2010 was 57 million East Caribbean dollars (21 million dollars)[6]. That is, 58.16% of the THE, with a total annual per capita GGHE of EC$ 1,096.15 (US$ 403.85). The GGHE represented 8.01% of the total government budget[8]. Private health expenditure covered the remaining 41.84% of the THE.

Social security expenditure made up 14% of the GGHE[8].

Private out-of-pocket expenditure represented 94.44% of the private health expenditure[8]. Premiums for private prepaid health plans represented the remaining 5.56%[8].

[i] According to the National Health Accounts (NHA) definition, by "government expenditure" it is meant all expenditure from public sources, like central government, local government, public insurance funds and parastatal companies.

2.2 Health Personnel and Infrastructure

The health workforce is described in Table 3 and in Figures 1 and 2. There are 20 licensed pharmacists[9], of which 9 work in the public sector[9]. There are 8 pharmaceutical technicians and assistants (in all sectors)[9].

There are 81 physicians[9] and 239 nursing and midwifery personnel[9] in St. Kitts and Nevis. The ratio of doctors to pharmacies is 10:1 and the ratio of doctors to nurses and midwifery personnel is 1:3.

Table 3. Human resources for health

Human Resource	
Licensed pharmacists (all sectors)	20 (3.8/10,000)
Pharmacists in the public sector	9 (1.7/10,000)
Pharmaceutical technicians and assistants (all sectors)	8 (1.5/10,000)
Physicians (all sectors)	81 (15.6/10,000)
Nursing and midwifery personnel (all sectors)	239 (45.9/10,000)

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

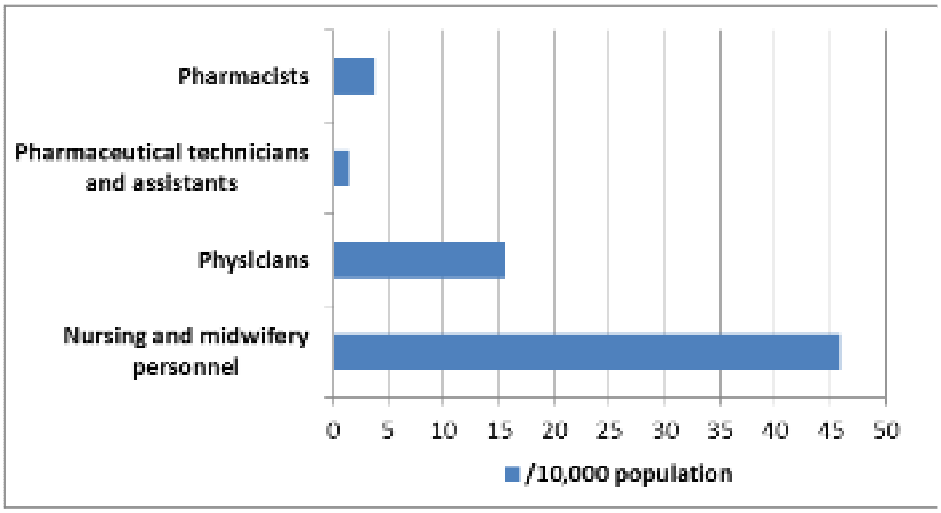
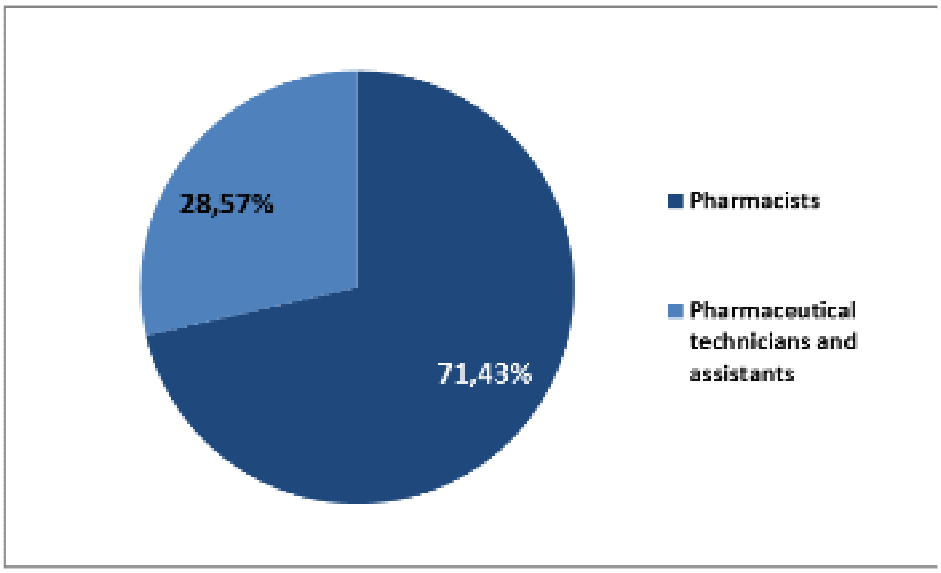


Figure 2. Distribution of pharmaceutical personnel



In St. Kitts and Nevis, there is no strategic plan for pharmaceutical human resource development in place[10].

The health infrastructure is described in Table 4. There are 2 hospitals[9] and 217 hospital beds[9] in total in St. Kitts and Nevis. There are 17[ii] primary health care units and centers[9] and 8[iii] licensed pharmacies[10].

Table 4. Health infrastructure statistics

Infrastructure	
Hospitals	2
Hospital beds	217 (5.2/1,000 population)
Primary health care units and centres	17
Licensed pharmacies	8

[ii] There are 11 Community Clinics in St. Kitts and 6 in Nevis.

[iii] In the public sector, pharmaceutical services are provided in 7 health centers / hospital pharmacies.

The annual starting salary for a newly registered pharmacist in the public sector is EC$ 48,780. Medical schools are 'offshore' campuses of American universities. One of these offers pharmacy training. However, pharmacists are usually trained in neighboring countries.

Section 3 - Policy Issues

This section addresses the main characteristics of the health / pharmaceutical policy in St. Kitts and Nevis.

3.1 Policy Framework

In St. Kitts and Nevis, a National Health Policy (NHP)[iv] from 1981 is currently being updated[9]. A draft National Medicines Policy (NMP) document[v] exists, but it is not officially adopted[9]. Policies addressing pharmaceuticals do not exist at present[9].

A policy relating to clinical laboratories does not exist[9]. Access to essential medicines/technologies as part of the fulfillment of the right to health, is not specified in the constitution or national legislation[9]. There are no official written guidelines on medicines donations[9].There is no national good governance policy in St. Kitts and Nevis[9].

A policy is not in place to manage / sanction conflict of interest issues in pharmaceutical affairs[9]. There is no code of conduct for public officials[9]. A whistle-blowing mechanism that allows individuals to raise concerns about wrongdoing occurring in the pharmaceutical sector of St. Kitts and Nevis, does not either exist[9].

[iv] The Caribbean Cooperation in Health Phase 3 (CCH3) is the health agenda for the Caribbean Community (CARICOM) countries approved by the Caucus of Ministers of Health in September 2009.

[v] The Caribbean Pharmaceutical Policy was approved by the CARICOM Council for Social and Human Development (COHSOD) in April 2011.

Section 4 – Medicines Trade and Production

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

4.1 Intellectual Property Laws and Medicines

St. Kitts and Nevis is a member of the World Trade Organization (WTO)[11]. Legal provisions granting patents on pharmaceuticals, laboratory supplies, medical supplies and medical equipment, do not exist[vi].

Intellectual Property Rights are managed and enforced by the Intellectual Property Office (IPO).

National Legislation has been modified to implement the Trade-Related aspects of Intellectual Property Rights (TRIPS) Agreement[12] and contains TRIPS-specific flexibilities and safeguards[12], presented in Table 5. St. Kitts and Nevis is not eligible for the transitional period to 2016[13].

[vi] According to the HERA report on Intellectual Property, the Patents Act (2000) was not being implemented. Regulations were still being prepared as of March 2009.

Table 5. TRIPS flexibilities and safeguards present in the national law

Flexibility and safeguards[vii]	Included
Compulsory licensing provisions that can be applied for reasons of public health	Yes [13]
Bolar exceptions[viii]	No [13]
Parallel importing provisions	No [13]

The country is engaged in capacity-strengthening initiatives to manage and apply Intellectual Property Rights (IPR) in order to contribute to innovation and promote public health[13]. There are no legal provisions for data exclusivity for pharmaceuticals[13], patent extension[13], or linkage between patent status and marketing authorization[10].

[vii] The current laws contain TRIPS flexibilities and safeguards to a very limited extent. The Patents Act excludes some subject matter from patentability, contains a de-minimis exception, an experimental use exception, permits national exhaustion, and optimally permits compulsory licensing. The Patents Act does not permit international exhaustion or parallel importation, does not contain an early working or regulatory review exception (bolar exception), does not require disclosure of source and origin of genetic resources, does not prohibit new uses and forms, and should consider a broader range of excluded subject matter from patentability.

[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. *Article 30*

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

4.2 Manufacturing

There are no licensed pharmaceutical manufacturers in St. Kitts and Nevis[10]. All the medicines need to be imported[10].

Section 5 – Medicines Regulation

This section details the pharmaceutical regulatory framework, resources, governing institutions and practices in St. Kitts and Nevis.

5.1 Regulatory Framework

In St. Kitts and Nevis, there are no legal provisions for Medicines Regulatory Authority (MRA)[10]. Nevertheless, some functions are performed by the Ministry of Health according to the provisions made in the Medical Act[14]. This Act has provisions for registration and inspections of professionals and premises. Funding for the mentioned activities is provided through the regular government budget[10].

