SURINAME

PHARMACEUTICAL COUNTRY PROFILE

Acknowledgements/Disclaimer

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I. Title

1. DRUG AND NACOTIC CONTROL – legislation & jurisprudence
2. PHARMACEUTICAL TRADE
3. LEGISLATION, PHARMACY
4. DRUG, ESSENTIAL – standards
5. DRUG INDUSTRY – economics
6. DRUG AND NARCOTIC CONTROL – organization & administration
7. NATIONAL DRUG POLICY
8. SURINAME

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Foreword

This 2010 Pharmaceutical Country Profile for Suriname has been produced by the Ministry of Health of Suriname with support of the Pan American Health Organization/World Health Organization.

This document contains information on structures, process and outcomes of the pharmaceutical sector in Suriname. Some of the data comes from global sources (e.g. the World Health Statistics) or from surveys conducted in the previous years, while other pieces of information have been collected at country level in 2010. Users are encouraged to confirm the validity of data in real time for the sources of data for the information which is presented in the tables that are at the end of this document.

On the behalf of the Ministry of Health (MOH) of Suriname, I wish to express my appreciation towards MOH staff, PAHO/WHO and the EC/ACP/WHO Partnership on Pharmaceutical Policies and the complete team that contributed to the data collection and to the development of this profile.

It is my hope that partners, researchers and all those that are interested in the pharmaceutical sector of Suriname will find this profile a useful tool in their activities.

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Director of Health, Ministry of Health of Suriname

Paramaribo, March 2011.

Table of content

Introduction

This Pharmaceutical Country Profile provides data on structures, processes and outcomes of the pharmaceutical sector of Suriname. The aim is to put together existing information and to make all relevant information on the pharmaceutical sector available to the public in a user-friendly format. In 2010, country profiles similar to this one have been developed for 13 pilot countries. During 2011, the World Health Organization plans to support all WHO Member States to develop similar country profiles.

The information is categorized in 8 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Regulation, (5) Medicines Financing, (6) Supply of Pharmaceuticals, (7) Rational Use of Medicines, and (8) Household Surveys. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). The narrative profile is based only on the core indicators; while the tables in the annexes present all indicators. For each piece of information, we have tried to indicate the year and source of the data; these are used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links are provided to the source documents so that the user 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 as well as experts from WHO Regional, Sub-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 the pilot countries was conducted using a user-friendly electronic questionnaire that included a comprehensive glossary.

Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide information available at the central level. To facilitate the work of national counterparts, the questionnaires were pre-filled using all data available at WHO HQ before being sent out to countries. A coordination team was nominated for each of the 13 pilot countries. For Suriname, the data collection was coordinated by Miriam A. Naarendorp, M.Sc. and Dr. Adriana M. Ivama with the support of Mr. Prim Ritoe. The completed questionnaires were then used to produce the country profiles. In order to do this in a structured and efficient manner, a text template was developed. Member states took part in the development of the profile and, once the final product 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 web site of PAHO/WHO.

This profile will be regularly updated by country teams. If you have any suggestions on corrections to make please send them to Miriam A. Naarendorp, sur.ppc@gmail.com, Ministry of Health, Suriname.

Section 1 - Health and Demographic Data

Suriname is located on the north east coast of South America covering a surface of 163,820 square kilometres. The country shares boarders with Guyana to the west, Brazil to the south, and French Guyana to the east.

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

1.1 Demographics and Socioeconomic Indicators

The total population of Suriname is 509,970 people with an annual population growth rate of 1.15%. Eighty-nine percent of the population live along the coastal strip (59.4% urban, 29.6% rural), which makes up 10% of the land surface. The remaining 11% of the population live in the interior that is characterized by rainforest vegetation.

The annual Gross Domestic Product (GDP) growth rate is 5.0%. The Gross National Incoming (GNI) per capita is US$ 4,678.57. This value considers both the formal and informal sectors [1]. The country's Gross National Product (GNP) was USD 1.6 Billion in 2006, equalling USD 3,173/capita. The economy is mainly based on the mining, agriculture, and manufacturing sectors.

1.2 Mortality and Causes of Death

The life expectancy at birth for men is 66 years and for women is 73 years. The infant mortality rate is 25/1,000 live births. For children under the age of 5, the mortality rate is 27/1,000 live births. The maternal mortality rate is 72/100,000 live births [2].

The top 10 diseases causing mortality in Suriname are:

1. Cardiovascular diseases

2. External causes of death: accidents, violence and injuries, homicide, suicide
3. Malignancies
4. Diseases originating in the Perinatal Period
5. Diabetes Mellitus
6. HIV / AIDS
7. Acute Respiratory infections
8. Diseases of the Urinary tract
9. Liver cirrhosis and other chronic Liver diseases
10. Congenital disorders.

The major causes of morbidity in Suriname are:

- *Primary health care setting*

  - 5 leading (syndromal) diagnoses at PHC consultations in children <5 years

    1. Lower respiratory disorders
    2. Symptoms not elsewhere classified
    3. Skin disorders
    4. Intestinal infections
    5. Helminthiasis

  - 5 leading (syndromal) diagnoses at PHC consultations in adults >20 years

    1. Hypertension
    2. Symptoms not elsewhere classified
    3. Hypertension and Diabetes
    4. Diabetes
    5. Symptoms of the muscular-skeleton system e.g. ischiatic pain, (lower) back pain, joint pain

- *Secondary health care setting*

    1. Cardiovascular diseases
    2. Communicable diseases

3. External causes: accidents, violence, injuries,
4. Pregnancy, childbirth, and the puerperium
5. Malignancies [3].

Section 2 - Health Services and Financing

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

Health care financing is separate from health care provision. Approximately 31% of the population - 'the under-privileged' - are covered through the Ministry of Social Affairs and Housing; 26% through the State Health Insurance Fund (government employees); 8% by the Medical Mission (communities in the interior; Ministry of Health subsidized); and 34% are covered by private health insurance, company plans, or pay out-of-pocket.

2.1 Health Expenditures

In Suriname, the total annual expenditure on health (THE) was SRD 608.6 million (US$ 221.3 million) in 2006. The total health expenditure was 7.73 % of the GDP. The total annual expenditure on health per capita was SRD 1181 (US$ 430).

The government[1] annual expenditure on health accounted for 47.65 % of the total expenditure on health, with a total per capita public expenditure on health of SRD 563 (US$ 205). The government annual expenditure on health represented 13.6 % of the total government budget of 2006.

The private health expenditure covered the remaining 52.35% of the total health expenditure.

[1] According to the NHA definition, by "government expenditure" it is meant all expenditure from public sources, like central government, local government, insurance funds and parastatal companies. The official exchanged rate from Surinamese Dollars (SRD) $ 2.80 to United States Dollars (USD) $ 1.00 in June, 2010 was used.

In 2006, 53 % of the total population was covered by a public health service or public health insurance or social insurance, or other sickness funds.

The total pharmaceutical expenditure (TPE) in Suriname was SRD 51.78 million (US$ 18.83 million). The total pharmaceutical expenditure per capita was SRD 102.68 (US$ 37.34). The pharmaceutical expenditure accounted for 0.98 % of the GDP and made up 8.5 % of the total health expenditure (figure 1).

Public expenditure on pharmaceuticals represented 12 % of the total expenditure on pharmaceuticals (figure 2). The total public expenditure on pharmaceuticals per capita was SRD 12.22 (US$ 4.44). The total private expenditure on pharmaceuticals was SRD 45.61 million (US$ 16.59 million) [4].

FIGURE 1: Share of Total Pharmaceutical Expenditure as percentage of the Total Health Expenditure. Total Health Expenditure was SRD 608.6 million (US$ 221.3 million) in 2006.

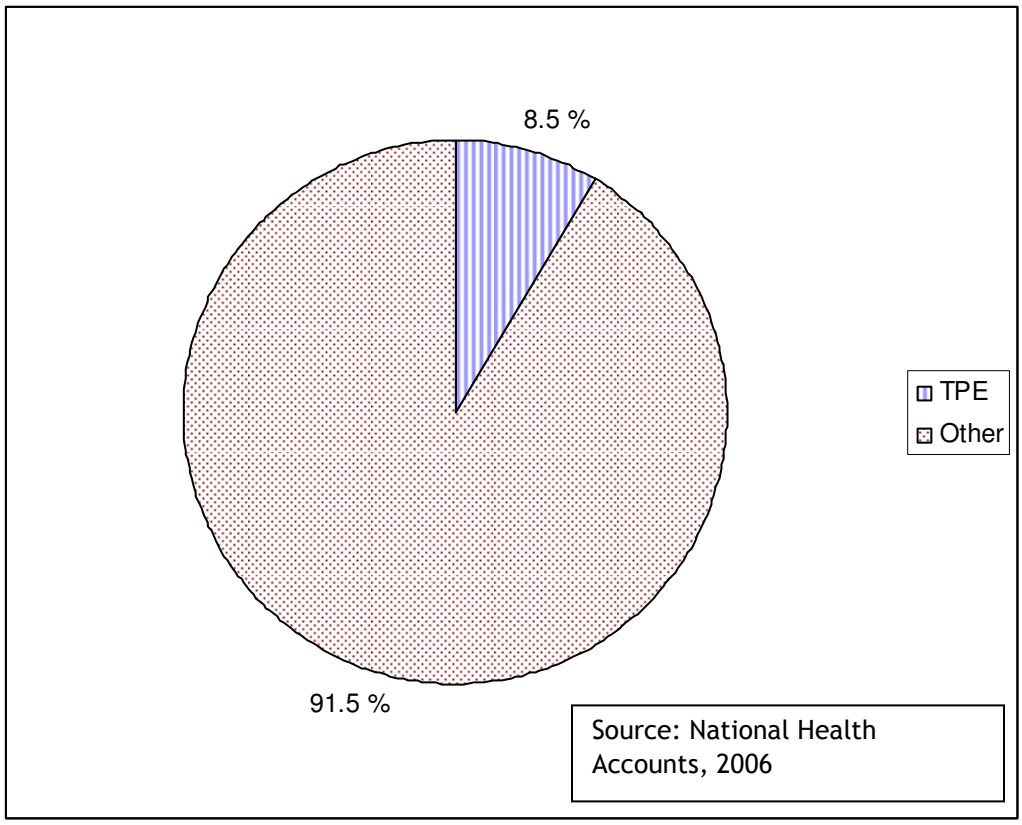
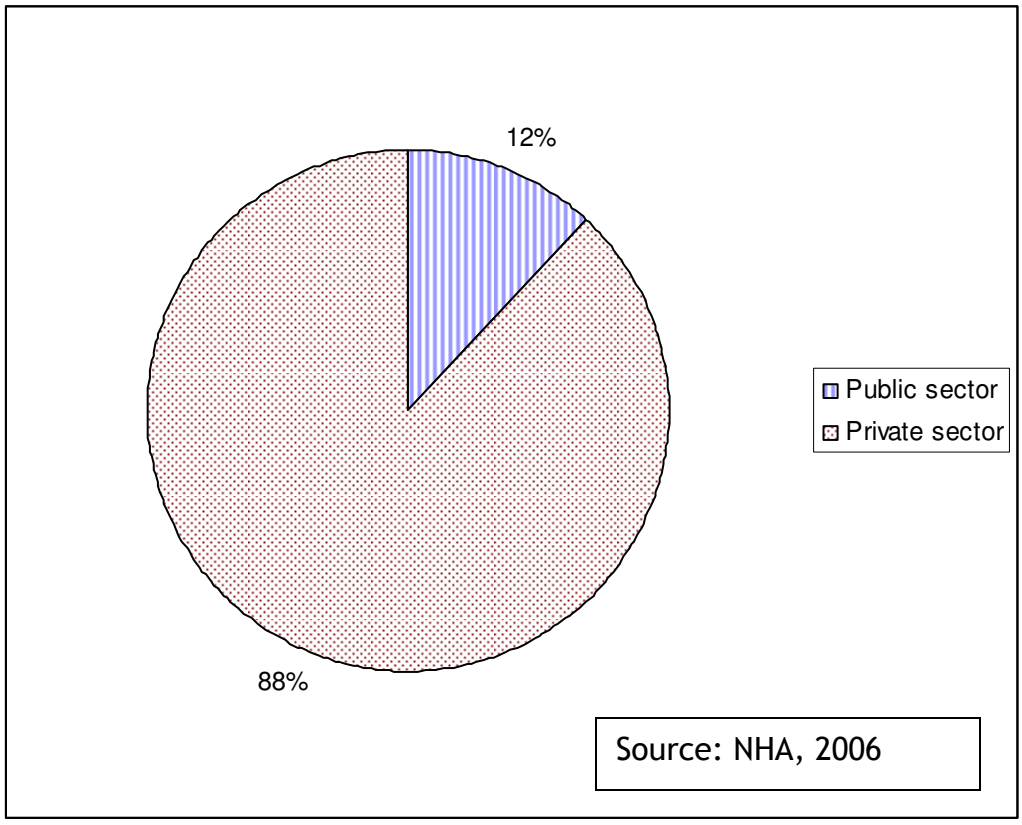


FIGURE 2: Share of public and private sector to Total Pharmaceutical Expenditure (2006).



