PAPUA NEW GUINEA

PHARMACEUTICAL COUNTRY PROFILE

Papua New Guinea Pharmaceutical Country Profile

Published by the Ministry of Health in collaboration with the World Health Organization

January 2012

This document was produced with the support of the World Health Organization (WHO) Representative Office in Papua New Guinea, and all reasonable precautions have been taken to verify the information contained herein. The published material does not imply the expression of any opinion whatsoever on the part of the World Health Organization, and is being distributed without any warranty of any kind – either expressed or implied. The responsibility for interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

Users of this Profile are encouraged to send any comments or queries to the following address:

Pharmaceutical Services
Medical Standards, National Department of Health,
P.O. Box 807, Waigani, NCD,
Papua New Guinea

Email: medical_supplies@health.gov.pg

Foreword

The 2011 Pharmaceutical Country Profile for Papua New Guinea has been produced by the Ministry of Health, in collaboration with the World Health Organization.

This document contains information on existing socio-economic and health-related conditions, resources; as well as on regulatory structures, processes and outcomes relating to the pharmaceutical sector in Papua New Guinea. The compiled data comes from international sources (e.g. the World Health Statistics [1, 2]), surveys conducted in the previous years and country level information collected in 2011. The sources of data for each piece of information are presented in the tables that can be found at the end of this document.

On behalf of the Ministry of Papua New Guinea, I wish to express my appreciation to Pharmaceutical Services for their contributions to the process of data collection and the development of this profile.

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

Mr. Pascoe Kase,
Acting Secretary,
National Department of Health

Date 1/2/2012

Table of content

Introduction

This Pharmaceutical Country Profile provides data on existing socio-economic and health-related conditions, resources, regulatory structures, processes and outcomes relating to the pharmaceutical sector of Papua New Guinea. The aim of this document is to compile all relevant, existing information on the pharmaceutical sector and make it available to the public in a user-friendly format. In 2010, the country profiles project was piloted in 13 countries (http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index.html). During 2011, the World Health Organization has supported all WHO Member States to develop similar comprehensive pharmaceutical country profiles.

The information is categorized in 9 sections, namely: (1) Health and Demographic data, (2) Health Services, (3) Policy Issues, (4) Medicines Trade and Production (5) Medicines Regulation, (6) Medicines Financing, (7) Pharmaceutical procurement and distribution, (8) Selection and rational use, and (9) Household data/access. The indicators have been divided into two categories, namely "core" (most important) and "supplementary" (useful if available). This narrative profile is based on data derived from both the core and supplementary indicators. The tables in the annexes also present all data collected for each of the indicators in the original survey form. For each piece of information, the year and source of the data are indicated; these have been used to build the references in the profile and are also indicated in the tables. If key national documents are available on-line, links have been provided to the source documents so that users can easily access these documents.

The selection of indicators for the profiles has involved all technical units working in the Essential Medicines Department of the World Health Organization (WHO), as well as experts from WHO Regional and Country Offices, Harvard Medical

School, Oswaldo Cruz Foundation (known as Fiocruz), University of Utrecht, the Austrian Federal Institute for Health Care and representatives from 13 pilot countries.

Data collection in all 193 member states has been conducted using a user-friendly electronic questionnaire that included a comprehensive instruction manual and glossary. Countries were requested not to conduct any additional surveys, but only to enter the results from previous surveys and to provide centrally available information. To facilitate the work of national counterparts, the questionnaires were pre-filled at WHO HQ using all publicly-available data and before being sent out to each country by the WHO Regional Office. A coordinator was nominated for each of the member states. The coordinator for Papua New Guinea was Ms. Mary Keurih.

The completed questionnaires were then used to generate individual country profiles. In order to do this in a structured and efficient manner, a text template was developed. Experts from member states took part in the development of the profile and, once the final document was ready, an officer from the Ministry of Health certified the quality of the information and gave formal permission to publish the profile on the WHO website.

This profile will be regularly updated by Pharmaceutical Services. Comments, suggestions or corrections may be sent to:

Ms. Jonila Kepas,
Pharmaceutical Services, Medical Standards,
National Department of Health
P.O. Box 807, Waigani, NCD
Papua New Guinea
Email: jonila_kepas@scalix.health.gov.pg

Section 1 - Health and Demographic Data

This section gives an overview of the demographics and health status of Papua New Guinea.

1.1 Demographics and Socioeconomic Indicators

The total population of Papua New Guinea in 2009 was 6,732,000 with an annual population growth rate of 2.5%[3]. The annual GDP growth rate is 4.5%[4]. The GDP per capita was US$ 1,172.42 (at the current exchange rate[i]).