The country is member of the Caribbean Community (CARICOM) and the Organisation of Eastern Caribbean States (OECS)[10].

In 2009, Health Research for Action (HERA) conducted the Regional Assessment of Drug Registration and Regulatory Systems in CARICOM Member States and the Dominican Republic[15].

5.2 Marketing Authorization (Registration)

In St. Kitts and Nevis, legal provisions do not require marketing authorization (registration) for pharmaceutical products on the market[10].

5.3 Regulatory Inspection

In St. Kitts and Nevis, legal provisions do not exist allowing for appointment of government pharmaceutical inspectors[10]. However, legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed[14]. Such inspections are not required by law, but are a pre-requisite for the licensing of public and private facilities[16]. Inspection requirements are the same for both categories of facilities[16].

5.4 Import Control

Legal provisions do not exist requiring authorization to import medicines[10]. Laws do not exist that allow the sampling of imported products for testing[10].

Legal provisions exist governing the importation of controlled medicines through authorized ports of entry[10]. However, regulations exist to allow for inspection of imported pharmaceutical products at the port of entry[17].

5.5 Licensing

In St. Kitts and Nevis, legal provisions do not exist requiring manufacturers to be licensed[10]. Good Manufacturing Practices (GMP) guidelines are not published by the government[10].

Legal provisions exist requiring importers, wholesalers, and distributors to be licensed[10]. Good Distribution Practices (GDP) are not published by the government[10].

Table 6. Legal provisions pertaining to licensing

Entity requiring licensing	
Importers	Yes
Wholesalers	Yes
Distributors	Yes

Legal provisions exist requiring pharmacists to be registered[14]. Legal provisions also exist requiring public and private pharmacies to be licensed[10]. National Good Pharmacy Practice (GPP) guidelines are not published by the government[10]. By law, a list of all licensed pharmaceutical facilities is not required to be published[10].

5.6 Market Control and Quality Control

In St. Kitts and Nevis, legal provisions do not exist for regulating the pharmaceutical market[10]. A laboratory does not exist in the country for Quality Control testing[10]. Quality monitoring in the public sector is conducted through the OECS / Pharmaceutical Procurement Service (PPS). When necessary medicines are sent for testing to Caribbean Regional Drug Test Laboratory (CRDTL).Medicines are tested for a number of reasons[10], summarized in Table 7.

Samples are not collected by government inspectors for undertaking post-marketing surveillance testing[10].

Table 7. Reason for medicines testing

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

5.7 Medicines Advertising and Promotion

In St. Kitts and Nevis, legal provisions or procedures do not exist to control the promotion and/or advertising of prescription medicines[18].

5.8 Clinical Trials

In St. Kitts and Nevis, legal provisions do not exist requiring authorization for conducting Clinical Trials[10]. There are no additional laws requiring the agreement by an ethics committee or institutional review board of the Clinical Trials to be performed[10]. Clinical Trials are not required to be entered into a registry, by law[10]. National Good Clinical Practices (GCP) are not published by the government[10]. The Ministry of Health, however, has a research policy which covers Clinical Trials.

[ix] Routine sampling in pharmacy stores and health facilities

[x] Routine sampling in retail outlets

5.9 Controlled Medicines

St. Kitts and Nevis is a signatory to a number of international conventions[19], detailed in Table 8.

Table 8. International conventions to which St. Kitts and Nevis is a signatory

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

Laws exist for the control of narcotic and psychotropic substances, and precursors[10].

In 1961, the legal provisions and regulations for the control of narcotic and psychotropic substances and precursors were reviewed by an international expert to assess the balance between the prevention of abuse an access for medical need[10].

Figures regarding the annual consumption of certain controlled substances[10] in the country are outlined in Table 9 below.

Table 9. Annual consumption of certain controlled substances

Controlled substance	Consumption (mg/capita)
Morphine	1.0000000
Fentanyl	0.0000605
Pethidine	10.1100000
Oxycodone	0.3110000
Phenobarbital	43.2640000

5.10 Pharmacovigilance

In St. Kitts and Nevis, there are no legal provisions that provide for pharmacovigilance activities[10], or for the monitoring of Adverse Drug Reactions (ADR)[10]. A national pharmacovigilance centre does not exist[10].

An official standardized form for reporting ADRs is used in the country. Information pertaining to ADRs is not stored in a national ADR database. The reports are not sent directly to the WHO collaborating centre in Uppsala[10]. The ADR notifications are sent to the OECS/PPS. Feedback is not provided to reporters[10]. Medication Errors (ME) are not reported[10]. Pharmacists and consumers have reported ADRs in the past two years[10].

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[10]. OECS/PPS performs the role of Pharmacovigilance Centre for the OECS countries. A clear communication strategy for routine communication and crises communication does not exist[10].

ADRs are not monitored in public health programs (example TB, HIV/AIDS)[10].

There are not training courses on pharmacovigilance[10].

A number of steps are being considered to enhance the pharmacovigilance system including:

I. Establishment of a team approach.
II. Design and implementation of strategies for data collection.
III. Production of procedures and guidelines.

Section 6 - Medicines Financing

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

6.1 Medicines Coverage and Exemptions

In St. Kitts and Nevis, concessions are made for certain groups to receive medicines free of charge[10] (see Table 10). Furthermore, due to the governmental policy regarding universal access, the public health system provides medicines free of charge for certain conditions[6] (see Table 11).

Table 10. Population groups provided with medicines free of charge

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

Table 11. Medications provided publicly, at no cost

Conditions	Covered
All diseases treated with medicines in the EML	Yes
Any non-communicable diseases	Yes
Malaria	Yes
Tuberculosis	Yes
Sexually transmitted diseases (STDs)	Yes
HIV/AIDS	Yes
Expanded Program on Immunization (EPI) vaccines for children	Yes
Other	No

The public health service provides coverage for medicines that are on the Essential Medicines List (EML) for inpatients and outpatients (via application for social assistance)[6].

Private health insurance schemes also provide medicines coverage[6], however, they are not required to provide coverage for medicines in the EML.

6.2 Patients Fees and Copayments

Co-payments or fee requirements for consultations are not levied at the point of delivery[10]. However, there are copayments imposed[xi] for medicines[10]. 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[10].

[xi] There is a service charge that goes into a consolidated fund with some exceptions.

6.3 Pricing Regulation for the Private Sector[xii]

In St. Kitts and Nevis, there are legal or regulatory provisions affecting pricing of medicines[10]. These provisions are aimed at the level of wholesalers and retailers.

The government does not run an active national medicines price monitoring system for retail prices[10]. Regulations do not exist mandating that retail medicine price information should be publicly accessible[6].

6.4 Prices, Availability and Affordability of Key Medicines

It is unknown if a WHO/Health Action International (HAI) pricing survey has been conducted in St. Kitts and Nevis[6].

6.5 Price Components and Affordability

It is unknown if a survey on medicine price components has been conducted in St. Kitts and Nevis[6].

6.6 Duties and Taxes on Pharmaceuticals (Market)

St. Kitts and Nevis imposes duties on imported active pharmaceutical ingredients (APIs) and on imported products[20]. Value-added tax (VAT) is imposed on

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

finished pharmaceutical products (17%)[10]. Provisions for duty exceptions for some pharmaceuticals are in place[20].

Section 7 - Pharmaceutical procurement and distribution

This section provides a short overview on the procurement and distribution of pharmaceuticals in St. Kitts and Nevis.

7.1 Public Sector Procurement

Public sector procurement in St. Kitts and Nevis is centralized[10]. The public sector procurement is centralized under the responsibility of a procurement unit which is a part of the Ministry of Health.

For pharmaceuticals, purchases are made through OECS/PPS[xiii]. The countries comprising the OECS have recognized that by improving the use of existing resources efficient procurement practices can be achieved. Of the four areas of drug supply management, which include selection, procurement, distribution and use, efficient procurement provides the greatest opportunity for cost-savings[21].

Public sector request for tender documents and awards are not publicly available[10]. Procurement is not based on the prequalification of suppliers[10]. A process to ensure the quality of the products procured does not exist[10].

There is no written public sector procurement policy[10].

[xiii] The OECS/PPS formerly the Eastern Caribbean Drug Service (ECDS), was established under a project funded by the United States Agency for International Development (USAID), and by 1989, the scheme was financially self-sufficient. The OECS/PPS is a self-financing public sector monopsony or buyers' cartel that covers its operating cost from a 15% surcharge. The OECS/PPS is an agency of the OECS, a formal grouping of nine eastern Caribbean Countries: Anguilla, Antigua and Barbuda, British Virgin Islands, Dominica, Grenada, Montserrat, St Kitts and Nevis, St Lucia and St Vincent and the Grenadines, with a combined population of approximately 550,000.

7.2 Public Sector Distribution

The government supply system department in St. Kitts and Nevis has a Central Medical Store (CMS) at National Level and a warehouse in the secondary tier of public sector distribution[10]. There are no national guidelines on Good Distribution Practices (GDP). A licensing authority that issues GDP licenses does not exist.

A number of processes[xiv] are in place at the CMS[10] as detailed in Table 12.

Table 12. Processes in place at the Central Medical Store

Process	
Forecasting of order quantities	No
Requisition / Stock orders	Yes
Preparation of picking / packing slips	Yes
Reports of stock on hand	No
Reports of outstanding order lines	No
Expiry dates management	Yes
Batch tracking	No
Reports of products out of stock	No

The percentage availability of key medicines at the CMS is 75%[21].

The CMS and the second tier warehouse are not certified by the International Organization for Standardization (ISO)[10].

[xiv] Plans are in place for the processes which are not yet in effect at the CMS.

7.3 Private Sector Distribution

Legal provisions do not exist for licensing wholesalers or distributors[10] in the private sector of St. Kitts and Nevis.