2.2 Health Personnel

Suriname has one medical school and one nursing school, but graduate pharmacists cannot be trained in-country. There is one vocational pharmacy assistant training programme.

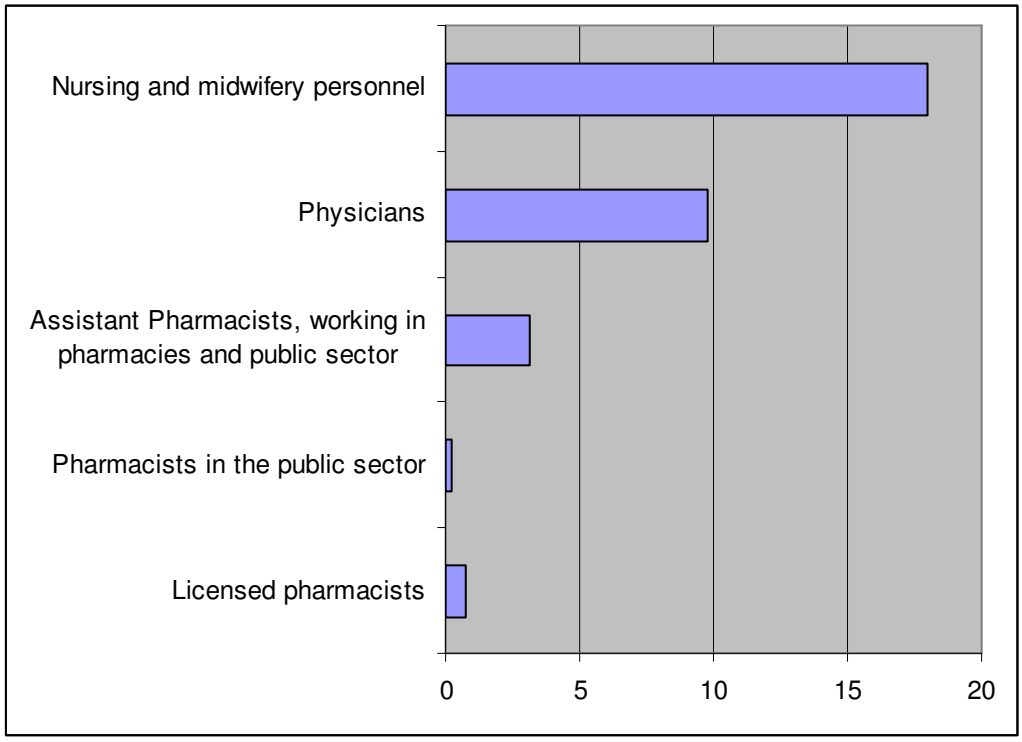
The number of pharmacists is 31, out of which 8 are currently not operating in the dispensing practice. They are assisted by over 160 trained pharmacy assistants (vocational training with a 3 year programme). There are 332 registered physicians, 42 dentists, and 127 medical specialists that are authorized to prescribe medicines.

Service delivery

The health workforce is described in the table below and in figure 3.

Licensed pharmacists	0.73/10,000 [3]
Pharmacists in the public sector	0.2/10,000 [5] [6]
Assistant Pharmacists, working in pharmacies and Public Sector.	3.14/10,000 [6a]
Physicians	9.8/10,000
Nursing and midwifery personnel	18/10,000 [3]

Figure 3: The density of the Health Workforce 2009 in Suriname



In Suriname, the strategic plan for pharmaceutical human resource development is currently being developed [5].

2.3 Health Infrastructure

Primary health care is provided on behalf of government by the Regional Health Services (state foundation) and the Medical Mission (NGO) - both subsidized by the Ministry of Health. Private sector primary health care is mainly provided by private medical practitioners. Four public (including one psychiatric centre) and two private hospitals provide secondary and specialist care. In addition, the military hospital caters for the military and their dependants.

Health services are provided by the Regional Health Services, the Medical Mission for Primary Health Care Foundation, large employer firms, general practitioners in private practice, and public and private hospitals. Financing of health care is separate from the provision of healthcare (as described in detail in Study 6).

The Regional Health Services (*Regionale Gezondheidsdienst*, RGD) runs over 40 clinics to provide primary health care for the poor and the near-poor in the coastal area. The RGD, which also has a pharmacy in Paramaribo, distributes medicines to more then 20 coastal facilities, which function as small pharmacies. Dispensed pharmaceuticals are paid out-of-pocket by clients or are charged to the clients' social or private insurance plans.

The Medical Mission for Primary Health Care (*Medische Zending*, Medical Mission) is a nongovernmental organization (NGO) based in Paramaribo. It operates nearly 40 clinics in the country's interior. Based on the distance to major health facilities and the population that they serve, Medical Mission facilities are classified as big, medium and small posts. All the facilities dispense medicines. The Medical Mission does not operate a pharmacy in Paramaribo. The Ministry of Health (MOH) subsidizes Medical Mission costs. Pharmaceuticals are provided free of charge to Medical Mission patients. Medical Mission patients who need hospital care are treated at the private

Diakonessen Hospital (through an agreement between these two institutions), and their costs are covered by the Ministry of Social Affairs (MSA).[2]

The health centre and hospital statistics are described in the table below.

Hospitals	0.12/10,000
Hospital beds	31.1/10,000
Primary health care units and centres	14.4/10,000
Licensed pharmacies	0.53/10,000 [3]

[2] Adopted/Adapted from Suriname country report (2009), HERA for Caricom , and MSH's Suriname Study on Public Sector Drug Procurement, May 2003

Section 3 - Policy Issues

This section addresses the main structures of the pharmaceutical policy in Suriname. Information about the capacity for manufacturing medicines and on regulations regarding patents is also provided.

The Ministry of Health central office, Inspectorate, and the Bureau of Public Health are responsible for policies, standard setting, inspection and monitoring, and program development.

3.1 Policy Framework

In Suriname, a National Health Policy (NHP) exists. It was updated in 2004 [7] [8]. An official National Medicines Policy document exists also in Suriname. It was updated in 2005 [9]. A group of policies addressing pharmaceuticals exist [10]. The Board of Essential Medicines Policy, which comprises of different actors of the Pharmaceutical Column, acts as an advisory board to the Minister of Health and is responsible for formulating the NMP. It was established my Ministerial Decree and appointed by the Minister of Health - is responsible for implementation of the National Medicines Policy, and (through subcommittees) for maintaining the essential medicines list and developing standard treatment guidelines.

The NMP and the group of policies cover:

- ☑ Selection of essential medicines
- ☑ Medicines pricing
- ☑ Procurement
- ☑ Distribution and regulation
- ☑ Rational use of medicines
- ☑ Monitoring and evaluation
- ☑ Traditional medicine [9].

A NMP implementation plan for the period 2005-2008 also does exist [11].
Access to essential medicines/technologies as part of the fulfilment of the right to health, is recognized in the constitution or national legislation [9]. There are official written guidelines on medicines donations which are covered in the Policy Note [12].
The pharmaceutical policy implementation has been assessed in the past, but this does not happen on a regular basis.
The WHO Level II survey in 2010 is the most recent assessment. The board for Essential Medicines Policy is responsible for the monitoring of the pharmaceutical policy [5] [9].

There is not a national good governance policy in Suriname, nor has one been developed as part of the public sector reform program.
For medicines, the inspectorate/MoH is responsible for overlooking the adherence to legislation [13].
There is no formal policy in place to manage and sanction conflict of interest issues in pharmaceutical affairs, but there are provisions in different documents. As a small country, there are constraints on human

Although there is no good governance policy, courts recognize the general principles of good governance. The government must ensure its actions and decisions comply with the following general principles:

- Governments actions need to be carefully prepared and include proper treatment of citizens, careful examination of the facts and interests and follow due procedure in decision making.
- The government must treat equal cases equally.
- If government creates expectation through its decisions, it is legally bound in fulfilling them.
- The government must justify its decisions: the facts must be correct and the reasoning should be logical and understandable.
- The government should formulate its decisions so that citizens know exactly where they stand or what the government requires of them.
- Governments should apply rules and regulations correctly and consistently.
- The government should ensure that the burdens or adverse effects of a government decision on a citizen should not exceed the general importance of the decision.
- The government should use statutory power only for the purpose for which power is given.
- The government may not follow the wrong procedure in its decision making.
- The government must be neutral, and express the necessary transparency and honesty in its decision making process [5] [13] [14].

resources in the MoH and separating all duties may not optimize the use of these resources. The alternative found currently being analyzed for use is to have conflict of interest declared and to manage it with a disclosure protocol in such way so to ensure that it does not unduly influence decision making [5]. There is not a formal code of conduct for public officials [14].

There is no whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of Suriname. The pharmaceutical inspectorate supervises adherence to laws and regulations [6].

3.2 Intellectual Property Laws and Medicines

Suriname is a member of the World Trade Organization [15]. The country has patent law [16] [17], but the national legislation has not been modified to implement the TRIPS Agreement, although draft legislation exists, which is TRIPS adherent. No patenting of pharmaceuticals occurs in the country to date. Suriname is not eligible for the transitional period to 2016.

Current laws do not contain (TRIPS) flexibilities and safeguards:

Compulsory licensing provisions that can be applied for reasons of public health	**Not present (present in draft legislation)**
Bolar exceptions	**Not present (present in draft legislation)**
Parallel importing provisions	**Not present**

The country is engaged in initiatives to strengthen capacity to manage and apply intellectual property rights to contribute to innovation and promote public health. There are no legal provisions for data exclusivity for pharmaceuticals. Legal provisions do not exist for patent extension. Laws do not exist for linkage between patent status and marketing authorization [17] [18].

3.3 Manufacturing

There are 3 licensed pharmaceutical manufacturers in Suriname. Suriname has no significant capacity for Research and Development for discovering new active substances, although the University and The Drug Supply Company have partnered to do research with international partners. The country does not produce active pharmaceutical ingredients (APIs), but there is limited capacity for the production of formulations from pharmaceutical starting material and for the repackaging of finished dosage forms.
The percentage of market share of pharmaceuticals produced by domestic manufacturers is 3 %. This is based on the sales of manufactured medicines of BGVS as part of their total volume of sales [17] [19].

Export of locally manufactured medicines is not done, and there is no research based pharmaceutical industry. For BGVS, the manufacturing arm is apparently not a substantial part of their operations; In 2007, BGVS sales of manufactured medicines amounted to USD 300,000 (preliminary figures).

3.4. Distribution and dispensing

There are 26 licensed pharmaceutical importers, the largest being the government owned Drug Supply Company Suriname (BGVS). For BGVS, the value of imported medicines was approximately USD 5 Million in 2007. Figures for the other importers were not available. Based on estimates that BGVS has a market share of around 30 to 50% the total value of imported medicines could be around USD 10 Million.