Of the total population, 40% is under 15 years of age and 4% is over 60 years of age. The urban population currently stands at 12% of the total population. The fertility rate in Papua New Guinea is 4.0 births per woman. The adult literacy rate for the population over 15 years is 60%[3].

1.2 Mortality and Causes of Death

The life expectancy at birth is 62 and 65 years for men and women respectively. The infant mortality rate (i.e. children under 1 year) is 52 /1,000 live births. For children under the age of 5, the mortality rate is 68 /1,000 live births. The maternal mortality rate is 250 /100,000 live births[3].

The top 10 diseases causing mortality in Papua New Guinea are [National Health Plan 2011-2020, 2008]

	Disease
1	Perinatal Conditions - CA
2	Pneumonia/ARI
3	Sepsis
4	Malaria and other vector-borne

[i] The current exchange rate for calculation is PGK 1 = USD 0.43199 on June 22nd, 2011, http://www.oanda.com/currency/converter/.

5	Tuberculosis
6	Malaria and other vector-borne
7	Obstetric and maternal conditions
8	Chronic respiratory
9	Anaemia -Haematology
10	Cardiovascular

The top 10 diseases causing morbidity[ii] in Papua New Guinea are [Western Pacific Country Health Information Profiles 2010, 2008, http://www.wpro.who.int/NR/rdonlyres/764EA005-06E5-4A34-B75B-23FC3EA6D47C/0/29finalPNGpro2010.pdf]

	Disease
1	Tuberculosis
2	Normal deliveries (incl. BBA)
3	Pneumonia
4	Malaria
5	Perinatal conditions
6	Direct obstetric causes
7	Diarrhoea
8	Diseases of the digestive system
9	Open wounds and injury to blood vessels
10	Anaemia

The adult mortality rate for both sexes between 15 and 60 years is 248 /1,000 population, while the neonatal mortality rate is 26 /1,000 live births. The age-standardised mortality rate by non-communicable diseases is 748 /100,000, 419 /100,000 by cardiovascular diseases and 113 /100,000 by cancer. The mortality rate for HIV/AIDS is 19 /100,000 and 26 /100,000 for tuberculosis. The mortality rate for malaria is 45 /100,000[1,3].

[ii] Leading causes of morbidity for inpatient care

Section 2 - Health Services

This section provides information regarding health expenditures and human resources for health in Papua New Guinea. 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.

2.1 Health Expenditures

In Papua New Guinea, the total annual expenditure on health (THE) in 2009 was 677 million PNG Kina (US$ 245.29 million)[5]. The total annual health expenditure was 3.12% of the GDP. The total annual expenditure on health per capita was 100.56 PNG Kina (US$ 36.53)[6].

The general government[iii] health expenditure (GGHE) in 2009, as reflected in the national health accounts (NHA) was PGK 535 million (US$ 193.84 million). That is, 79.03% of the total expenditure on health, with a total annual per capita public expenditure on health of PGK 79.47 (US$ 28.79). Private health expenditure covers the remaining 20.97% of the total health expenditure. The government annual expenditure on health represents 8.0% of the total government budget.

The public pharmaceutical expenditure in Papua New Guinea in 2010 was 94 million PNG Kina (US$ 40 million), which is a per capita public pharmaceutical expenditure of 13.96 PNG Kina (US$ 6.03)[7].

Social security expenditure makes up 0.0% of government expenditure on health. Private out-of-pocket expenditure as % of private health expenditure is 40.5%.

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

Premiums for private prepaid health plans are 6.5% of total private health expenditure[5].