Section 8 - Selection and rational use of medicines

This section outlines the structures and policies governing the selection of essential medicines and promotion of rational use of medicines (RUM) in St. Kitts and Nevis.

8.1 National Structures

The OECS/PPS Essential Medicines List (EML) is used as a reference in the public sector[10]. This EML was lastly updated in 2011. There are currently 630 medicines on the list, and contains specific formulations for children[10]. A national medicines formulary also exists[10].

National Standard Treatment Guidelines (STGs) for the most common illnesses are produced / endorsed by the Ministry of Health[15]. Specific STGs cover primary and secondary care[18].

There is no public or independently funded national medicines information centre[10]. Public education campaigns on RUM topics have not been conducted in the last two years[10]. A survey on RUM has not either been conducted in the same period[10]. There is no national programme or committee, involving government, civil society, or professional bodies, to monitor and promote RUM[10].

A written National Strategy for containing antimicrobial resistance does not exist[10]. There is no national intersectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection[10]. There is, however, a national institution in charge of the coordination of epidemiological surveillance of antimicrobial resistance[18].

8.2 Prescribing

Legal provisions exist to govern the licensing and prescribing practices of prescribers[10]. Legal provisions restricting dispensing by prescribers do not exist[10]. Prescribers in the private sector dispense medicines[10].

There no regulations requiring hospitals to organize / develop Drug and Therapeutics Committees (DTCs)[18].

The training curriculum for doctors includes components on EML and STGs. Mandatory continuing education that includes pharmaceutical issues is required for doctors and paramedical staff[18].

Prescribing by International Nonproprietary Name (INN) name is not obligatory[18].

The average number of medicines prescribed per patient contact in public health facilities is 3.5[22]. Of the medicines prescribed in the outpatient public health care facilities, 92% (mean) are on the EML[22] and 80% (mean) are prescribed by INN name[22]. Of the patients treated in the outpatient public health care facilities, 20% (mean) receives antibiotics[22] and 1% (mean) receive injections[22]. Of prescribed drugs, 97% (mean) are dispensed to patients[22]. Of medicines in public health facilities, 98% (mean) are adequately labeled[10].

A professional association code of conduct which governs the professional behavior of nurses exists.

100% of diarrheas in children were treated with Oral Rehydration Solution (ORS) in 2010[10].

8.3 Dispensing

Legal provisions in St. Kitts and Nevis exist to govern dispensing practices of pharmaceutical personnel[14]. The basic pharmacist training curriculum includes a spectrum of components as outlined in Table 13.

Table 13. Core aspects of the pharmacist training curriculum

Curriculum	Covered
Concept of EML	No
Use of STGs	No
Drug information	Yes
Clinical pharmacology	Yes
Medicines supply management	No

Mandatory continuing education that includes RUM is not required for pharmacists[18].

Generic substitution at the point of dispensing is allowed in public and private facilities[18]. Antibiotics and injectable medicines are not sold over-the-counter without a prescription[18].

A professional association code of conduct governing the professional behavior of pharmacists does not exist[10].

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FEDERATION OF SAINT KITTS AND NEVIS

Pharmaceutical Country Profile

ANNEX

Survey Data

(Fragment of the questionnaire)

2011

Section 0 General Info

0.01 Contact Info

0.01.01	Country (precoded)	Saint Kitts and Nevis
0.01.02	Name coordinator	Mr Erickson France
0.01.03	Address (Street, City)	J N France General Hospital; Buckley's Site; Basseterre
0.01.04	Phone number	(869) 465 2551 Ext 162
0.01.05	Email address	cms.skb@gmail.com
0.01.06	Web address	www.gov.kn
0.01.07	Institution	Ministry of Health, St Kitts and Nevis

Section 1 Health and Demographic data

1.00 Respondent Information Section 1

1.00.01	Name of person responsible for filling out Survey section 1	Dr Patrick Martin, Chief Medical Officer
1.00.02	Phone number	(869) 465 2521
1.00.03	Email address	skncmo@yahoo.com
1.00.04	Other respondents for filling out this section	

1.01 Demographic and Socioeconomic Indicators

Core questions (click here for help)

			Year	Source
1.01.01	Population, total (,000)	52	2010	Gov't statistics
1.01.02	Population growth rate (Annual %)	1.3	2008	WHS
1.01.03	Total Gross Domestic Product (GDP) (millions US$)	526	2010	World Bank Data
1.01.04	GDP growth (Annual %)	-2.4	2010	World Bank
1.01.05C	GDP per capita (US$ current exchange rate)	10684.9		
1.01.06	Comments and References	1.01.03. GDP Per Capita: US $10,028 (HIU) Exchange rate USD = 2.69989 ECD		

Supplementary questions (click here for help)

			Year	Source
1.01.07S	Population < 15 years (% of total population)	27	2008	WHS
1.01.08S	Population > 60 years (% of total population)	12	2008	WHS

1.01.09S	Urban population (% of total population)	32	2008	WHS
1.01.10S	Fertility rate, total (Births per woman)	1.8	2008	WHS
1.01.11S	Population living with less than $1.25/day (international PPP) (%)			
1.01.12S	Population living below nationally defined poverty line (%)	22%	2008	Country Poverty Assess.
1.01.13S	Income share held by lowest 20% of the population (% of national income)			
1.01.14S	Adult literacy rate, 15+ years (% of relevant population)	98%	2008	Country Poverty Assess.
1.01.15S	Comments and References			

1.02 Mortality and Causes of Death

Core questions (click here for help)

			Year	Source
1.02.01	Life expectancy at birth for men (Years)	70	2010	PAHO
1.02.02	Life expectancy at birth for women (Years)	76	2010	PAHO
1.02.03	Infant mortality rate, between birth and age 1 (/1,000 live births)	18	2010	
1.02.04	Under 5 mortality rate (/1,000 live births)	21	2010	Vital Statistics Registry, MoH
1.02.05	Maternal mortality ratio (/100,000 live births)	152	2010	

1.02.06	Please provide a list of top 10 diseases causing mortality		2010	Health Information Unit
1.02.06.01	Disease 1	Cerebrovascular disease		
1.02.06.02	Disease 2	Ischaemic heart disease		
1.02.06.03	Disease 3	Cancer		
1.02.06.04	Disease 4	Diabetes Mellitus		
1.02.06.05	Disease 5	Homicide		
1.02.06.06	Disease 6			
1.02.06.07	Disease 7			
1.02.06.08	Disease 8			
1.02.06.09	Disease 9			
1.02.06.10	Disease 10			
1.02.07	Please provide a list of top 10 diseases causing morbidity		2010	Health Information Unit
1.02.07.01	Disease 1	Respiratory Tract Infections including asthma		
1.02.07.02	Disease 2	Gastroenteritis		
1.02.07.03	Disease 3	Hypertension		
1.02.07.04	Disease 4	Diabetes Mellitus		
1.02.07.05	Disease 5	Substance Abuse Disorders		
1.02.07.06	Disease 6			
1.02.07.07	Disease 7			
1.02.07.08	Disease 8			
1.02.07.09	Disease 9			

1.02.07.10	Disease 10	
1.02.08	Comments and References	Absolute infant mortality: 12 / Absolute maternal mortality: 1

Supplementary questions (click here for help)

			Year	Source
1.02.09S	Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	138	2008	WHS
1.02.10S	Neonatal mortality rate (/1,000 live births)	12.2	2010	Vital Statistics Registry, MoH
1.02.11S	Age-standardized mortality rate by non-communicable diseases (/100,000 population)	691	2004	WHS
1.02.12S	Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	424	2009	WHS
1.02.13S	Age-standardized mortality rate by cancer (/100,000 population)	108	2009	WHS
1.02.14S	Mortality rate for HIV/AIDS (/100,000 population)	2	2010	Health Information Unit
1.02.15S	Mortality rate for tuberculosis (/100,000 population)	0	2008	WHS
1.02.16S	Mortality rate for Malaria (/100,000 population)	0	2010	Health Information Unit
1.02.17S	Comments and References			

Section 2 Health Services

2.00 Respondent Information Section 2

2.00.01	Name of person responsible for filling out this section of the instrument	Dr Patrick Martin, Chief Medical Officer
2.00.02	Phone number	(869) 465 2521
2.00.03	Email address	skncmo@yahoo.com
2.00.04	Other respondents for filling out this section	Mr Erickson France, Central Medical Stores; Mr Clifford Griffin, Policy and Development-Ministry of Health

2.01 Health Expenditures

Core questions (click here for help)

			Year	Source
2.01.01.01	Total annual expenditure on health (millions NCU)	98	2010	Health Information Unit est
2.01.01.02	Total annual expenditure on health (millions US$ average exchange rate)	37	2010	Health Information Unit
2.01.02C	Total health expenditure as % of Gross Domestic Product	6.12		
2.01.03.01C	Total annual expenditure on health per capita (NCU)	1,760.78		
2.01.03.02C	Total annual expenditure on health per capita (US$ average exchange rate)	652.14		
2.01.04.01	General government annual expenditure on health (millions NCU)	57	2010	Health Information Unit
2.01.04.02	General government annual expenditure on health (millions US$ average exchange rate)	21	2010	Health Information Unit