Twenty-eight pharmacies are licensed. This number includes the pharmacies operating in the public (3) and private (2) hospitals and the Regional Health Services pharmacy. Retail pharmacies are concentrated in the urban areas of Paramaribo and Nickerie (2) and Commewijne (1). Most of them provide services to clients registered with the State Health Insurance Fund and can provide pharmaceutical services for its members. In addition, there are

dispensaries (e.g. Military Hospital, Regional Health Services clinics) and drug stores authorized to sell a limited number of medicines (OTC) to (selected) clients.

Section 4 - Regulation

This section covers a broad range of pharmaceutical regulatory policy, institutions and practices in Suriname.

4.1 Regulatory Framework

In Suriname, there are legal provisions establishing the powers and responsibilities of the medicines regulatory authorities (MRA). Authority to administer the medicines laws are centralized with Ministry of Health executives overseeing regulation and enforcement and the regulatory functions are performed by different departments of the MoH. There is no established regulatory authority that encompasses all standard regulatory functions. Medicines regulation responsibilities are currently divided between two entities, the Pharmaceutical Inspectorate and the Registration Committee:

- The powers and duties of the Pharmaceutical Inspectorate are not established by law. Currently activities are carried out on behalf of the Director of Health (previously the 'Medical Inspector' with defined duties for inspection of pharmacies under the 'Supervision of Public Health' Act of 1938). Powers and role of inspectors are also mentioned in the new Standards Act of 2004.
- The Registration Committee is the body that issues marketing approval for medicines. As stipulated in the Act of 1973, members are appointed by the President of the Republic of Suriname on recommendation of the Ministry of Health. The Registration Committee reports to the Director of Health, but it is otherwise independent.

The MRA does not have its own website. The MRA is involved in harmonization/collaboration initiatives. These include the Pan American Network in Drug Regulatory Harmonization (PANDRH), the Caribbean Community (CARICOM) and the Union of South-American Nations (UNASUR).

Two reports on the medicines regulatory system have been produced in the last five year. These are the *Regional Assessment of Drug Registration and Regulatory Systems in CARICOM Member States and the Dominican Republic* (2009), and the *MoH Suriname/HERA report on Strengthening of Pharmaceutical Quality Assurance & Legislation* [5] [18] [19].

4.2 Marketing Authorization

In Suriname, there are legal provisions requiring marketing authorization (registration) for all pharmaceutical products on the market. The Packed Medicine or Registration Act of 1973 made registration mandatory and established a registration committee. Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products. The number of pharmaceutical products registered in Suriname is 2,777 (June, 2010). Legal provisions require the MRA to make the list of registered pharmaceutical products publicly available regularly. This register is constantly updated in real time. It is not accessible through the internet, but it is available upon request from the Registration Bureau. Medicines are registered by their INN (International Non-proprietary Names) or Brand name + INN. Legal provisions require a fee to be paid for Medicines Market Authorization (registration) of applications [5] [20].

4.3 Regulatory Inspection

In Suriname, legal provisions exist allowing for appointment of government pharmaceutical inspectors. Pharmaceutical Inspections are carried out on behalf of the Director of Health (previously the 'Medical Inspector') with defined duties for inspection of pharmacies under the 'Supervision of Public Health' Act of 1938. Powers and role of inspectors are also mentioned in the new Standards Act of 2004. The Regulatory Authority has 3 inspectors. There are Legal Provisions permitting inspectors to inspect premises where pharmaceutical activities are performed, but there are no legal provisions requiring inspections to be performed.

Inspection is not a pre-requisite for licensing facilities. Although inspection is not a pre-requisite for licensing of facilities; nevertheless, there is a need to prove the compliance with the regulation and legal requirements. Inspections are a way to verify the compliance. Inspection requirements are the same for public and private facilities [5] [21]. The country is currently engaged in establishing a multi-disciplinary committee that has to advise MOH on its licensing and permit policies, based on the HERA recommendations.

4.4 Import Control

There are legal provisions related to importation of medicines for:

- Sampling of imported products for testing.
- Requiring importation of medicines through authorized ports of entry.
- Inspection of imported pharmaceutical products at the authorized port of entry [21-23].

4.5 Licensing

In Suriname, legal provisions exists requiring manufacturers to be licensed, but there are no regulations requiring manufacturers to comply with Good Manufacturing Practices (GMP). Good Manufacturing Practices are not published by the government.

Legal provisions also exists requiring importers, wholesalers and distributers to be licensed. However, the distinction between importers, wholesalers and distributors is not clear in Suriname. There are no legal provisions requiring wholesalers and distributors to comply with Good Distributing Practices and National Good Distribution Practices are not published by the government.

Legal provisions exists requiring pharmacists to be registered and requiring private and public pharmacies to be licensed. However, National Good Pharmacy Practice Guidelines are not published by the government [5] [23] [24].

4.6 Market Control and Quality Control

In Suriname, there are legal provisions for controlling the pharmaceutical market. There is a laboratory for Quality Control testing. The laboratory is currently not independent as it is a part of BGVS. The country is engaged in efforts to improve on pharmaceutical laboratory testing; new equipment has been procured and it is expected that an independent laboratory will be established at the Central Laboratory in 2012. Samples are collected by government inspectors for undertaking post-marketing surveillance testing. The laboratory routinely samples imported medicines, locally produced medicines, and also analyzes for third parties on request. For the imported medicines, reports of analysis are shared with the Inspectorate before marketing the product. In 2009, 370 samples were taken for quality control testing. Of the samples tested, 2 failed to meet the quality standards. The results are not publicly available [5] [21] [25].

As a CARICOM Member State, Suriname is allowed to use the services of the Caribbean Regional Drug Test Laboratory (CRDTL)- This Laboratory serves CARICOM member states and it is becoming part of the Caribbean Public Health Agency (CARPHA). The structure and functioning of the CRDTL has not been assessed formally to include this laboratory in the MRA structure of the country

4.7 Medicines Advertising and Promotion

In Suriname, there are legal provisions to control the promotion and/or advertising of prescription medicines. However, the enactment of the related committee was never done and specific regulations were not made; the legal framework remains therefore incomplete. There are no legal provisions prohibiting direct advertising of prescription medicines to the public and requiring a pre-approval for medicines advertisements and promotional materials. Also, Guidelines/Regulations do not exist for advertising and promotion of non-prescription medicines. There is no national code of conduct concerning advertising and promotion of medicines by marketing authorization holders [5] [23].

4.8 Clinical Trials

In Suriname, the legal provision requires authorization for conducting Clinical Trials. There is the Decree C-46 no. 75 regarding the consent that the Director of Health has to grant for medical investigative examinations to be conducted on persons. This decree was established to prevent exposing the population to unscrupulous research. There are Laws requiring the agreement by an ethics committee/institutional review board of the Clinical Trials to be performed. The national ethics committee is related to advising in Ethical Aspects of Research involving Human beings. The committee was established by an ordinance of the MoH, advising the Director of Health, who has the legal mandate to take decisions related to research [5] [26].

4.9 Controlled Medicines

Suriname is signatory to the:

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

There are laws for the control of narcotic and psychotropic substances, and precursors. The annual consumption of Morphine is 0.4587 mg/capita [5] [27-29].

4.10 Pharmacovigilance

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

A Pharmacovigilance (PV) Centre has been established in 2006, but currently it is not part of a regulatory authority. The centre currently employs two staff members and an intern. It is envisioned that the PV centre will be incorporated (also legally) in the NDRA.

An official standardized form for reporting ADRs is available. A national ADR database exists in Suriname. In the past 2 years, 220 ADR reports were sent to the WHO database in Uppsala. ADRs are monitored in at least one public health program. Active monitoring of ADRs is conducted for HIV/AIDS, Malaria, TB and Immunization programs besides the voluntary reports received. The pharmacovigilance is implemented in the programme roll out [5] [30]. Immunization ADRs (ESAVI's) are recorded in a specially designed WHO database.

Section 5 - Medicines Financing

In this section, information is provided on the structure of user fees for medicines and on the existence of public programmes providing free medicines. Policies and regulations in place that affect the prices of medicines (e.g. price control and taxes) are presented.

5.1 Medicines Coverage and Exemptions

The Ministry of Social Affairs in Suriname funds health services for the poor and near poor. The Ministry of Health is tasked with the general care of the population, especially for the elderly, physically and mentaly challenged people and the youth; and the social security system with sister ministries, to ensure social care and security. The Ministry of Health, in this regulation is tasked with health care in the widest sense of the word; supervision and surveillance, accessibility and availability of services throughout the country, including medicines and health products. The country is involved in an excercise to develop and pass a mandatory general health insurance law. The bill has been made. It is expected that in the next 5 years it will be passed and implemented. http://www.volksgezondheid.gov.sr/azv.html

Public programmes exist providing free medicines for:

- ☑ malaria,
- ☑ tuberculosis,
- ☑ sexually transmitted diseases,
- ☑ HIV/AIDS, and
- ☑ Extended Programme of Immunization (EPI) - vaccines.

All health insurance schemes in Suriname cover medicines. The coverage depends on the origin/status of the patient and small fixed co-payments may be requested. The public servants are covered by the State Health Insurance Foundation (SZF) and The Ministry of Social Affairs in Suriname, finances health

care delivery, amongst others Essential Medicines to the poor and near poor thru MOH facilities.

Private coverage is provided by private security schemes and companies.

Health insurance provides coverage for medicines that are on the Essential Medicines List (EML) for both inpatients and outpatients. Private health insurance schemes provide medicines coverage. They are required to provide at least partial coverage for medicines that are on the EML. Most private health insurance schemes have as a basis the EML, but certain conditions may be excluded from treatment.

Private pharmacies are contracted to dispense medicines to patients with public health insurance for civil servants and similar entities ('Staatsziekenfonds'). Similarly, certain public health programs such as the National Aids Programme have emulated this model to ensure service delivery to specific categories of patients.

The table below describes the coverage for different groups of patients:

Main Source of Patients	Insurance Scheme	Medicines coverage	Comments	Copayment (SRD)
Civil servants & families	State Health Insurance Foundation (Staatszieken Fonds, SZF)	EML	Social Insurance	0-2,00/ prescription item
Poor & near Poor	Ministry of Social Affairs	EML	Social Insurance	0,50-1,00/ prescription leaflet
Private citizens or companies paying annual fee for health insurance	Private Insurers	EML & EML +	Fee depends on coverage/ cases where 'expensive' drugs on EML associated with specific conditions have been have been removed from coverage	None

Workers & families	Companies	Tailor made/ sometimes EML based	Tailor made	None
Specific Diagnosed patients	MOH Programmes	Established package of medicines treating condition	eg. TB, Malaria, HIV-AIDS (HAART & OI medicines)	None

In the event that a patient requires medicine which is not included in the EML, the situation is assessed and an approval from the 'Geneeskundige Commissie' is required both for in and out patients. The 'Geneeskundige Commissie' is established by law [5] [31] [32].

5.2 Patients Fees and Copayments

In the health system of Suriname, at the service delivery point, there are no fee requirements for consultations if the patient has health insurance, but there are fixed copayments for medicines in several cases (see table above). These copayments are based on fees for services and are subtracted from the final bill that is presented by pharmacies to the funding agent.
The medicines from the Essential Medicines List are provided on a fixed co-payment basis. The civil servants are covered by the State Health Insurance Foundation (SZF) (mandatory). The SZF also insures private patinets against a fee. If prescription items are dispensed based on an SZF prescription, patients pay a fixed fee SRD 2.00 per prescription line, senior citizens pay SRD 0.50 cents per pescription item and certain categories of civil servants are exempt from payment. For clients whose medical costs are covered by other financiers, the out of pocket contribution varies from SRD 0 to SRD 1.00 per prescription leaflet. Salaries of public health personnel are part of the regular budgetary expenditures. 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 [5] [31].