2.01.05	Government annual expenditure on health as percentage of total government budget (% of total government budget)	8.01	2008	NHA data
2.01.06C	Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	57.93	2008	NHA data
2.01.07.01C	Annual per capita government expenditure on health (NCU)	1,020.08		
2.01.07.02C	Annual per capita government expenditure on health (US$ average exchange rate)	377.81		
2.01.08C	Private health expenditure as % of total health expenditure (% of total expenditure on health)	42.09	2008	NHA data
2.01.09	Population covered by a public health service or public health insurance or social health insurance, or other sickness funds of total population)			
2.01.10	Population covered by private health insurance (% of total population)			
2.01.11.01	Total pharmaceutical expenditure (millions NCU)			
2.01.11.02	Total pharmaceutical expenditure (millions US$ current exchange rate)			
2.01.12.01C	Total pharmaceutical expenditure per capita (NCU)	PREFILL CALC		
2.01.12.02C	Total pharmaceutical expenditure per capita (US$ current exchange rate)	PREFILL CALC		
2.01.13C	Pharmaceutical expenditure as a % of GDP (% of GDP)	PREFILL CALC		
2.01.14C	Pharmaceutical expenditure as a %	PREFILL CALC		

	of Health Expenditure (% of total health expenditure)			
2.01.15.01	Total public expenditure on pharmaceuticals (millions NCU)			
2.01.15.02	Total public expenditure on pharmaceuticals (millions US$ current exchange rate)			
2.01.16C	Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	PREFILL CALC		
2.01.17.01C	Total public expenditure on pharmaceuticals per capita (NCU)	PREFILL CALC		
2.01.17.02C	Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	PREFILL CALC		
2.01.18.01	Total private expenditure on pharmaceuticals (millions NCU)			
2.01.18.02	Total private expenditure on pharmaceuticals (millions US$ current exchange rate)			
2.01.19	Comments and References	2.01.01.02.C = 7.01 2.01.01.03.C= 1884.62 2.01.03.02C = 711.54 2.01.06C = 58.16% 2.01.07.01C = 1096.15 2.01.07.02C = 403.85 2.01.08C = 41.84%		

Supplementary questions (click for help)

			Year	Source
2.01.20S	Social security expenditure as % of government expenditure on health (%	14	2010	NHA data

	of government expenditure on health)			
2.01.21S	Market share of generic pharmaceuticals [branded and INN] by value (%)			
2.01.22S	Annual growth rate of total pharmaceuticals market value (%)			
2.01.23S	Annual growth rate of generic pharmaceuticals market value (%)			
2.01.24S	Private out-of-pocket expenditure as % of private health expenditure (% of private expenditure on health)	94.44	2008	NHA data
2.01.25S	Premiums for private prepaid health plans as % of total private health expenditure (% of private expenditure on health)	5.56	2008	NHA data
2.01.26S	Comments and References			

2.02 Health Personnel and Infrastructure

Core questions (click for help)

			Year	Source
2.02.01	Total number of pharmacists licensed/registered to practice in your country	20	2010	Policy Development, MoH
2.02.02C	Pharmacists per 10,000 population	3.3		
2.02.03	Total number of pharmacists working in the public sector	9	2010	Policy Development, MOH
2.02.04	Total number of pharmaceutical technicians and assistants	8	2010	Policy Development, MOH

2.02.05	A strategic plan for pharmaceutical human resource development is in place in your country?	Yes ☐ No ☒	2010	CMS
2.02.06	Total number of physicians	81	2010	Policy Development, MOH
2.02.07C	Physicians per 10,000 pop	43.3		
2.02.08	Total number of nursing and midwifery personnel	239	2011	Policy development, MoH
2.02.09C	Nurses and midwives per 10,000 pop	38.8		
2.02.10	Total number of hospitals	2	2011	Policy Development, MOH
2.02.11	Total number of hospitals bed	217	2011	Policy Development, MoH
2.02.12	Total number of primary health care units and centers	17	2011	Policy Development, MoH
2.02.13	Total number of licensed pharmacies	8	2011	CMS
2.02.14	Comments and References	2.02.02C = 3.85 2.02.07C = 15.58 2.02.08C = 45.96 2.02.12 There are 11 Community Clinics in St Kitts and 6 in Nevis. 2.02.13 In the public sector pharmaceutical services are provided in 7 health centers / hospital pharmacies.		

Supplementary questions (click here for help)

			Year	Source
2.02.15S	Starting annual salary for a newly registered pharmacist	48,780	2010	National estimates

	in the public sector (NCU)			
2.02.16S	Total number of pharmacists who graduated (first degree) in the past 2 years in your country			
2.02.17S	Are there accreditation requirements for pharmacy schools?	Yes ☐ No☐		
2.02.18S	Is the Pharmacy Curriculum regularly reviewed?	Yes ☐ No ☐		
2.02.19S	Comments and References	Medical schools are 'offshore' campuses of American universities. One of these offers pharmacy training. However, pharmacists are usually being trained in neighboring countries.		

Section 3 Policy issues

3.00 Respondent Information Section 4

3.00.01	Name of person responsible for filling out this section of the instrument	Mr Elvis Newton, Permanent Secretary-Ministry of Health		
3.00.02	Phone number	(869) 465-2521		
3.00.03	Email address	elvis.newton@gmail.com		
3.00.04	Other respondents for filling out this section			

3.01 Policy Framework

Core questions (click here for help)

			Year	Source
3.01.01	National Health Policy exists. If yes, please write year of the most recent document in the "year" field.	Yes ☒ No ☐	1981	Policy Development, MOH
3.01.02	National Health Policy Implementation plan exists. If yes, please write the year of the most recent document in the "year"	Yes ☐ No ☒	2011	Policy Development, MOH
3.01.03	Please provide comments on the Health policy and its implementation plan			
3.01.04	National Medicines Policy official document exists. If yes, please write the year of the most recent document in the "year" field.	Yes ☐ No ☒	2011	Policy Development, MOH
3.01.05	Group of policies addressing pharmaceuticals exist.	Yes ☐ No ☒	2011	Policy Development, MOH
3.01.06	National Medicines Policy covers the following components:			

3.01.06.01	Selection of Essential Medicines	☐Yes		
3.01.06.02	Medicines Financing	☐Yes		
3.01.06.03	Medicines Pricing	☐Yes		
3.01.06.04	Medicines Procurement	☐Yes		
3.01.06.05	Medicines Distribution	☐Yes		
3.01.06.06	Medicines Regulation	☐Yes		
3.01.06.07	Pharmacovigilance	☐Yes		
3.01.06.08	Rational Use of Medicines	☐Yes		
3.01.06.09	Human Resource Development	☐Yes		
3.01.06.10	Research	☐Yes		
3.01.06.11	Monitoring and Evaluation	☐Yes		
3.01.06.12	Traditional Medicine	☐Yes		
3.01.07	National medicines policy implementation plan exists. If yes, please write year of the most recent document.	Yes ☐ No ☒	2011	Policy Development, MOH
3.01.08	Policy or group of policies on clinical laboratories exist. If yes, please write year of the most recent document in the "year" field	Yes ☐ No ☒	2011	Policy Development, MOH
3.01.09	National clinical laboratory policy implementation plan exists. If yes, please write year of the most recent document in the "year" field	Yes ☐ No ☒	2011	Policy Development, MOH
3.01.10	Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	Yes ☐ No ☒	2011	Policy Development, MoH

3.01.11	There are official written guidelines on medicines donations.	Yes ☐ No ☒	2011	Policy Development, MoH
3.01.12	Is pharmaceutical policy implementation being regularly monitored/assessed?	Yes ☐ No ☒	2011	Policy Development, MoH
3.01.12.01	Who is responsible for pharmaceutical policy monitoring?			
3.01.13	Is there a national good governance policy?	Yes ☐ No ☒	2011	Policy Development, MoH
3.01.13.01	Multisectoral	☐ Yes		
3.01.13.02	For the pharmaceutical sector	☐ Yes		
3.01.13.03	Which agencies are responsible?			
3.01.14	A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	Yes ☐ No ☒	2011	Policy Development, MoH
3.01.15	There is a formal code of conduct for public officials.	Yes ☐ No ☒	2011	Policy Development, MoH
3.01.16	Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsperson)?	Yes ☐ No ☒	2011	Policy Development, MoH
3.01.16.01	Please describe:			
3.01.17	Comments and References	3.01.01. The Caribbean Cooperation in Health Phase 3 (CCH3) is the health agenda for the CARICOM countries approved by the CAUCUS of Ministers of Health in September 2009. 3.01.04. There is a draft. 3.01.11. A Caribbean Pharmaceutical Policy was approved by CARICOM Council of Social and Human Development (COHSOD) in April 2011.		

Section 4 Medicines Trade and Production

4.00 Respondent Information Section 4

4.00.01	Name of person responsible for filling out this section of the instrument	Claudette Jenkins, Registrar -Intellectual Property
4.00.02	Phone number	(869) 465 3916
4.00.03	Email address	cjtriniskb@hotmail.com
4.00.04	Other respondents for filling out this section	Desiree Huggins, Executive Officer in the Ministry of International Trade, Industry, Commerce and Consumer Affairs; Mr Erickson France, Central Medical Stores

4.01 Intellectual Property Laws and Medicines

Core questions (click here for help)

			Year	Source
4.01.01	Country is a member of the World Trade Organization	Yes ☒ No ☐	1996	WTO
4.01.02	Legal provisions provide for granting of Patents on:		2000	Patents Act
4.01.02.01	Pharmaceuticals	Yes ☐ No ☒		
4.01.02.02	Laboratory supplies	Yes ☐ No ☒		
4.01.02.03	Medical supplies	Yes ☐ No ☒		
4.01.02.04	Medical equipment	Yes ☐ No ☒		
4.01.03.01	Please provide name and address of the institution responsible for managing and enforcing intellectual property rights	Intellectual Property Office(IPO), Judicial Complex, Basseterre, St Kitts		
4.01.03.02	Please provide URL			
4.01.04	National Legislation has been modified to implement the TRIPS Agreement	Yes ☒ No ☐	2009	HERA/CARICOM