5.3 Pricing Regulation for the Private Sector (not including the non-profit voluntary sector)

In Suriname, there are legal or regulatory provisions affecting pricing of medicines. These provisions are aimed at the level of manufacturers, wholesalers and retailers. The legislation establishes maximum allowed sale prices and maximum profits (for example, for retailer pharmacies the price cannot be more than 35% above the wholesaler price). In Suriname, commodities which have been deemed medicines may only be sold to patients by pharmacies or in certain instances ie. Over the Counter (OTC) medicines in lincensed drugstores. Prices have to be submitted to the Pharmaceutical Inspectorate for each importation, calculated based upon the established model by the Ministry of Trade. The State funding agents (Staatsziekenfonds and ministry of social affairs and housing) also establish reimbursement prices of medicines based on prices of wholesalers (ie. model contract between SZF and Pharmacies). A special unit from Ministry of Trade monitors the prices, but there are no regulations mandating that retail medicine price information should be publicly accessible. The *Law SB 2005, no 43, establishing the tariffs in health care* provides for the possibility for public availability of information but it was not implemented [5] [9] [23] [33].

5.4 Prices, Availability and Affordability of Key Medicines

The Ministry of Health received training in January 2010 and was preparing to conduct a WHO/HAI pricing survey on medicines by the time this publication was prepared.

5.5 Duties and Taxes on Pharmaceuticals (Market)

There are duties on imported raw materials and on imported finished products. Import duties ranging from 0% to 40% can be applied on raw materials for pharmaceutical purposes. Active substances have a duty of 5%. Drugs (in dosage

forms) have a duty between 0% and 15%. The category 0 % applies to resources of interest to public health (e.g. insulin). VAT on pharmaceuticals or any other product is 1.5%. VAT on finished pharmaceutical products is 0% [34].
There is no linkage between EML status and duties incurred, although it has been recommended that this link be established.

Section 6 - Pharmaceutical procurement and distribution in the public sector

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

6.1 Public Sector Procurement

The public sector procurement in Suriname is centralized and decentralized. There is a central procurement agency, BGVS, which is a public-owned autonomous agency. Yet, pharmacies can also buy from private distributors.

The public sector tender bids and awards are publicly available. The unregistered products of suppliers of products not yet registered have to be prequalified, but this is not necessary for suppliers that intend to supply registered medicines. If an unregistered drug is potentially awarded, the supplier is supposed to register before a contract will be awarded. [5] [25] [35].

In 1983 the government reorganized pharmaceutical procurement, distribution and dispensing by establishing the *'Bedrijf Geneesmiddelen Voorziening Suriname'* (BGVS, Medicines Supply Company Suriname). The main objective of the BGVS was to ensure the supply of essential medicines and supplies of assured quality and affordable price.
The BGVS is a state-owned company located in the north of Paramaribo. Its predecessor was part of the Pharmaceutical Services Department of the Ministry of Health.
Legally, the BGVS is a "sui generis" company, which means that its rules, responsibilities, and activities are regulated by the BGVS decree, rather than by a corporate act, as in the case of a "limited company". The most important regulations in the decree are:

- The Minister of Health appoints a Board of Directors, which has three to seven members
- The Board of Directors nominates the General Manager and, if needed, Deputy-General managers, who are appointed by the Minister of Health.
- The General Manager is responsible for the day-to-day executive management of the company, with power to hire and fire personnel and effect payments
- The General Manager is also responsible for the annual budgets and financial reports. These documents need to be presented, after approval by the Board of Directors, to the Minister of Health within certain periods of time described in the decree. The financial accounts are subject to annual external audits.
- The public and private pharmacies can also buy from private distributors/wholesalers, besides the BGVS.

6.2 Public Sector Distribution

The government supply system department in Suriname has a Central Medical Store at a National Level (BGVS). There are 2 public warehouses in the secondary tier of the public sector distribution, namely:

- Medical Mission, a Faith Based Organization subsidized by Government and tasked with primary healthcare delivery in the interior;
- Regional Health Services, a government-owned foundation tasked with primary healthcare delivery in the coastal area, where there are no estabished pharmacies.

Both of these organizations operate warehouses for medicines in the capital from where medicines are distributed to their clinics. They procure from BGVS and also from other sources. The Regional Health Services also operate a pharmacy in Paramaribo. There are no national guidelines on Good Distribution Practices (GDP). There is not a licensing authority that issues GDP licenses. Importers/ distributors are required however to be licensed by the Ministry of Trade & Industries after having been duly advised by MOH (the Pharmaceutical Inspectorate). A list of GDP certified wholesalers and distributors in the public sector does not exist [5]. Currently about 20 importers/ wholesalers, including the BGVS has been licensed. The country is currently engaged in establishing a multi-disciplinary committee that has to advise MOH on its licensing and permit policies, based on the HERA recommendations.

6.3 Private Sector Distribution

Legal provisions exist for licensing wholesalers and distributors in the private sector of Suriname. A list of Good Distribution Practices (GDP) certified wholesalers and distributors does not exist in the private sector. There is no National regulation regarding GDP, nevertheless there are requirements for the storage and distribution of medicines, established by Ministry of Trade and Industry, which is the licensing authority.

Section 7 - Selection and rational use of medicines

This section presents the structures and policies that are in place in Suriname for selection of essential medicines and promotion of rational drug use.

7.1 National Structures

A National Essential Medicines List (EML) exists in Suriname and it is publicly available (http://www.volksgezondheid.gov.sr/ngk.html). The latest version of the national essential medicines list (4th edition) is dated October 2004. An addendum was published in 2007, 2008, 2009 and 2010; a complete review is scheduled for 2010-2011. There are approximately 315 active ingredients on it comprised in about 500 dosage forms. There is a written process for selecting medicines on the EML. 60% public health facilities have a copy of the EML [32] [36].

National Standard Treatment Guidelines (STGs) for the most common illnesses are not produced by the MoH in Suriname. There are number of guidelines produced and distributed in the country (e.g. HIV/AIDS, diabetes and hypertension), but there is no official booklet or compilation endorsed by the MoH. The Ministry has officially endorsed for Malaria and HIV (adults, children and PMTCT). In other infectious diseases international WHO endorsed guidelines are used. Standard Treatment Guidelines are developed by the Medical Profession. In conjunction with these and other stakeholders MOH is in the process of forming a protocol commission that has to develop STGs for especially the communicable diseases.

There is no public or independently funded national medicines information centre that provides information on medicines to prescribers, dispensers and consumers. A survey on rational use of medicines has been conducted in the previous two years. There is no national programme or committee, involving government, civil society, and professional bodies, to monitor and promote

rational use of medicines. There is no written National Strategy to contain antimicrobial resistance.

In the past a national antibiotics committee had been installed by ministerial order, however no final document was produced. Currently the MOH Laboratory Coordinator and the medical microbiologist of the Academic Hospital are in the process of developing a plan of action for developing a national antibiotics policy document including guidelines for rational use and surveillance. The Ministry of Health will re-activate the national antibiotics committee. Technical Assistance from Netherlands has been secured and a draft strategy for discussion is expected to be ready by 2011 [5] [32].

7.2 Prescribing

In Suriname, there are legal provisions to govern the licensing and prescribing practices of prescribers. Legal provisions exist to restrict dispensing by prescribers. The Pharmaceutical Act of 1896 is the basic regulatory framework and it was ammended several times.There are no regulations requiring hospitals to organize/develop Drug and Therapeutics Committees (DTCs).

The core medical training curriculum includes components on:

- ☑ The concept of EML
- ☑ Use of STGs
- ☑ Problem based pharmacotherapy [5] [37].

The core nursing training curriculum includes components on:

- ☑ The concept of EML
- ☑ Use of STGs
- ☑ Pharmacovigilance.

The core paramedical staff training curriculum includes components on:

- ☑ The concept of EML
- ☑ Use of STGs [38].

Mandatory continuing education that includes pharmaceutical issues is not required for doctors, nurses and paramedical staff, but continuing education is provided by MOH and entities such as SPAOGS (=foundation for Post Academic Education in Health Care[3].

Prescribing by INN name is not obligatory in the public and private sector. The average number of medicines prescribed per patient contact in public health facilities is 2. 73.6% of medicines prescribed to outpatients in public health care facilities are in the national EML and 45.5% are prescribed by INN name. 13.3% of outpatients in public health care facilities receive antibiotics and 3.3% receive injections. 89.6% of prescribed drugs in public health facilities are dispensed to patients and 100% are adequately labelled [5] [32]. No legal barriers exists to dispense generics when brand names are prescribed, and this is common practise, as reimbursement prices tend to be tied to the wholesale prices of generic medicines.

7.3 Dispensing

In Suriname, legal provisions exist to govern dispensing practices of pharmaceutical personnel [26]. There is no pharmacy school in the country, however vocational training for assistant pharmacists (3-4 year formal MOH supervised training) is undertaken Mandatory continuing education that includes pharmaceutical issues is not required for pharmacists, however pharmacists partake in SPAOGS and other training opportunities.
Substitution of generic equivalents at the point of dispensing in public and private sector facilities is allowed. The dispensing of antibiotics or injectables without prescription is not permited by the regulations. These regulations may not always be applied in practice and these items might be sold over-the-

[3] Stichting Post Academisch Onderwijs in de Geneeskunde Suriname http://www.spaogs.org/smartcms/default.asp?contentID=518).

counter. Yet there is no survey conducted and the extent of the issue is unknown [5] [37].

Section 8 - Household data/access

This section provides information about household surveys held in the past in Suriname regarding actual access to medicines by normal and poor households.

In the past 5 years, the WHO Level II household survey(s) has been undertaken to assess the access to medicines (2010).

In Suriname, 49% of adult patients with an acute condition took all medicines prescribed. Of the patients not taking all medicines, 23% reported that they did not because they could not afford them.

78% of adult patients with chronic conditions took all medicines prescribed [32].

Final considerations

The information presented is very useful as it reflects the whole pharmaceutical sector in the country and represents important tool for identifying gaps and challenges and establishing priorities.
Health and Demographic data shows a transitional demographic and epidemiological profile.
The governmental health expenditure corresponds to the 47.65 % of the total expenditure on health and the total pharmaceutical expenditure (TPE) in Suriname and the public expenditure on pharmaceuticals represented 12 % of the total expenditure on pharmaceuticals, with a high private expenditure on medicines (88%). The data shows the need of strengthening the medicines coverage in the public sector.
From the data from the health professionals presented, it is evident the constraint on pharmacists in the country (0.73/10,000). The development of a strategic plan for pharmaceutical human resource development would be recommended.
The National Medicines Policy, is dated from 2005 with an implementation plan for the period 2005-2008. This pharmaceutical profile, together with several other sources of evidence available as the surveys conducted at national level on the Pharmaceutical Situation and Quality Assurance and the surveys on Medicines Regulation and Intellectual Property Assessments conducted by CARICOM are important sources for updating the National medicines policy and to develop an implementation plan.
Suriname has extensive legal provisions, nevertheless they are old, and fragmented and need to be updated, to ensure a legal base for current issues and situations. At the same time, the institutional regulatory structure seems is fragmented, not integrated and not comprehensive and needs to be reviewed[4].

[4] MOH Suriname, based on a recommendation of the REG, in 2008 awarded a consultancy to analyze the current Quality and Legislative framework and propose changes and recommendations [18]

It is recommended changing the approach and the focus from the products to the patient and its safety. This is the tendency for the upcoming review of the National Pharmaceutical Policy and guidelines for good pharmacy practice to be developed. It will also include the different aspects of governance, with the strengthening of regulation and its essential regulatory functions with an adequate institutional framework and the necessary enforcement mechanisms and medicines and service provision with the respective quality assurance systems.

The financing mechanisms for medicines in the public sector, even though they may be considered complex and fragmented, are able to provide a comprehensive coverage and lay a foundation for a General Health Insurance, as is the goal of MOH. The ongoing process of review of the public health insurance represents a good opportunity for reviewing the financing and coverage mechanisms for medicines.

There is a good availability of the medicines from the NEML in the health facilities as 89.6% of prescribed drugs in public health facilities are dispensed to patients and 100% are adequately labelled. Nevertheless, the implementation of quality assurance systems with implementation of good practices in all steps of the pharmaceutical chain may be considered a priority for improving the quality of the services.

Regarding the Rational Use of Medicines, a positive aspect is the existence of the National Essential Medicines List (NEML), which is updated in real time. There is a relatively good adherence to the NEML as the 73.6% of medicines prescribed to outpatients in public health care facilities are in the national EML. Nevertheless, the medicines that are prescribed which use the INN needs to be improved as only 45.5% are prescribed by INN name in the public sector (as it is not mandatory).

Promoting rational use in the prescribing and dispensing can also be part of the priorities. Some measures to be adopted may be associated with the updating of the NEML, the development and adoption of Standard Therapeutic

Guidelines (STG) for the most significant clinical conditions as well as the capacity building for providing and using independent and unbiased medicines information.[5]

Once the priorities and gaps are identified, the data contained in this document is also useful as baseline for future interventions and to be established benchmarks as part of a strategic plan for the development of the public pharmaceutical sector in Suriname.

[55] The NEML Committee is involved in development of a website to promote transparency and give insight in its decision-making process. The website is in a pilot phase. It is expected that the website will be fully functional in 2011

References

[1] Macro-economic units. Paramaribo, General Bureau of Statistics in Suriname, 2007. Available at: http://www.statistics-suriname.org/images/stories/pdf/macro%5C%27s%202003-2007.pdf, 30-06-2010.

[2] World Health Statistics. Geneva, World Health Organization, 2010. Available through the Global Health Observatory: http://apps.who.int/ghodata/, 12-05-2010.

[3] National Health Information Systems (NHIS). Paramaribo, Ministry of Health of Suriname, 2007. Available at: http://www.paho.org/English/DD/AIS/surreport.pdf, 01-07-2010.

[4] National health accounts: country information Suriname. Geneva, World Health Organization, 2006. Available at: http://www.who.int/nha/country/sur/en/, 08-06-2010.

[5] The Ministry of Health of Suriname. Paramaribo, Available at: http://volksgezondheid.gov.sr/, 01-07-2010.

[6] Standaard overeenkomst Apotheken. Paramaribo, Stichting Staatsziekenfonds, 1993. (Dutch version only).

[6a] The Ministry of Health of Suriname. Office of the Pharmaceutical Inspectorate; annual collection of data 2010.

[7] Suriname health sector plan 2004-2008 'Health care: a joint responsibility'. Paramaribo, Ministry of Public Health Suriname, 2004. Available at: https://country-matrix-repository.box.net/shared/p5i4uvep4k#/shared/p5i4uvep4k/1/42637793/434491045/1, 29-07-2010.

[8] Country pharmaceutical situations. Fact book on WHO Level I Indicators 2007. Geneva, World Health Organization, 2007.

[9] National Medicines Policy Suriname 2005-2008. Paramaribo, Ministry of Health; Board for Essential Medicines, 2005. Available at: http://www.volksgezondheid.gov.sr/word/ngbenglish.doc, 01-07-2010.

[10] Note of quality Assurance of Medicines (2010)

[11] National Medicines Program Suriname 2005 – 2008 (implementation plan). Paramaribo, Ministry of Health Suriname, 2005. Available at: LINK/MEDNET, 2010.
[12] Adoption of WHO guidelines: Guidelines for drug donations. Geneva, World Health Organization, 1999. Available at: http://whqlibdoc.who.int/hq/1999/WHO_EDM_PAR_99.4.pdf, 29-07-2010 (update available in 2010).
[13] Governance manual: Country coordinating mechanism for the global fund to fight AIDS, TB and Malaria in Suriname (GF/CCM). Paramaribo: Ministry of Health/Global Fund, 2009.
[14] Civil servants act GB 1962 no. 17 (SB 186 no. 141 establishes general rules of procedure for all civil servants). Paramaribo, GOS, 1962.
[15] World Trade Organization, Geneva. Website: www.wto.org, 29-07-2010.
[16] Patent act (1910), reviewed in 1969.
[17] Regional assessment of patent and related issues and access to medicines. Reet, Health Research for Action (HERA)/Caribbean Community (CARICOM), 2009. Available at: http://pancap.org/index.php?option=com_content&task=view&id=195&Itemid=, 2010.
[18] Strengthening of pharmaceutical quality assurance & legislation. Reet, Health Research for Action (HERA)/Ministry of Health of Suriname, 2010 [internal working document].
[19] Regional assessment of drug regulation and regulatory systems. Reet, Health Research for Action (HERA)/Caribbean Community (CARICOM), 2009. Available at: LINK, DATE of last visit.
[20] The packed medicines or registration Act 1973 (Besluit verpakte geneesmiddelen GB 1973 no. 155).
[21] 'Supervision of Public Health Act of 1938'; Standard Acts of 2004.
[22] Decree of September 15, 1981 (Business and Professions Licensing Decree) No. 145 SB 1981.

[23] The amendment of GB1973, no. 1, from 4th of January 1973, further amending the Pharmaceutical Act of 1896.

[24] GB 1896 no.26 GB 1960 no 77 GB 1973 no1 GB 1973 no. 155.

[25] Bedrijf Geneesmiddelen Voorziening (Drug Supply Company) Suriname. Paramaribo, Ministry of Health prequalification document etc. Website: http://www.volksgezondheid.gov.sr/procurementsbgvs.html, 28-07-2010.

[26] Decree C46 no 75 of 6 June 1981

[27] Report of the International Narcotics Control. Vienna, International Narcotics Control Board, 2009. Available at: www.incb.org, 08-06-2010.

[28] Law of February 12 1998 (SB 1998) no 14: Also called the Narcotic Drugs Act; Opium Act of 1955 (GB 1955 no. 91, mo.37 as last amended by SB 1988).

[29] Evaluation of progress in drug control Suriname 2005-2006. Washington, Organization of American States, 2006. Available at: http://apps.who.int/medicinedocs/en/m/abstract/Js17101e/.

[30] Implementing pharmacovigilance in Suriname 2006-2009. Paramaribo, PAHO/WHO; Ministry of Health, 2009. Available at: http://apps.who.int/medicinedocs/documents/s17112e/s17112e.pdf.

[31] Wet van tot vaststelling van de 14-E afdeling van ontwerp begroting van uitgaven en ontvangsten voor het dienstjaar 2010 betreffende het ministerie van volksgezondheid (Law for design of the health budget: Expenditure and income regarding the Ministry of Health for 2010; *National approved budget*). Paramaribo, Republic of Suriname, 2010.

[32] DRAFT WHO Level II Survey Suriname, 2010. *Not published yet*.

[33] Laws and decrees regarding pricing of medicines:

- Decree E-2A SB 1980 no. 82;
- Decree SB 1981 no. 172;
- Decree SB 1984, no. 66;
- Decree SB 1986 no. 2;
- Law SB 1989, no. 42;
- Law SB 2005, no. 43

[34] CARICOM external tariff 2007 (Tarieflijst). Paramaribo, Ministry of Finance, 2008.
[35] Decree SB 1983 no 20
[36] Nationale Geneesmiddelenklapper 4de editie (EML). Paramaribo, Ministry of Health of Suriname, 2004. Available at: http://volksgezondheid.gov.sr/pdf/ngkachtergrond.pdf, 28-07-2010.
[37] The Pharmaceutical Act of 1896.
[38] De Stichting Centrale opleiding voor Verpleegkundigen en beoefenaren van Aanverwante Beroepen (C.O.V.A.B.) (Nursing school), Paramaribo. Website: http://www.covab.sr/index.htm, 29-07-2010.

Suriname Pharmaceutical Country Profile

ANNEX

Survey Data

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Drs. Naomi Jesurum, Pharm D (Pharmacovigilance)
Drs. Sheila Kort PhD (Quality Control Lab/BGVS)

Section 1 Health and Demographic data

1.01 Demographic and Socioeconomic Indicators

Core Questions

Population, total (,000)	509,970	2007	General Bureau of Statistics in Suriname
Population growth rate (Annual %)	1.15	2007	General Bureau of Statistics in Suriname
GDP growth (Annual %)	5.0	2007	General Bureau of Statistics in Suriname
GNI per capita (US$ current exchange rate)	4,678.57	2007	General Bureau of Statistics in Suriname
Supplementary questions			
Population < 15 years (% of total population)	30	2007	General Bureau of Statistics in Suriname
Population > 60 years (% of total population)	9	2007	General Bureau of Statistics in Suriname
Urban population (% of total population)	72.3	2007	General Bureau of Statistics in Suriname
Fertility rate, total (Births per woman)	2.53	2010	General Bureau of Statistics in Suriname
Adult literacy rate, 15+ years (% of total population)	92.2	2007	General Bureau of Statistics in Suriname

1.02 Mortality and Causes of Death

Core questions

Life expectancy at birth for men (Years)	66	2007	World Health Statistics
Life expectancy at birth for women (Years)	73	2007	World Health Statistics
Infant mortality rate, between birth and age 1 (/1,000 live births)	21	2007	GBS. Census 7, 2004
Under 5 mortality rate (/1,000 live births)	19	2010	GBS. Census 7, 2004
Maternal mortality ratio (/100,000 live births)	72	2005	World Health Statistics
Please provide a list of top 10 diseases causing mortality	1 Cardiovascular diseases 2 External causes of death: Accidents, violence and injuries, homicide, suicide 3 Malignancies 4 Diseases originating in de Perinatal Period 5 Diabetes Mellitus 6 HIV / AIDS 7 Acute Respiratory infections	2007	NHIS

	8 Diseases of the Urinary tract 9 Liver cirrhosis and other chronic Liver diseases 10 Congenital disorders.		
Please provide a list of top 10 diseases causing morbidity	▪ in the primary health care setting: Five leading (syndromal) diagnoses at PHC consultations in children <5 years 1 Lower respiratory disorders 2 Symptoms not elsewhere classified 3 Skin disorders 4 IIntestinal infections 5 Helminthiasis Five leading (syndromal) diagnoses at PHC consultations in adults >20 years 1 Hypertension 2 Symptoms not elsewhere classified 3 Hypertension and Diabetes 4 Diabetes 5 Symptoms of the musculo-skeleton system e.g. ischiatic pain, (lower) back pain, joint pain ▪ in the Secondary health care setting: 1 Cardiovascular diseases 2 Communicable diseases 3 External causes: accidents, violence, injuries, 4 Pregnancy, childbirth, and the puerperium 5 Malignancies	2007	NHIS
Supplementary questions			
Adult mortality rate for both sexes between 15 and 60 years (/1,000 population)	3.5	2007	MoH Statistics

Neonatal mortality rate (/1,000 live births)	14	2007	MoH Statistics
Age-standardized mortality rate by non-communicable diseases (/100,000 population)	728	2004	World Health Statistics
Age-standardized mortality rate by cardiovascular diseases (/100,000 population)	389	2004	World Health Statistics
Age-standardized mortality rate by cancer (/100,000 population)	109	2004	World Health Statistics
Mortality rate for HIV/AIDS (/100,000 population)	30	2007	MoH Statistics
Mortality rate for tuberculosis (/100,000 population)	2	2007	MoH Statistics
Mortality rate for Malaria (/100,000 population)	0	2006	MoH Statistics
Comments	No age standardized mortality rates are available, so correction of the pre-filled spaces was not possible.		