4.01.05	Current laws contain (TRIPS) flexibilities and safeguards	Yes ☒ No☐	2009	HERA/CARICOM
4.01.06	Country is eligible for the transitional period to 2016	Yes ☐ No☒	2011	IPO
4.01.07	Which of the following (TRIPS) flexibilities and safeguards are present in the national law?		2011	IPO
4.01.07.01	Compulsory licensing provisions that can be applied for reasons of public health	Yes ☒ No ☐		
4.01.07.02	Bolar exception	Yes ☐ No ☒		
4.01.08	Are parallel importing provisions present in the national law?	Yes ☐ No ☒	2011	IPO
4.01.09	The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health	Yes ☒ No ☐	2011	IPO
4.01.10	Are there legal provisions for data exclusivity for pharmaceuticals	Yes ☐ No ☒	2011	IPO
4.01.11	Legal provisions exist for patent extension	Yes ☐ No ☒	2011	IPO
4.01.12	Legal provisions exist for linkage between patent status and Marketing Authorization	Yes ☐ No ☒	2011	CMS
4.01.13	Comments and References	4.01.02. According to HERA/CARICOM report on IP (2009) the Patents Act, 2000 (entered into force in 2002 via Appointed Day Order No. 20 of 2002), which repealed the earlier Patents Act, Cap 189, and the Registration of United Kingdom Patents Act, Cap 190. However, the Patents Act 2000 is NOT being implemented, and Regulations were still being prepared as of March 2009. 4.01.04. The approved Patents Act 2000 is TRIPS-compliant, but it is not yet being implemented. 4.01.05: The current laws contain (TRIPS) flexibilities and safeguards to a very limited extent.		

		The Patents Act excludes some subject matter from patentability, contains a de-minimis exception, an experimental use exception, permits national exhaustion, and optimally permits compulsory licensing.The Patents Act does not permit international exhaustion or parallel importation, does not contain an early working or regulatory review exception (Bolar exception), does not require disclosure of source and origin of genetic resources, does not prohibit new uses and forms, and should consider a broader range of excluded subject matter from patentability. 4.01.12: There is insufficient data available to assess whether legal provision exist for linkage between patent staus and Marketing Authorization. MA is not performed in the country.		

4.02 Manufacturing

Core questions (click here for help)

			Year	Source
4.02.01	Number of licensed pharmaceutical manufacturers in the country	0	2011	CMS
4.02.02	Country has manufacturing capacity		2011	CMS
4.02.02.01	R&D to discover new active substances	Yes ☐ No ☒ Unknown ☐		
4.02.02.02	Production of pharmaceutical starting materials (APIs)	Yes ☐ No ☒ Unknown ☐		
4.02.02.03	Production of formulations from pharmaceutical starting material	Yes ☐ No ☒ Unknown ☐		
4.02.02.04	Repackaging of finished dosage forms	Yes ☐ No ☒ Unknown ☐		
4.02.03	Percentage of market share by value produced by domestic manufacturers (%)	0	2011	CMS
4.02.04	Comments and References	there is no manufacturers in the country, all the medicines are imported.		

Supplementary questions (click here for help)

		Year	Source

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

Section 5 Medicines Regulation

5.00 Respondent Information Section 4

5.00.01	Name of person responsible for filling out this section of the instrument	Mr Erickson France
5.00.02	Phone number	(869) 465 2521
5.00.03	Email address	cms.skb@gmail.com
5.00.04	Other respondents for filling out this section	Dr Patrick Martin,

5.01 Regulatory Framework

Core questions (click here for help)

			Year	Source
5.01.01	Are there legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA)?	Yes ☐ No ☒	2011	Central Medical Stores
5.01.02	There is a Medicines Regulatory Authority	Yes ☐ No ☒	2011	Central Medical Stores
5.01.03	If yes, please provide name and address of the Medicines regulatory authority	There is not a Medicines Regulatory Authority by the definition. Nevertheless, some regulatory functions are performed by the Ministry of Health, according the provisions of the Medical Act (2002).		
5.01.04	The Medicines Regulatory Authority is:		2011	Central Medical Stores
5.01.04.01	Part of MoH	☐ Yes		
5.01.04.02	Semi autonomous agency	☐ Yes		
5.01.04.03	Other (please specify)			
5.01.05	What are the functions of the National Medicines Regulatory Authority?		2011	Central Medical Stores

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)	Medical Act (2002) has provisions for registration and inspections of professionals and premisses.		
5.01.06	Number of the MRA permanent staff	0	2011	Central Medical Stores
5.01.06.01	Date of response	November 01, 2011		
5.01.07	The MRA has its own website	Yes ☐ No ☒	2011	Central Medical Stores
5.01.07.01	- If yes, please provide MRA Web site address (URL)			
5.01.08	The MRA receives external technical assistance	Yes ☐ No ☒	2011	Central Medical Stores
5.01.08.01	If yes, please describe:			
5.01.09	The MRA is involved in harmonization/ collaboration initiatives	Yes ☒ No ☐	2011	Central Medical Stores
5.01.09.01	- If yes, please specify	St. Kitts and Nevis is member of CARICOM and OECS. HERA/CARICOM. Assessment of Regulatory Systems and		

		Registration in the CARICOM Countries and Dominican Republic, 2009.		
5.01.10	An assessment of the medicines regulatory system has been conducted in the last five years.	Yes ☒ No ☐	2009	HERA/ CARICOM
5.01.11	Medicines Regulatory Authority gets funds from regular budget of the government.	Yes ☒ No ☐	2011	Central Medical Stores
5.01.12	Medicines Regulatory Authority is funded from fees for services provided.	Yes ☐ No ☒	2011	Central Medical Stores
5.01.13	Medicines Regulatory Authority receives funds/support from other sources	Yes ☐ No ☒	2011	Central Medical Stores
5.01.13.01	- If yes, please specify			
5.01.14	Revenues derived from regulatory activities are kept with the Regulatory Authority	Yes ☐ No ☒	2011	Central Medical Stores
5.01.15	The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes ☐ No ☒	2011	Central Medical Stores
5.01.16	Comments and References			

5.02 Marketing Authorization (Registration)

Core questions (click here for help)

			Year	Source
5.0201	Legal provisions require a Marketing Authorization (registration) for all pharmaceutical products on the market	Yes ☐ No ☒	2011	CMS

5.0202	Are there any mechanism for exception/waiver of registration?	Yes ☐ No ☒	2011	Health Information Unit
5.0203	Are there mechanisms for recognition of registration done by other countries	Yes ☐ No ☐		
5.0203.01	If yes, please explain:			
5.0204	Explicit and publicly available criteria exist for assessing applications for Marketing Authorization of pharmaceutical products	Yes ☐ No ☒	2011	CMS
5.0205	Information from the prequalification programme managed by WHO is used for product registration	Yes ☐ No ☒	2011	CMS
5.0206	Number of pharmaceutical products registered in your country			
5.0207	Legal provisions require the MRA to make the list of registered pharmaceuticals with defined periodicity publicly available	Yes ☐ No ☐		
5.0207.01	If yes, how frequently updated			
5.0207.02	If yes, please provide updated list or URL *			
5.0208	Medicines registration always includes the INN (International Non-proprietary Names)	Yes ☒ No ☐	2011	CMS
5.0209	Legal provisions require the payment of a fee for Medicines Marketing Authorization (registration) applications	Yes ☐ No ☒	2011	CMS
5.0210	Comments and References			
Supplementary questions (click here for help)				
			Year	Source

5.0211S	Legal provisions require Marketing Authorization holders to provide information about variations to the existing Marketing Authorization	Yes ☐ No ☐		
5.0212S	Legal provisions require publication of a Summary of Product Characteristics (SPCs) of the medicines registered	Yes ☐ No ☐		
5.0213S	Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes ☐ No ☒	2011	CMS
5.0214S	Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the Marketing Authorization application	Yes ☐ No ☒	2011	CMS
5.0215S	Legal provisions require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	Yes ☐ No ☒	2011	CMS
5.0216S	Legal provisions allow applicants to appeal against MRAs decisions	Yes ☐ No ☒	2011	CMS
5.0217S	Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity (NCE) (US$)			
5.0218S	Registration fee - the Amount per application for a generic pharmaceutical product (US$)			
5.0219S	Time limit for the assessment of a Marketing Authorization application (months)			
5.0220S	Comments & References			

5.03 Regulatory Inspection

Core Questions (click here for help)

			Year	Source
5.03.01	Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes ☐ No ☒	2011	CMS
5.03.02	Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed	Yes ☒ No ☐	2002	Medical Act
5.03.02.01	If yes, legal provisions exist requiring inspections to be performed	Yes ☐ No ☒		
5.03.03	Inspection is a pre-requisite for licensing of:		1969	Public Health Act, 22
5.03.03.01	Public facilities	Yes ☒ No ☐		
5.03.03.02	Private facilities	Yes ☒ No ☐		
5.03.04	Inspection requirements are the same for public and private facilities	Yes ☒ No ☐	1969	Public Health Act, 22
5.03.05.01	Local manufactures are inspected for GMP compliance	Yes ☐ No ☒	2011	CMS
5.03.05.02	Private wholesalers are inspected	Yes ☐ No ☒		
5.03.05.03	Retail distributors are inspected	Yes ☐ No ☒		
5.03.05.04	Public pharmacies and stores are inspected	Yes ☐ No ☒		
5.03.05.05	Pharmacies and dispensing points of health facilities are inspected	Yes ☐ No ☒		
5.03.05.06	Please provide details on frequency of inspections for the different categories of facilities			

5.03.06	Comments and References			
5.04 Import Control				
Core Questions (click here for help)				
			Year	Source
5.04.01	Legal provisions exist requiring authorization to import medicines	Yes ☐ No ☒	2011	CMS
5.04.02	Legal provisions exist allowing the sampling of imported products for testing	Yes ☐ No ☒	2011	CMS
5.04.03	Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes ☒ No ☐	2011	CMS
5.04.04	Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized ports of entry	Yes ☒ No ☐	1974	Fiscal Incentives Act
5.04.05	Comments and References			
5.05 Licensing				
			Year	Source
5.05.01	Legal provisions exist requiring manufacturers to be licensed	Yes ☐ No ☒	2011	CMS
5.05.02	Legal provisions exist requiring both domestic and international manufacturers to comply with Good manufacturing Practices (GMP)	Yes ☐ No ☐		
5.05.02.01	If no, please explain			
5.05.03	GMP requirements are published by the government.	Yes ☐ No ☒	2011	CMS
5.05.04	Legal provisions exist requiring importers to be licensed	Yes ☒ No ☐	2011	CMS

5.05.05	Legal provisions exist requiring wholesalers and distributors to be licensed	Yes ☒ No ☐	2011	CMS
5.05.06	Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices **When filling in this part, please also fill in the relevant questions in the procurement and distribution section (Section 7)**	Yes ☐ No ☐		
5.05.07	National Good Distribution Practice requirements are published by the government	Yes ☐ No ☒	2011	CMS
5.05.08	Legal provisions exist requiring pharmacists to be registered	Yes ☒ No ☐	2002	Medical Act
5.05.09	Legal provisions exists requiring private pharmacies to be licensed	Yes ☒ No ☐	2011	CMS
5.05.10	Legal provision exist requiring public pharmacies to be licensed	Yes ☒ No ☐	2011	CMS
5.05.11	National Good Pharmacy Practice Guidelines are published by the government	Yes ☐ No ☒	2011	CMS
5.05.12	Legal provisions require the publication of a list of all licensed pharmaceutical facilities	Yes ☐ No ☒	2011	CMS
5.05.13	Comments and References			

5.06 Market Control and Quality Control **Core Questions (click here for help)**				
			Year	Source
5.06.01	Legal Provisions for regulating the pharmaceutical market exist	Yes ☐ No ☒	2011	CMS

5.06.02	Does a laboratory exist in the country for Quality Control testing?	Yes ☐ No ☒	2011	CMS
5.06.02.01	If yes, is the laboratory part of the MRA?	Yes ☐ No ☐		
5.06.02.02	Does the regulatory authority contract services elsewhere?	Yes ☐ No ☐		
5.06.02.03	If yes, please describe			
5.06.03	Is there any national laboratory accepted for collaboration with WHO prequalification Programme? Please describe.			
5.06.04	Medicines are tested:		2011	CMS
5.06.04.01	For quality monitoring in the public sector (routine sampling in pharmacy stores and health facilities)	Yes ☐ No ☒		
5.06.04.02	For quality monitoring in private sector (routine sampling in retail outlets)	Yes ☐ No ☒		
5.06.04.03	When there are complaints or problem reports	Yes ☒ No ☐		
5.06.04.04	For product registration	Yes ☐ No ☒		
5.06.04.05	For public procurement prequalification	Yes ☒ No ☐		
5.06.04.06	For public program products prior to acceptance and/or distribution	Yes ☒ No ☐		
5.06.05	Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes ☐ No ☒	2011	CMS
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	CMS
5.06.09	Comments and References	5.06.04.01: Quality monitoring in the public sector is conducted through the OECS/PPS facility		

5.07 Medicines Advertising and Promotion

Core Questions (click here for help)

			Year	Source
5.07.01	Legal provisions exist to control the promotion and/or advertising of prescription medicines	Yes ☐ No ☒	2007	WHO level 1
5.07.02	Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:			
5.07.03	Legal provisions prohibit direct advertising of prescription medicines to the public	Yes ☐ No ☒	2007	WHO level I
5.07.04	Legal provisions require a pre-approval for medicines advertisements and promotional materials	Yes ☐ No ☒	2007	WHO level I
5.07.05	Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	Yes ☐ No ☒	2007	WHO level I
5.07.06	A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	Yes ☐ No ☒	2011	CMS

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

5.08 Clinical trials

Core Questions (click here for help)

			Year	Source
5.08.01	Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	Yes ☐ No ☒	2011	Central Medical Stores
5.08.02	Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes ☐ No ☒	2011	Central Medical Stores
5.08.03	Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Yes ☐ No ☒	2011	Central Medical Stores
5.08.04	Comments and References			

Supplementary questions (click here for help)

		Year	Source

5.08.05S	Legal provisions exist for GMP compliance of investigational products	Yes ☐ No ☒	2011	Central Medical Stores
5.08.06S	Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	Yes ☐ No ☒	2011	Central Medical Stores
5.08.07S	National GCP regulations are published by the Government.	Yes ☐ No ☒	2011	Central Medical Stores
5.08.08S	Legal provisions permit inspection of facilities where clinical trials are performed	Yes ☐ No ☒	2011	Central Medical Stores
5.08.09S	Comments and References			

5.09 Controlled Medicines

Core Questions (click here for help)

			Date	Source
5.09.01	The country has adopted the following conventions:			
5.09.01.01	Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1994	International Narcotics Control Board, 2010
5.09.01.02	The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes ☒ No ☐	1994	International Narcotics Control Board, 2010
5.09.01.03	Convention on Psychotropic Substances 1971	Yes ☒ No ☐	1994	International Narcotics Control Board, 2010
5.09.01.04	United Nations Convention against the Illicit Traffic in Narcotic Drugs and	Yes ☒ No ☐	1995	International Narcotics

	Psychotropic Substances, 1988			Control Board, 2010
5.09.02	Laws for the control of narcotic and psychotropic substances, and precursors exist	Yes ☒ No ☐	2011	Central Medical Stores
5.09.03	Annual consumption of Morphine (mg/capita)	1	2011	Central Medical Stores
5.09.04	Comments and References	The Pharmacy data was obtained from records of licenses issued		

Supplementary questions (click here for help)

			Year	Source
5.09.05S	The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have been reviewed by a WHO International Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need	Yes ☒ No ☐ Unknown ☐	2011	CMS
5.09.05.01S	If yes, year of review	1961		
5.09.06S	Annual consumption of Fentanyl (mg/capita)	0.0000605	2010	CMS
5.09.07S	Annual consumption of Pethidine (mg/capita)	10.11	2010	CMS
5.09.08S	Annual consumption of Oxycodone (mg/capita)	0.311	2010	CMS
5.09.09S	Annual consumption of Hydrocodone (mg/capita)			
5.09.10S	Annual consumption of Phenobarbital (mg/capita)	43.264	2010	CMS
5.09.11S	Annual consumption of Methadone (mg/capita)			

5.09.12S	Comments and References	data from licensing records		
5.10 Pharmacovigilance **Core Questions (click here for help)**				
			Year	Source
5.10.01	There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	Yes ☐ No ☒	2011	CMS
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 ☐		
5.10.03	Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	Yes ☐ No ☒	2011	CMS
5.10.04	A national pharmacovigilance centre linked to the MRA exists in your country	Yes ☐ No ☒	2011	CMS
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	CMS
5.10.06	A national Adverse Drug Reactions database exists in your country	Yes ☐ No ☒	2011	CMS

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	CMS
5.10.09.01	If yes, number of reports sent in the last two years			
5.10.10	Is there a national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication?	Yes ☐ No ☒	2011	CMS
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	1) Establishment of a team approach. 2) Design and implement strategies for collection of data. 3) Production of procedures and guidelines		
5.10.14	Comments and References	St. Kitts and Nevis as member of OECS/PPS can send ADR reports to PPS/OECS.		

Supplementary questions (click here for help)

			Year	Source
5.10.15S	Feedback is provided to reporters	Yes ☐ No ☒	2011	CMS
5.10.16S	The ADR database is computerized	Yes ☐ No ☒	2011	CMS

5.10.17S	Medication errors (MEs) are reported	Yes ☐ No ☒	2011	CMS
5.10.18S	How many MEs are there in the ADRs database?			
5.10.19S	There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	Yes ☐ No ☐		
5.10.20S	In the past two years, who has reported ADRs?		2011	CMS
5.10.20.01S	Doctors	☐ Yes		
5.10.20.02S	Nurses	☐ Yes		
5.10.20.03S	Pharmacists	☒ Yes		
5.10.20.04S	Consumers	☒ Yes		
5.10.20.05S	Pharmaceutical Companies	☐ Yes		
5.10.20.06S	Others, please specify whom			
5.10.21S	Was there any regulatory decision based on local pharmacovigilance data in the last 2 years?	Yes ☐ No ☐		
5.10.22S	Are there training courses in pharmacovigilance?	Yes ☐ No ☒	2011	CMS
5.10.22.01S	If yes, how many people have been trained in the last two years?			
5.10.23S	Comments and References			

Section 6 Medicines Financing

6.00 Respondent Information Section 5

6.00.01	Name of person responsible for filling out this section of the instrument	MDr Patrick Martin, Chief Medical Officer
6.00.02	Phone number	(869) 465 2521
6.00.03	Email address	skncmo@yahoo.com
6.00.04	Other respondents for this sections	Mr Erickson France

6.01 Medicines Coverage and Exemptions

Core Questions (click here for help)

			Year	Source
6.01.01	Do the followings receive medicines free of charge:		2011	CMS
6.01.01.01	Patients who cannot afford them	Yes ☒ No ☐		
6.01.01.02	Children under 5	Yes ☒ No ☐		
6.01.01.03	Pregnant women	Yes ☒ No ☐		
6.01.01.04	Elderly persons	Yes ☒ No ☐		
6.01.01.05	Please describe/explain your yes answers for questions above			
6.01.02	Is there a public health system or social health insurance scheme or public programme providing medicines free of charge for :		2011	Health Information Unit
6.01.02.01	All medicines included in the EML	Yes ☒ No ☐		
6.01.02.02	Any non-communicable diseases	Yes ☒ No ☐		
6.01.02.03	Malaria medicines	Yes ☒ No ☐		
6.01.02.04	Tuberculosis medicines	Yes ☒ No ☐		