Section 2 Health Services & Expenditure

2.01 Health Expenditures

Core Questions

Total annual expenditure on health (millions US$ average exchange rate)	192	2006	National Health Accounts
Total annual expenditure on health (millions NCU)	527	2006	NHA
Total health expenditure as % of Gross Domestic Product	8.5	2006	NHA
Total annual expenditure on health per capita (US$ average exchange rate)	324	2006	NHA
Total annual expenditure on health per capita (NCU)	892	2006	NHA
General government annual expenditure on health (millions US$ average exchange rate)	70	2006	NHA
General government annual expenditure on health (millions NCU)	192	2006	NHA
Government annual expenditure on health as percentage of total government budget (% of total government budget)	13.6	2006	NHA
Government annual expenditure on health as % of total expenditure on health (% of total expenditure on health)	42.6	2006	NHA
Annual per capita government expenditure on health (US$ average exchange rate)	138	2006	NHA
Annual per capita government expenditure on health (NCU)	380	2006	NHA
Private health expenditure as % of total health expenditure (% of total expenditure on health)	52.3	2006	NHA
Population covered by a public health service or public health insurance or social insurance, or other sickness funds (% of total population)	53		
Total pharmaceutical expenditure (millions US$ current exchange rate)	18.83	2006	NHA
Total pharmaceutical expenditure (millions NCU)	51.78	2006	NHA
Total pharmaceutical expenditure per capita (US$ current exchange rate)	37.34	2006	NHA
Total pharmaceutical expenditure per	102.68	2006	NHA

capita (NCU)			
Pharmaceutical expenditure as a % of GDP (% of GDP)	0.98	2006	NHA
Pharmaceutical expenditure as a % of Health Expenditure (% of total health expenditure)	12	2006	NHA
Total public expenditure on pharmaceuticals (millions US$ current exchange rate)	2.24	2006	NHA
Total public expenditure on pharmaceuticals (millions NCU)	6.17	2006	NHA
Share of public expenditure on pharmaceuticals as percentage of total expenditure on pharmaceuticals (%)	12	2006	NHA
Total public expenditure on pharmaceuticals per capita (US$ current exchange rate)	4.44	2006	NHA
Total public expenditure on pharmaceuticals per capita (NCU)	12.22	2006	NHA
2.02 Health Personnel and Infrastructure			
Core Questions			
Total number of pharmacists licensed/registered to practice in your country	37	2010	National Health Information Systems (NHIS)
Total number of pharmacists working in the public sector	10	2010	MoH/PCC
Total number of pharmaceutical technicians and assistants	-	2010	Pharmaceutical Inspectorate
A strategic plan for pharmaceutical human resource development is in place in your country?	No	2010	MoH
Total number of physicians	500	2010	NHIS
Total number of nursing and midwifery personnel	916	2010	NHIS
Total number of hospitals	6	2010	NHIS
Total number of hospitals bed	1,585	2010	NHIS
Total number of primary health care units and centres	736	2010	NHIS
Total number of licensed pharmacies	27	2010	NHIS
Supplementary Questions			
Starting annual salary for a newly registered pharmacist in the public sector - NCU	67,200	2010	Government Hospital/MoH net Civil Servant pharmacist working in hospital gross
Total number of pharmacists who graduated (first degree) in the past 2 years in your country	0	2010	Suriname does not have a pharmacy school

Comments	- A Hospital is a foundation not adherent to civil servant salary scale; - Suriname does not have a Pharmacy School;

Section 3 Policy issues

3.01 Policy Framework

Core Questions

National Health Policy exists. If yes, please write year of the most recent document in the "year" field.	Yes	2010	WHO Level I -
National Medicines Policy official document exists. If yes, please write the year of the most recent document in the "year" field.	Yes	2005	MoH http://www.volksgezondheid.gov.sr/word/ngbenglish.doc
Group of policies addressing pharmaceuticals exist.	Yes	2010	Note of Quality Assurance of Medicines (2010) - PPC/MOH
National Medicines Policy covers the following components:			
Selection of Essential Medicines	Yes		
Medicines Financing	Yes		
Medicines Pricing	Yes		
Medicines Procurement	Yes		
Medicines Distribution	Yes		
Medicines Regulation	Yes		
Pharmacovigilance	No		
Rational Use of Medicines	Yes		
Human Resource Development	No		
Research	No		
Monitoring and Evaluation	Yes		
Traditional Medicine	No		
National medicines policy implementation plan exists. If yes, please write year of the most recent document in the "year" field and attach document or provide URL below*	Yes	2005	PPC/MoH
Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution or national legislation?	Yes	2005	NMP/MoH
There are official written guidelines on medicines donations.	Yes	2007	Adoption of WHO guidelines
Is pharmaceutical policy implementation being regularly monitored/assessed?	No	2010	MoH
Who is responsible for pharmaceutical policy monitoring?	Board for Essential Medicines Policy - See NMP		

Is there a national good governance policy?	No	2010	MoH/PPC
A policy is in place to manage and sanction conflict of interest issues in pharmaceutical affairs.	No	2010	MoH
There is a formal code of conduct for public officials. Please attach document or provide URL below *	No	1962	MOH - Civil servants Act GB1962 no. 17 last changed SB 186 no. 41 establishes general rules of procedures for all Civil Servants.
Is there a whistle-blowing mechanism allowing individuals to raise a concern about wrongdoing occurring in the pharmaceutical sector of your country (ombudsman)?	No	2010	PPC/MoH
Please describe:	There is no (national) ombudsman. The pharmaceutical Inspectorate supervises adherence to laws and regulations		
Comments	For medicines - the Inspectorate/moH is responsible for overlooking the adherence to legislation/regulation		
3.02 Intellectual Property Laws and Medicines **Core Questions**			
Country is a member of the World Trade Organization	Yes	2010	WTO website
Legal provisions provide for granting of Patents on pharmaceuticals	Yes	2010	Patent Act (1910), reviewd in 1969 and it is not enforced as no pharmaceutical patents are granted (HERA/CARICOM, 2010)
National Legislation has been modified to implement the TRIPS Agreement	No	2010	HERA consultant report for MoH & Caricom
Current laws contain (TRIPS) flexibilities and safeguards	No	2010	HERA consultant report for MoH & Caricom
Country is eligible for the transitional period to 2016	No	2010	HERA consultant report for MoH & Caricom
Which of the following (TRIPS) flexibilities and safeguards are present in the national law?			
Compulsory licensing provisions that can be applied for reasons of public health	No	2010	HERA consultant report for MoH & Caricom
Bolar exception	No	2010	HERA consultant report for MoH & Caricom

Are parallel importing provisions present in the national law?	No	2010	HERA consultant report for MoH & Caricom
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	2010	HERA consultant report for MoH & Caricom
Are there legal provisions for data exclusivity for pharmaceuticals	No	2010	HERA consultant report for MoH & Caricom
Legal provisions exist for patent extension	No	2010	HERA consultant report for MoH & Caricom
Legal provisions exist for linkage between patent status and marketing authorization	No	2010	HERA consultant report for MoH & Caricom
3.03 Manufacturing **Core Questions**			
Number of licensed pharmaceutical manufacturers in the country	3	2009	Caricom Hera Report DRA
Country has manufacturing capacity for:		2010	Caricom Hera Report IP
R&D to discover new active substances	No		
Production of pharmaceutical starting materials (APIs)	No		
Production of formulations from pharmaceutical starting material	Yes		
Repackaging of finished dosage forms	Yes		
Percentage of market share by value produced by domestic manufacturers (%)	3 %	2010	PPC/MOH based on HERA/CARICOM DRA Report (2009)
Supplementary Questions			
Number of multinational pharmaceutical companies manufacturing medicines locally	0	2010	MoH/PPC
Number of manufacturers that are GMP certified	0	2010	MOH PPC/ HERA DRA reports (caricom & MOH)

Section 4 Regulation

4.01 Regulatory Framework

Core Questions

Are there legal provisions establishing the powers and responsibilities of the medicines regulatory authority?	Yes	2010	HERA MoH QA consultants report
Part of MOH	Yes		
Semi autonomous agency	Yes		
Other (specify)	The regulatory functions are performed by different units of the MoH. They are residing in one regulatory authority		
The MRA has its own website	No	2010	MoH/PPC
The MRA is involved in harmonization/ collaboration initiatives	Yes	2010	MoH/PPC
- If yes, please specify	Pan American Network on Drug Regulatory Harmonization (PANDRH)/ CARICOM/ UNASUR		
An assessment of the medicines regulatory system has been conducted in the last five years.	Yes	2009 - 2010	HERA/CARICOM/MoH
Comments	CARICOM/HERA. Regional Assessment of Drug Registration and Regulatory Systems in CARICOM Member States and the DR, 2009. MoH/HERA Strengthening of Pharmaceutical Quality Assurance & Legislation		

Supplementary Questions

Formal code of conduct exists for staff involved in medicines regulation	No	2010	MoH
Medicines Regulatory Authority gets funds from regular budget of the government.	Yes	2010	MoH Budget
Medicines Regulatory Authority is funded from fees for services provided.	No	2010	Officially fees for service go to the government of Suriname (GOS) Central Finances
Medicines Regulatory Authority receives funds/support from other	Yes	2010	MoH/PPC

sources			
- If yes, please specify	Grants & Donor funds through MOH. Eg. IDB Grant		
Revenues derived from regulatory activities are kept with the regulatory authority	No	2010	MoH/Registration Cie
The Regulatory Authority is using a computerized information management system to store and retrieve information on registration, inspections, etc.	Yes	2010	MoH/MRA
Comments	The regulatory system has to be reviewed and the functions have to be optimized.		
4.02 Marketing Authorization (Registration) **Core Questions**			
Legal provisions require a marketing authorization (registration) for all pharmaceutical products on the market	Yes	1973	The Packed Medicine or Registration Act of 1973 (Besluit Verpakte Geneesmiddelen GB 1973 no. 155)
Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products	Yes	1973	The Packed Medicine or Registration Act of 1973 (Besluit Verpakte Geneesmiddelen GB 1973 no. 155)
Number of pharmaceutical products registered in your country	2,777	2010	Registered Packed Pharmaceuticals in June, 8th 2010. Source: Registration Bureau/MOH
Legal provisions require the MRA to make publicly available the registered pharmaceutical with defined periodicity	Yes	1973	The Packed Medicine or Registration Act of 1973 (Besluit Verpakte Geneesmiddelen GB 1973 no. 155)
- If yes, how frequently updated	Real time		
- If yes, please provide updated list or URL *	Not available on internet - List is available upon request from Registration Bureau (attached)		
Medicines are registered by their INN (International Non-proprietary Names) or Brand name + INN	Yes	2010	Registration Bureau/MoH
Legal provisions require paying a fee for Medicines Market Authorization (registration) applications	Yes	1973	The Packed Medicine or Registration Act of 1973 (Besluit Verpakte Geneesmiddelen GB 1973 no. 155)