6.01.02.05	Sexually transmitted diseases medicines	Yes ☒ No ☐		
6.01.02.06	HIV/AIDS medicines	Yes ☒ No ☐		
6.01.02.07	Expanded Program on Immunization (EPI) vaccines	Yes ☒ No ☐		
6.01.02.08	If others, please specify			
6.01.02.09	Please describe/explain your yes answers for questions above	as per government policy regarding UNiversal Access		
6.01.03	Does a national health insurance, social insurance or other sickness fund provide at least partial medicines coverage?	Yes ☒ No ☐	2011	Health Information Unit
6.01.03.01	Does it provide coverage for medicines that are on the EML for inpatients	Yes ☒ No ☐		
6.01.03.02	Does it provide coverage for medicines that are on the EML for outpatients	Yes ☒ No ☐		
6.01.03.03	Please describe the medicines benefit of public/social insurance schemes	via application for social assistance		
6.01.04	Do private health insurance schemes provide any medicines coverage?	Yes ☒ No ☐	2011	Health Information Unit
6.01.04.01	If yes, is it required to provide coverage for medicines that are on the EML?	Yes ☐ No ☒		
6.01.05	Comments and References			

6.02 Patients Fees and Copayments

Core Questions (click here for help)

			Year	Source
6.02.01	In your health system, at the point of delivery, are there any co-	Yes ☐ No ☒	2011	CMS

	payment/fee requirements for consultations			
6.02.02	In your health system, at the point of delivery, are there any co-payment/fee requirements for medicines	Yes ☒ No ☐	2011	CMS
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	CMS
6.02.03.01	Please describe the patient fees and copayments system	Minimal Administrative Fee		
6.02.04	Comments and References	6.02.03; There is a service charge that goes into a consolidated fund with some exceptions		

6.03 Pricing Regulation for the Private Sector

Core Questions (click here for help)

			Year	Source
6.03.01	Are there legal or regulatory provisions affecting pricing of medicines	Yes ☒ No ☐	2011	CMS
6.03.01.01	If yes, are the provisions aimed at Manufacturers	Yes ☐ No ☒		
6.03.01.02	If yes, are the provisions aimed at Wholesalers	Yes ☒ No ☐		
6.03.01.03	If yes, are the provisions aimed at Retailers	Yes ☒ No ☐		
6.03.01.04	Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.)	Value added tax is place on some medicines		
6.03.02	Government runs an active national medicines price monitoring system	Yes ☐ No ☒	2011	CMS

	for retail prices			
6.03.03	Regulations exists mandating that retail medicine price information should be publicly accessible	Yes ☐ No ☒	2011	Health Information Unit
6.03.03.01	-if yes, please explain how the information is made publically available			
6.03.04	Comments and References			

6.04 Prices, Availability and Affordability

Core Questions (click here for help)

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

	Basket Of key medicines			Public procurement	Public patient	Private patient		
	Availability (one or both of)	**Mean (%)**	**Orig**		6.04.01.01	6.04.01.03		
			LPG		6.04.01.02	6.04.01.04		
		Median (%)	**Orig**		6.04.02.01	6.04.02.03		

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

6.05 Price Components and Affordability

Core Questions (click here for help)

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

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

6.06 Duties and Taxes on Pharmaceuticals (Market)				
Core Questions (click here for help)				
			Year	Source

6.06.01	There are duties on imported active pharmaceutical ingredients (APIs)	Yes ☒ No ☐	2007	Common External Tariff
6.06.02	There are duties on imported finished products	Yes ☒ No ☐	2007	Common External Tariff
6.06.03	VAT (value-added tax) or any other tax is levied on finished pharmaceuticals products	Yes ☒ No ☐	2010	Value-added Tax
6.06.04	There are provisions for tax exceptions or waivers for pharmaceuticals and health products	Yes ☒ No ☐	2007	Common External Tariff
6.06.05	Please specify categories of pharmaceuticals on which the taxes are applied and describe the exemptions and waivers that exist			
6.06.06	Comments and References	The Common External Tariff is one of the key elements of the CARICOM Single Market and Economy. 6.06.05 Some pharmaceuticals within a category may be duty free, whilst others taxes are applied within the same category.		

Supplementary questions (click here for help)

			Year	Source
6.06.07S	Duty on imported active pharmaceutical ingredients, APIs (%)			
6.06.08S	Duty on imported finished products (%)			
6.06.09S	VAT on pharmaceutical products (%)	0.17	2011	CMS
6.06.10S	Comments and References	6.06.09S; Some of the pharmaceuticals products are exempted from VAT whilst others are 17%		

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 Erickson France
7.00.02	Phone number	(869) 465 2551 Ext 162
7.00.03	Email address	cms.skb@gmail.com
7.00.04	Other respondents for filling out this section	

7.01 Public Sector Procurement

Core Questions (click here for help)

			Date	Source
7.01.01	Public sector procurement is:		2011	CMS
7.01.01.01	Decentralized	☐ Yes		
7.01.01.02	Centralized and decentralized	☐ Yes		
7.01.01.03	Please describe	Fully centralized		
7.01.02	If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:		2011	CMS
7.01.02.01	Part of MoH	Yes ☒ No ☐		
7.01.02.02	Semi-Autonomous	Yes ☐ No ☒		

7.01.02.03	Autonomous	Yes ☐ No ☒		
7.01.02.04	A government procurement agency which procures all public goods	Yes ☐ No ☒		
7.01.03	Public sector requests for tender documents are publicly available	Yes ☐ No ☒	2011	CMS
7.01.04	Public sector tender awards are publicly available	Yes ☐ No ☒	2011	CMS
7.01.05	Procurement is based on prequalification of suppliers	Yes ☐ No ☒	2011	CMS
7.01.05.01	If yes, please describe how it works			
7.01.06	Comments and References	For pharmaceticals, purchases are made through OECS/PPS. The countries comprising the OECS have recognized that by improving the use of existing resources could be achieved by efficient procurement practices. Of the four areas of drug supply management, which include selection, procurement, distribution, and use, efficient procurement provides the greatest opportunity for cost-savings. The OECS/Pharmaceutical Procurement Service (OECS/PPS), formerly the Eastern Caribbean Drug Service (ECDS), was established under a project funded by USAID, and by 1989, the scheme was financially self-sufficient. The OECS/PPS is a self-financing public sector monopsony or buyers' cartel that covers its opearting cost from a 15% surcharge. The OECS/PPS is an agency of the OECS, a formal grouping of nine eastern Caribbean Countries: Anguilla, Antigua and Barbuda, British Virgin Islands, Dominica, Grenada, Montserrat, St Kitts and Nevis, St Lucia and St Vincent and the Grenadines, with a combined population of approximately 550,000. Source: http://www.oecs.org/pps/about_pps		

Supplementary questions (click here for help)

			Year	Source
7.01.07S	Is there a written public sector procurement policy?. If yes, please write the year of approval in the "year" field	Yes ☐ No ☒	2011	CMS
7.01.08S	Are there legal provisions giving priority in public procurement to goods produced by local	Yes ☐ No ☒	2011	CMS

	manufacturers?			
7.01.09S	The key functions of the procurement unit and those of the tender committee are clearly separated	Yes ☐ No ☐		
7.01.10S	A process exists to ensure the quality of products procured	Yes ☐ No ☒	2011	CMS
7.01.10.01S	If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes ☐ No ☐		
7.01.10.02S	If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Yes ☐ No ☐		
7.01.10.03S	If yes, a list of pre-qualified suppliers and products is publicly available	Yes ☐ No ☐		
7.01.11S	List of samples tested during the procurement process and results of quality testing are available	Yes ☐ No ☒		
7.01.12S	Which of the following tender methods are used in public sector procurement:		2011	CMS
7.01.12.01S	National competitive tenders	Yes ☐ No ☒		
7.01.12.02S	International competitive tenders	Yes ☒ No ☐		
7.01.12.03S	Direct purchasing	Yes ☐ No ☒		
7.01.13S	Comments and References			

7.02 Public Sector Distribution

Core Questions (click here for help)

			Year	Source
7.02.01	The government supply system department has a Central Medical	Yes ☒ No ☐	2011	CMS

	Store at National Level			
7.02.02	Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	1	2011	CMS
7.02.03	There are national guidelines on Good Distribution Practices (GDP)	Yes ☐ No ☒	2011	CMS
7.02.04	There is a licensing authority that issues GDP licenses	Yes ☐ No ☒	2011	CMS
7.02.04.01	If a licensing authority exists, does it accredit public distribution facilities?	Yes ☐ No ☒		
7.02.05	List of GDP certified warehouses in the public sector exists	Yes ☐ No ☒	2011	CMS
7.02.06	List of GDP certified distributors in the public sector exists	Yes ☐ No ☒	2011	CMS
7.02.07	Comments and References			

Supplementary questions (click here for help)

			Year	Source
7.02.08S	Which of the following processes is in place at the Central Medical Store:		2011	CMS
7.02.08.01S	Forecasting of order quantities	Yes ☐ No ☒		
7.02.08.02S	Requisition/Stock orders	Yes ☒ No ☐		
7.02.08.03S	Preparation of picking/packing slips	Yes ☒ No ☐		
7.02.08.04S	Reports of stock on hand	Yes ☐ No ☒		
7.02.08.05S	Reports of outstanding order lines	Yes ☐ No ☒		
7.02.08.06S	Expiry dates management	Yes ☒ No ☐		