Supplementary Questions			
Legal provisions require marketing authorization holders to provide information about variations to the existing marketing authorization	Yes	1973	The Packed Medicine or Registration Act of 1973 (Besluit Verpakte Geneesmiddelen GB 1973 no. 155)
Legal provisions require to publish the Summary Product Characteristics (SPCs) of the medicines registered	No	2010	MoH/PPC
Legal provisions require the establishment of an expert committee involved in the marketing authorization process	Yes	1973	The Packed Medicine or Registration Act of 1973 (Besluit Verpakte Geneesmiddelen GB 1973 no. 155)
Certificate for Pharmaceutical Products in accordance with the WHO Certification scheme is required as part of the marketing authorization application	Yes	2007	RB and CPP/MoH
Legal provision require declaration of potential conflict of interests for the experts involved in the assessment and decision-making for registration	Yes	2010	Law: Landsverorderning 4 Jan 1973
Legal provisions allow applicants to appeal against MRAs decisions	Yes	2010	Law: Landsbesluit 16 Oktober 1973
Registration fee - the amount per application for pharmaceutical product containing New Chemical Entity,NCE (US$)	18	2010	Registration Committe
Registration fee - the Amount per application for a multisource pharmaceutical product (US$)	18	2010	Registration Committee
Time limit for the assessment of a marketing authorization application (Months)	6	1973	Law: Landsbesluit 16 Oktober 1973
Comments	Annual Retention Fee - US$ 9.00, Application for variations (includes processing): US$ 18.00		
4.03 Regulatory Inspection **Core Questions**			
Legal provisions exist allowing for appointment of government pharmaceutical inspectors	Yes	1938/ 2004	'Supervision of Public Health' Act of 1938; Standards Act of 2004
Does the Regulatory Authority have inspectors?	Yes	2010	MoH
If yes, how many?	3 (one staff member works part time)	2010	MoH
Legal provisions exist permitting	Yes	1938/	'Supervision of Public

inspectors to inspect premises where pharmaceutical activities are performed		2004	Health' Act of 1938; Standards Act of 2004
Legal provisions exist requiring inspection to be performed	No	2010	MoH
Inspection is a pre-requisite for licensing of facilities	No	2010	MoH
Inspection requirements are the same for public and private facilities	Yes	2010	MoH
4.04 Import Control **Core Questions**			
Legal provisions exist requiring authorization to import medicines	Yes	1981	Decree of September 15, 1981 (Business and Professions Licensing Decree) No. 145 SB 1981
Legal provisions exist allowing the sampling of imported products for testing	Yes	1896/ 1973	The amendment of GB1973, no. 1, from 4th of January 1973, further amending the Pharmaceutical Act of 1896
Legal provisions exist requiring importation of medicines through authorized ports of entry	Yes	1981	Decree of September 15, 1981 (Business and Professions Licensing Decree) No. 145 SB 1981
Legal provisions exist allowing inspection of imported pharmaceutical products at the authorized port of entry	Yes	1938	Public Health Act, 1938. No. 131
4.05 Licensing **Core Questions**			
Legal provisions exist requiring manufacturers to be licensed If yes please provide documents below. Please attach document or provide URL below *	Yes	1973	The amendment of GB1973, no. 1, from 4th of January 1973, further amending the Pharmaceutical Act of 1896
Legal provisions exist requiring manufacturers to comply with Good manufacturing Practices (GMP)	No	2010	MoH
GMP requirements are published by the government. If yes, please provide reference or URL below *	No	2010	MoH
Legal provisions exist requiring importers to be licensed	Yes	1896/ 1973	(GB 1896 no. 26/ GB 1960 no 77/ GB 1973 no. 1; GB 1973 no. 155)
Legal provisions exist requiring wholesalers and distributors to be	Yes	1896/ 1973	(GB 1896 no. 26/ GB 1960 no 77/ GB 1973

licensed			no. 1; GB 1973 no. 155)
Legal provisions exist requiring wholesalers and distributors to comply with Good Distributing Practices	No	2010	MoH
National Good Distribution Practice requirements are published by the government	No	2010	MoH
Legal provisions exist requiring pharmacists to be registered	Yes	2010	MoH
Legal provisions exists requiring private pharmacies to be licensed	Yes	2010	MoH
Legal provision exist requiring public pharmacies to be licensed	Yes	2010	MoH
National Good Pharmacy Practice Guidelines are published by the government	No	2010	MoH
Comments	In Suriname there is no clear distinction between importers, wholesalers, distributors		
Supplementary Questions			
Legal provisions require the publication of different categories of all pharmaceutical facilities licensed	No	2010	MoH/PPC
Comments	Legal framework and instruments are not comprehensive and are outdated		
4.06 Market Control and Quality Control **Core Questions**			
Legal Provisions for controlling the pharmaceutical market exist	Yes	1938	Public Health Act, 1938, no. 131; Trade license
Does a laboratory exist in the country for Quality Control testing?	Yes	2010	BGVS
If not, does the regulatory authority contract services elsewhere?	No	2010	MoH/PPC
Please describe where the Regulatory Authority Contracts services	CRDTL can be used, but it has not been used yet.		
Samples are collected by government inspectors for undertaking post-marketing surveillance testing	Yes	2010	MoH/BGVS
How many Quality Control samples were taken for testing in the past two years?	370	2010	BGVS QC Lab
What is the total number of samples tested in the previous two years that failed to meet quality standards?	2	2010	IBID
Results of quality testing in past two years are publicly available	No	2010	IBID

Comments	Lab has been restructured. Currently it is not independent. As part of importing company the lab analyzed number of samples (see table attached; some of which were also send to Regulatory Authority)		
4.07 Medicines Advertising and Promotion **Core Questions**			
Legal provisions exist to control the promotion and/or advertising of prescription medicines	Yes	1896/ 1973	The amendment of GB1973, no. 1, from 4th of January 1973, further amending the Pharmaceutical Act of 1896
Who is responsible for regulating, promotion and/or advertising of medicines? Please describe:	Regulation is not conducted as the enactment of the related committee was never done and specific regulations were not made - (incomplete legal framework).		
Legal provisions prohibit direct advertising of prescription medicines to the public	No	2010	MoH
Legal provisions require a pre-approval for medicines advertisements and promotional materials	No	2010	MoH
Guidelines/Regulations exist for advertising and promotion of non-prescription medicines	No	2010	MoH
A national code of conduct exists concerning advertising and promotion of medicines by marketing authorization holders and is publicly available	No	2010	MoH
4.08 Clinical trials **Core Questions**			
Legal provisions exist requiring authorization for conducting Clinical Trials by the MRA	No	2010	MoH/PPC
Legal provisions exist requiring the agreement by an ethics committee/ institutional review board of the Clinical Trials to be performed	Yes	1981	Decree C-46 no. 75 of 6 June 1981
Legal provisions exist requiring registration of the clinical trials into international/national/regional registry	Unknown	2010	MoH
Supplementary Questions			
Legal provisions exist for GMP compliance of investigational products	No	2010	MoH
Legal provisions require sponsor, investigator to comply with Good Clinical Practices (GCP)	No	2010	MoH

National GCP regulations are published by the Government.	No	2010	MoH
Legal provisions permit inspection of facilities where clinical trials are performed	No	2010	MoH
4.09 Controlled Medicines **Core Questions**			
The country is a signatory to conventions			
Single Convention on Narcotic Drugs, 1961	Yes	2006	International Narcotics Control Board
The 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes	2006	International Narcotics Control Board
Convention on Psychotropic Substances 1971	Yes	2006	International Narcotics Control Board
United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes	2006	International Narcotics Control Board
Laws for the control of narcotic and psychotropic substances, and precursors exist.	Yes	1955/ 1988	Law of February 12, 1998 (SB1998 no.14), also called the Narcotic Drugs Act; Opium Act of 1955 (GB1955 no.91, no.37 as last amended by SB1988)
Annual consumption of Morphine (mg/capita)	0.4587	2008	MoH Phl
Supplementary Questions			
The laws and regulations for the control of narcotic and psychotropic substances, and precursors has 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	2006	CICAD
Annual consumption of Fentanyl (mg/capita)	0.00313	2008	MoH Phl
Annual consumption of Pethidine (mg/capita)	0.3485	2008	MoH Phl
Annual consumption of Oxycodone (mg/capita)	0	2010	MoH Phl
Annual consumption of Hydrocodone (mg/capita)	0	2010	MoH Phl
Annual consumption of Phenobarbital (mg/capita)	1848.91	2009	BGVS

Annual consumption of Methadone (mg/capita)	0		MoH Phl
Comments	Consumption data phenobarbital from BGVS database.		
4.10 Pharmacovigilance **Core Questions**			
There are legal provision in the Medicines Act that provides for pharmacovigilance activities as part of the MRA mandate	No	2010	MoH
Legal provisions exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA	No	2010	MoH
Legal provisions about monitoring Adverse Drug Reactions (ADR) exist in your country	No	2010	MoH
A national Pharmacovigilance centre linked to the MRA exists in your country	No	2009	Implementing Pharmacovigilance in Suriname: 2006-2009
If a national pharmacovigilance centre exists in your country, how many staff does it employ full-time	None	2009	Implementing Pharmacovigilance in Suriname: 2006-2009
If a national pharmacovigilance center exists in your country, an analysis report has been published in the previous two years. Please attach document or provide URL below *	Yes	2009	Implementing Pharmacovigilance in Suriname: 2006-2009
If a national pharmacovigilance center exists in your country, it publishes an ADR bulletin	Yes	2009	Implementing Pharmacovigilance in Suriname: 2006-2009
An official standardized form for reporting ADRs is used in your country. If yes, please attach document below *	Yes	2009	Implementing Pharmacovigilance in Suriname: 2006-2009
A national Adverse Drug Reactions database exists in your country.	Yes	2009	Implementing Pharmacovigilance in Suriname: 2006-2009
Are ADR reports set to the WHO database in Uppsala?	Yes	2009	Implementing Pharmacovigilance in Suriname: 2006-2009
If yes, number of reports sent in the past two years	220	2009	Implementing Pharmacovigilance in Suriname: 2006-2009
ADRs are monitored in at least one	Yes	2009	Implementing

public health program (for example TB, HIV, AIDS)?			Pharmacovigilance in Suriname: 2006-2009
Supplementary Questions			
How many ADR reports are in the database?	260	2009	Implementing Pharmacovigilance in Suriname: 2006-2009 / request update from Naomi
How many reports have been submitted in the past two years?	260	2009	Implementing Pharmacovigilance in Suriname: 2006-2009
Feedback is provided to reporters	Yes	2010	MoH
The ADR database is computerized	Yes	2009	Implementing Pharmacovigilance in Suriname: 2006-2009
Medications errors (MEs) are reported.	Yes	2010	MoH
There is a risk management plan presented as part of product dossier submitted for Marketing Authorization?	No	2010	MoH
In the past two years, who has reported ADRs?		2009	Implementing Pharmacovigilance in Suriname: 2006-2009
Doctors	Yes		
Nurses	No		
Pharmacists	Yes		
Consumers	No		
Pharmaceutical Companies	No		
Was there any regulatory decision based on local PV data in the last 2 years?	No	2010	MoH
Are there training courses in Pharmacovigilance?	Yes	2010	MoH
If yes, how many people have been trained in the past two years?	100	2010	MoH
Comments	Two people have been trained outside of Suriname. Local training has been going on for local people i.e. vaccine monitoring		

Section 5 Medicines Financing

5.01 Medicines Coverage and Exemptions

Core Questions

If a public programme providing free medicines exists, medicines are available free-of-charge for:			
Patients who cannot afford them	Yes	2010	National approved budget
Children under 5	No	2010	MoH
Pregnant women	No	2010	MoH
Elderly persons	No	2010	MoH
Please describe/explain your yes answers for questions above	Ministry of Social Affairs has a programme for poor and near poor to provide free essential medicines		
If a public programme providing some/all medicines free exists, the following types of medicines are free			
All medicines for all conditions	No	2010	N/A
Any non-communicable diseases	No	2010	MoH
Malaria medicines	Yes	2010	National
Tuberculosis medicines	Yes	2010	National approved budget
Sexually transmitted diseases medicines	Yes	2010	National approved budget
HIV/AIDS medicines	Yes	2010	National approved budget
EPI vaccines	Yes	2010	National approved budget
If others, please specify	EML Medicines		
Does a public health service, public health insurance, social insurance or other sickness fund provides at least partial medicines coverage	Yes	2010	MoH
Does it provide coverage for medicines that are on the EML for inpatients	Yes		
Does it provide coverage for medicines that are on the EML for outpatients	Yes		
Does it provide at least partial medicines coverage for inpatients	Yes		
Does it provide at least partial medicines coverage for outpatients	Yes		
Do private health insurance schemes provide any medicines coverage?	Yes	2010	WHO Level II Survey
If yes, is it required to provide at least partial coverage for medicines that are on the EML?	Yes		

Comments	Most private insurance schemes have as a basis EML. Certain conditions are excluded from treatment.		
5.02 Patients Fees and Copayments **Core Questions**			
In your health system, at the point of delivery, are there any copayment/fee requirements for consultations	No	2007	MoH
In your health system, at the point of delivery, are there any copayment/fee requirements for medicines	Yes	2010	MoH
Is revenue from fees or from the sale of medicines used to pay the salaries or supplement the income of public health personnel in the same facility	No	2010	MoH
Please describe the patient fees and copayments system	Co-payment is based on fee for service and is subtracted from the final bill of funding agent.		
5.03 Pricing Regulation for the Private Sector **Core Questions**			
Are there legal or regulatory provisions affecting pricing of medicines	Yes	2005	The amendment of GB1973, no. 1, from 4th of January 1973; Decree E-2 SB 1980, no 62; Decree E-2A SB 1980 no 82; Decree SB 1981 no 172; Decree SB 1984, no 66; Decree SB 1986, no 2, regarding the investigation, prosecution and trial of economic crimes; Law SB 1989, no 42; Law 2005, no 43; and National Medicines Policy (2005)
If yes, are the provisions aimed at Manufacturers	Yes	2010	MoH
If yes, are the provisions aimed at Wholesalers	Yes	2010	Decree SB 1981 no 172 - also for importers;
If yes, are the provisions aimed at Retailers	Yes	2010	Decree E-2A SB 1980 no 82,
Please explain the positive answers above: (explain scope of provisions i.e generics vs. originator or subsets of medicines, EML etc.	The abovementioned legislation establishes maximum allowed sale prices (wholesalers and retail; importers and manufacturers).		
Government runs an active national	Yes	2010	MoH

medicines price monitoring system for retail prices			
Regulations exists mandating that retail medicine price information should be publicly accessible	No	2010	MoH
5.06 Duties and Taxes on Pharmaceuticals (Market) **Core Questions**			
There are duties on imported active pharmaceutical ingredients (APIs)	Yes	2007	CARICOM
There are duties on imported finished products	Yes	2007	CARICOM

Section 6 Pharm.procurement and distribution

6.01 Public Sector Procurement

Core Questions

Public sector procurement is		1983	Decree SB 1983, no 20, more information available at: http://www.volksgezondheid.gov.sr/procurementsbgvs.htm
Decentralized	No		
Centralized and decentralized	Yes		
Please describe	BGVS is a public owned agency, nevertheless the pharmacies can also buy from private distributors.		
If public sector procurement is wholly or partially centralized, it is under the responsibility of a procurement agency which is:		2010	MoH/BGVS
Part of MoH	No		
Semi-Autonomous	No		
Autonomous	Yes		
A government procurement Agency which procures all public goods	No		
Public sector tenders bids documents are publicly available	Yes	2010	Website MoH: http://www.volksgezondheid.gov.sr/
Public sector awards are publicly available	Yes	2010	Website MoH: http://www.volksgezondheid.gov.sr/
Procurements are based on prequalification of suppliers	Yes	2010	Website MoH: http://www.volksgezondheid.gov.sr/
If yes, please describe how it works	The suppliers of products not registered have to be prequalified. It is not necessary for providers who have the medicines registered in the country		

Supplementary Questions

Is there a written public sector procurement policy?. If yes, please write the year of approval in the "year" field.	No	2010	MoH
Are there provisions giving priority in public procurement to goods produced by local manufacturers?	No	2010	MoH
The key functions of the procurement unit and those of the tender committee are clearly separated	Yes	2010	BGVS
A process exists to ensure the quality	Yes	2010	MoH/BGVS

of products procured			
If yes, the quality assurance process includes pre-qualification of products and suppliers	Yes		
If yes, explicit criteria and procedures exist for pre-qualification of suppliers	Yes		
If yes, a list of pre-qualified suppliers and products is publicly available	No		
List of samples tested during the procurement process and results of quality testing is available	No	2010	MoH
Which of the following tender methods are used in public sector procurement:		2010	MoH
National competitive tenders	No		
International competitive tenders	Yes		
Direct purchasing	Yes		
Comments	When bid is awarded, suppliers are required to register medicines with MRA		
6.02 Public Sector Distribution			
Core Indicators			
The government supply system department has a Central Medical Store at National Level	Yes	2010	MoH
Number of public warehouses in the secondary tier of public distribution (State/Regional/Provincial)	2	2010	MoH
There are national guidelines on Good Distribution Practices (GDP)	No	2010	MoH
There is a licensing authority that issues GDP licenses	No	2010	MoH
List of GDP certified warehouses in the public sector exists	No	2010	MoH
List of GDP certified distributors in the public sector exists	No	2010	MoH
Supplementary Questions			
Which of the following processes at the Central Medical Store is in place		2010	MoH/BGVS
Forecasting of order quantities	Yes		
Requisition/Stock orders	Yes		
Preparation of picking/packing slips	Yes		
Reports of stock on hand	Yes		
Reports of outstanding order lines	Yes		
Expiry dates management	Yes		
Batch tracking	Yes		
Reports of products out of stock	Yes		
Percentage of selected medicines	10	2010	MoH/BGVS

with at least one stock out in the past year (%)			
Routine Procedure exists to track the expiry dates of medicines	Yes	2010	MoH
The Public Central Medical Store is GDP certified by a licensing authority	No	2010	MoH
The Public Central Medical Store is ISO certified	No	2010	MoH
The second tier public warehouses are GDP certified by a licensing authority	No	2010	MoH
The second tier public warehouses are ISO certified	No	2010	MoH
6.03 Private Sector Distribution **Core Questions**			
Legal provisions exist for licensing wholesalers in the private sector	Yes		
Legal provisions exist for licensing distributors in the private sector	Yes		
List of GDP certified wholesalers in the private sector exists	No		
List of GDP certified distributors in the private sector exists	No		
Comments	There is no National regulation regarding GDP, nevertheless there are requirements to the storage and distribution of medicines (ordinances and regulations - incomplete regulatory framework).		

Section 7 Selection and rational use

7.01 National Structures

Core Questions

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.	No	2010	WHO Level II
If yes, STG's are applied to Primary care. Please use the "year" field to write the year of last update of primary care STGs.	No		WHO Level II
If yes, STG's are applied to Secondary (hospitals). Please use the "year" field to write the year of last update of secondary care STGs.	No		WHO Level II
If yes, STG's are applied to Paediatric conditions. Please use the "year" field to write the year of last update of paediatric condition STGs.	No		WHO Level II
National essential medicines list (EML) exists. If yes, please write year of last update of EML in the "year" field and attach document or provide URL below.	Yes	2010	MoH PPC
If yes, number of medicines on the EML	315		
If yes, there is a written process for selecting medicines on the EML	Yes		
If yes, the EML is publicly available	Yes		
% of public health facilities with copy of EML (mean)- Survey data	60	2010	WHO Level II
% of public health facilities with copy of STGs (mean)- Survey data	27.5	2010	WHO Level II
A public or independently funded national medicines information centre provides information on medicines to prescribers, dispensers and consumers	No	2010	MoH
Public education campaigns on rational medicine use topics have been conducted in the previous two years	Unknown	2010	MoH
A survey on rational use of medicines has been conducted in the previous	Yes	2010	WHO Level II

two years			
A national programme or committee (involving government, civil society, and professional bodies) exists to monitor and promote rational use of medicines	No	2010	MoH
A written National Strategy exists to contain antimicrobial resistance. If yes, please write year of last update of the strategy in the "year" field.	No	2010	MoH
Supplementary Questions			
The EML includes formulations specific for children	Yes	2010	EML (NGK) - current version updated in 2010: http://www.volksgezondheid.gov.srEML (NGK)
There are explicit documented criteria for selection of medicines in the EML	Yes	2010	MOH: http://www.volksgezondheid.gov.sr/
There is a formal committee or other equivalent structure for the selection of products on the national EML	Yes	2010	MOH: http://www.volksgezondheid.gov.sr/
If yes, provide the official documentation establishing the committee *	There is an internal procedure on an ordenance (beschikking) and the committee is approved by the Council of Ministers.		
If yes, conflict of interest declarations are required from members of national EML committee	No		
National medicines formulary exists	No	2010	MoH
Is there a funded national inter-sectoral task force to coordinate the promotion of appropriate use of antimicrobials and prevention of spread of infection?	No	2010	MoH
A national reference laboratory/or any other institution has responsibility for coordinating epidemiological surveillance of antimicrobial resistance	Yes	2010	MoH
7.02 Prescribing **Core Questions**			
Legal provisions exist to govern the licensing and prescribing practices of prescribers, if yes please attach document or provide URL below *	Yes	2010	The Pharmaceutical Act of 1896 and amendments
Legal provisions exist to restrict	Yes	2010	The Pharmaceutical

dispensing by prescribers, if yes please attach document or provide URL below *			Act of 1896 and amendments
Regulations require hospitals to organize/develop Drug and Therapeutics Committees (DTCs)	No	2010	MoH
The core medical training curriculum includes components on:		2010	MoH
Concept of EML	Yes		
Use of STGs	Yes		
Pharmacovigilance	No		
Problem based pharmacotherapy	Yes		
The core nursing training curriculum includes components on:		2010	COVAB
Concept of EML	Yes		
Use of STGs	Yes		
Pharmacovigilance	Yes		
The core training curriculum for paramedical staff includes components on:		2010	COVAB
Concept of EML	Yes		
Use of STGs	Yes		
Pharmacovigilance	No		
Mandatory continuing education that includes pharmaceutical issues is required for Doctors	No	2010	MoH
Mandatory continuing education that includes pharmaceutical issues is required for Nurses	No	2010	MoH
Mandatory continuing education that includes pharmaceutical issues is required for Paramedical staff	No	2010	MoH
Prescribing by INN name is obligatory in:			
Private sector	No	2010	MoH
Public sector	No	2010	MoH
Average number of medicines prescribed per patient contact in public health facilities (mean)	2	2010	WHO Level II
% of medicines prescribed in outpatient public health care facilities that are in the national EML (mean)	73.6	2010	WHO Level II
% of medicines in outpatient public health care facilities that are prescribed by INN name (mean)	45.5	2010	WHO Level II
% of patients in outpatient public	13.3	2010	WHO Level II

health care facilities receiving antibiotics (mean)			
% of patients in outpatient public health care facilities receiving injections (mean)	3.3	2010	WHO Level II
% of prescribed drugs dispensed to patients (mean)	89.6	2010	WHO Level II
% of medicines adequately labelled in public health facilities (mean)	100	2010	WHO Level II
Supplementary Questions			
A professional association code of conduct exists governing professional behaviour of doctors	Unknown	2010	MoH
A professional association code of conduct exists governing professional behaviour of nurses	No		
Diarrhoea in children treated with ORS (%)	70	2010	WHO Level II
7.03 Dispensing **Core Questions**			
Legal provisions exist to govern dispensing practices of pharmaceutical personnel	Yes	2010	The Pharmaceutical Act of 1896 and amendments
The basic pharmacist training curriculum includes components on:		2010	MoH
Concept of EML	No		
Use fo STGs	No		
Drug Information	No		
Clinical pharmacology	No		
Medicines supply management	No		
Mandatory continuing education tat includes rational use of medicines is required for pharmacists	N0	2010	MoH
Substitution of generic equivalents at the point of dispensing in public sector facilities is allowed	Yes	2010	MoH
Substitution of generic equivalents at the point of dispensing in private sector facilities is allowed	Yes	2010	MoH
Antibiotics are sold over-the-counter without a prescription	Unknown	2010	MoH
Injectable medicines are sold over-the-counter without a prescription	Yes	2007	MoH
Comments	There is no pharmacy school in de country		
Supplementary Questions			
A professional association code of conduct exists governing professional behaviour of pharmacists	No	2010	MoH

Are the following categories of staff prescribing prescription-only medicines at primary care level in the public sector?		2010	MoH
Doctors	Yes		
Nurses	No		
Pharmacists	No		

Section 8 Household data/access

8.01 Data from Household Surveys

Core Questions

What household surveys have been undertaken in the past 5 years to assess access to medicines?	WHO Level II - Houshold Survey 2010		
Adults with an acute condition in two-week recall period who took all medicines prescribed by an authorized prescriber (%)	49	2010	WHO Level II
Adults with acute conditions not taking all medicines because they cannot afford them (%)	23	2010	WHO Level II
Adults with chronic conditions taking all medicines prescribed by an authorized prescriber (%)	78	2010	WHO Level II