7.02.08.07S	Batch tracking	Yes ☐ No ☒		
7.02.08.08S	Reports of products out of stock	Yes ☐ No ☒		
7.02.09S	Percentage % availability of key medicines at the Central Medical Store	75	2011	OECS PPS
7.02.10S	Average stock-out duration for a basket of medicines at the Central Medical Store, in days			
7.02.11S	Routine Procedure exists to track the expiry dates of medicines at the Central Medical Store	Yes ☒ No ☐	2011	CMS
7.02.12S	The Public Central Medical Store is GDP certified by a licensing authority	Yes ☐ No ☒	2011	CMS
7.02.13S	The Public Central Medical Store is ISO certified	Yes ☐ No ☒	2011	CMS
7.02.14S	The second tier public warehouses are GDP certified by a licensing authority	Yes ☐ No ☒	2011	CMS
7.02.15S	The second tier public warehouses are ISO certified	Yes ☐ No ☒	2011	CMS
7.02.16S	Comments and References	7.02.08S: Plans are in place for the tproceses which are not yet in effect at the Central medical Stores to come in effect in November 2011		

7.03 Private Sector Distribution

Core Questions (click here for help)

			Year	Source
7.03.01	Legal provisions exist for licensing wholesalers in the private sector	Yes ☐ No ☒	2011	CMS
7.03.02	Legal provisions exist for licensing distributors in the private sector	Yes ☐ No ☒	2011	CMS

7.03.03	List of GDP certified wholesalers in the private sector exists	Yes ☐ No ☒	2011	CMS
7.03.04	List of GDP certified distributors in the private sector exists	Yes ☐ No ☒	2011	CMS
7.03.05	Comments and References			

Section 8 Selection and rational use

8.00 Respondent Information Section 7

8.00.01	Name of person responsible for filling out this section of the instrument	Mr Erickson France
8.00.02	Phone number	(869) 465 2551 Ext 162
8.00.03	Email address	cms.skb@gamil.com
8.00.04	Other respondents for filling out this section	

8.01 National Structures

Core Questions (click here for help)

			Year	Source
8.01.01	National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field	Yes ☒ No ☐	2011	CMS
8.01.01.01	If yes, number of medicines on the EML (no. of INN)	630		
8.01.01.02	If yes, there is a written process for selecting medicines on the EML	Yes ☐ No ☒		
8.01.01.03	If yes, the EML is publicly available	Yes ☐ No ☐		
8.01.01.04	If yes, is there any mechanism in place to align the EML with the Standard Treatment Guidelines (STG)	Yes ☐ No ☐		
8.01.02	National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the MoH. If yes, please insert year of last update of STGs in the "year" field	Yes ☒ No ☐		HERA

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

	field			
8.01.13	Comments and References	08.08.01 The OECS/PPS essential medicines list is used as a reference for the public sector.		

Supplementary questions (click here for help)

			Year	Source
8.01.14S	The Essential Medicines List (EML) includes formulations specific for children	Yes ☒ No ☐	2011	CMS
8.01.15S	There are explicitly documented criteria for the selection of medicines in the EML	Yes ☐ No ☒	2011	CMS
8.01.16S	There is a formal committee or other equivalent structure for the selection of products on the National EML	Yes ☐ No ☒	2011	CMS
8.01.16.01S	If yes, conflict of interest declarations are required from members of national EML committee	Yes ☐ No ☐		
8.01.17S	National medicines formulary exists	Yes ☒ No ☐	2011	CMS
8.01.18S	Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection?	Yes ☐ No ☒	2011	CMS
8.01.19S	A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes ☒ No ☐	2007	WHO level I
8.01.20S	Comments and References	8.01.16S: there are plans in place to form a formal committee		

8.02 Prescribing

Core Questions (click here for help)

			Year	Source
8.02.01	Legal provisions exist to govern the licensing and prescribing practices of prescriber	Yes ☒ No ☐	2011	CMS
8.02.02	Legal provisions exist to restrict dispensing by prescribers	Yes ☐ No ☒	2011	CMS
8.02.03	Do prescribers in the private sector dispense medicines?	Yes ☒ No ☐	2011	CMS
8.02.04	Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	Yes ☐ No ☒	2007	WHO level I
8.02.05	Do more than half of referral hospitals have a DTC?	Yes ☐ No ☒ Unknown ☐	2011	CMS
8.02.06	Do more than half of general hospitals have a DTC?	Yes ☐ No ☒ Unknown ☐	2011	CMS
8.02.07	Do more than half of regions/provinces have a DTC?	Yes ☐ No ☒ Unknown ☐	2011	CMS
8.02.08	The core medical training curriculum includes components on:		2007	WHO level I
8.02.08.01	Concept of EML	Yes ☐ No ☒		
8.02.08.02	Use of STGs	Yes ☐ No ☒		
8.02.08.03	Pharmacovigilance	Yes ☐ No ☐		
8.02.08.04	Problem based pharmacotherapy	Yes ☐ No ☐		
8.02.09	Mandatory continuing education that includes pharmaceutical issues is required for doctors (see physician)	Yes ☒ No ☐	2007	WHO level 1
8.02.10	Mandatory continuing education that includes pharmaceutical issues is required for nurses	Yes ☐ No ☐		
8.02.11	Mandatory continuing education that includes pharmaceutical issues	Yes ☒ No ☐	2007	WHO level

	is required for paramedical staff			I
8.02.12	Prescribing by INN name is obligatory in:		2007	WHO level I
8.02.12.01	Public sector	Yes ☐ No ☒		
8.02.12.02	Private sector	Yes ☐ No ☒		
8.02.13	Average number of medicines prescribed per patient contact in public health facilities (mean)	3.5	2010	Community Pharmacy Records
8.02.14	% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	92	2010	Institutional and Community Pharmacy records
8.02.15	% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	80	2010	Community Pharmacy Records
8.02.16	% of patients in outpatient public health care facilities receiving antibiotics (mean)	20	2010	Community Pharmacy Records
8.02.17	% of patients in outpatient public health care facilities receiving injections (mean)	1	2010	Community Pharmacy records
8.02.18	% of prescribed drugs dispensed to patients (mean)	97	2010	Community Pharmacy Records
8.02.19	% of medicines adequately labelled in public health facilities (mean)	98	2010	Central Medical Stores
8.02.20	Comments and References			

Supplementary questions (click here for help)

			Year	Source
8.02.21S	A professional association code of conduct exists governing	Yes ☐ No ☐		

	professional behaviour of doctors			
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) (%)	100	2010	CMS
8.02.24S	Comments and References	8.02.23S: Data quoted is for public care		

8.03 Dispensing

Core Questions (click here for help)

			Year	Source
8.03.01	Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes ☒ No ☐	1938	Medical Act of St Kitts and Nevis
8.03.02	The basic pharmacist training curriculum includes components on:		2011	CMS
8.03.02.01	Concept of EML	Yes ☐ No ☒		
8.03.02.02	Use of STGs	Yes ☐ No ☒		
8.03.02.03	Drug Information	Yes ☒ No ☐		
8.03.02.04	Clinical pharmacology	Yes ☒ No ☐		
8.03.02.05	Medicines supply management	Yes ☐ No ☒		
8.03.03	Mandatory continuing education that includes rational use of medicines is required for pharmacists	Yes ☐ No ☒	2007	WHO level I
8.03.04	Generic substitution at the point of dispensing in public sector facilities is allowed	Yes ☒ No ☐	2007	WHO level I
8.03.05	Generic substitution at the point of dispensing in private sector	Yes ☒ No ☐	2007	WHO level

	facilities is allowed			I
8.03.06	In practice, (even though this may be contrary to regulations) are antibiotics sometimes sold over-the-counter without any prescription?	Yes ☐ No ☒ Unknown ☐	2007	WHO level I
8.03.07	In practice, (even though this may be contrary to regulations) are injections sometimes sold over-the-counter without any prescription?	Yes ☐ No ☒ Unknown ☐	2007	WHO level I
8.03.08	Comments and References	8.03.04/.05 The use of generic medicines is neither actively promoted nor is it regulated. However, prescription forms are designed in a way that the prescriber needs to indicate that substitution should not be done.		

Supplementary questions (click here for help)

			Year	Source
8.03.09S	A professional association code of conduct exists governing professional behaviour of pharmacists	Yes ☐ No ☒	2011	CMS
8.03.10S	In practice, (even though this may be contrary to regulations) do the following groups of staff *sometimes* prescribe prescription-only medicines at the primary care level in the public sector?		2007	WHO level I
8.03.10.01S	Nurses	Yes ☐ No ☐ Unknown ☐		
8.03.10.02S	Pharmacists	Yes ☐ No ☒ Unknown ☐		
8.03.10.03S	Paramedics	Yes ☐ No ☐ Unknown ☐		
8.03.10.04S	Personnel with less than one month training	Yes ☐ No ☒ Unknown ☐		
8.03.11S	Comments and References			

Section 9 Household data/access

9.00 Respondent Information section 8

9.00.01	Name of person responsible for filling out this section of the instrument	Ms Beverly Harris, Director of Statistics and Economic Planning
9.00.02	Phone number	(869) 465 2521
9.00.03	Email address	
9.00.04	Other respondents for filling out this section	

9.01 Data from Household Surveys

Core Questions (click here for help)

			Year	Source
9.01.01	What household surveys have been undertaken in the past 5 years to assess access to medicines?	0		
9.01.02	Adults with acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			
9.01.03	Adults with acute conditions not taking all medicines because they cannot afford them (%)			
9.01.04	Adults (from poor households) with an acute health condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)			
9.01.05	Adults (from poor households) with an acute condition in two-week recall period who did not take all medicines because they cannot afford them (%)			

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

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