2.2 Health Personnel and Infrastructure

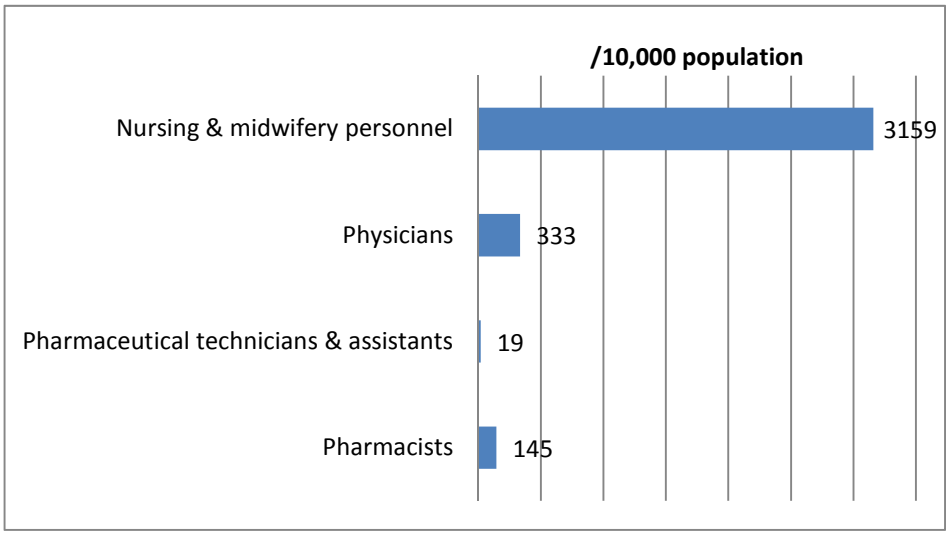
The health workforce is described in Table 1 below and in Figure 1 and 2. There are 145 (0.22 /10,000) licensed pharmacists registered with the Pharmacy Board as of 2011, of which 27 (0.040 /10,000) work in the public sector. There are 19 (0.028 /10,000) registered pharmaceutical technicians and assistants (in all sectors). There are approximately 8 times fewer pharmacy technicians as pharmacists.

There are 333 (0.49 /10,000) physicians and 3,159 (4.69 /10,000) nursing and midwifery personnel in Papua New Guinea. The ratio of doctors to pharmacists is 2.3 and the ratio of doctors to nurses and midwifery personnel is 0.11.

Table 1: Human resources for health in Papua New Guinea

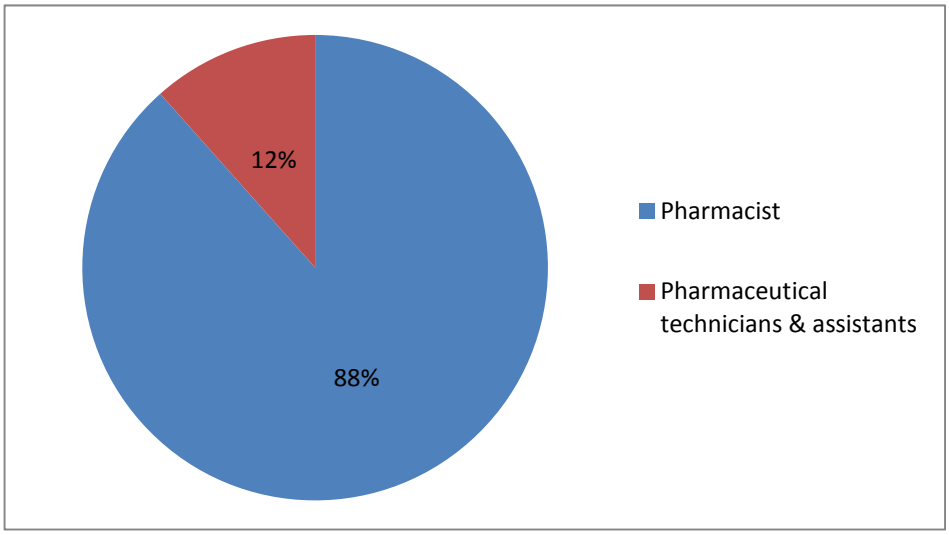
Human Resource	
Licensed pharmacists (all sectors)	145 (0.22 /10,000)[8]
Pharmacists in the public sector	27[8]
Pharmaceutical technicians and assistants (all sectors)	19 (0.028 /10,000)[8]
Physicians (all sectors)	333 (0.49 /10,000)[3]
Nursing and midwifery personnel (all sectors)	3,159 (4.69 /10,000)[3]

Figure 1: The density of the Health Workforce in Papua New Guinea (all sectors)



[National Pharmacy Board, 2011; World Health Statistics 2011, 2008]

Figure 2: Distribution of Pharmaceutical Personnel, Papua New Guinea (2011)



In Papua New Guinea, there is no strategic plan for pharmaceutical human resource development in place.

The health workforce is described in Table 2 below. There are 19 hospitals in Papua New Guinea and 2,770 primary health care units and centres. There are 76 licensed pharmacies.

Table 2: Health centre and hospital statistics

Infrastructure	
Hospitals	19[9]
Primary health care units and centres	2,770[9]
Licensed pharmacies	76[8]

The annual starting salary for a newly registered pharmacist in the public sector is 26,000 PNG Kina (US$ 11,232)[10]. The total number of pharmacists who graduated (as a first degree) in the past 2 years is 40[11]. Accreditation requirements for pharmacy schools are not in place. The pharmacy curriculum is regularly reviewed.

Section 3 - Policy Issues

This section addresses the main characteristics of the pharmaceutical policy in Papua New Guinea. The many components of a national pharmaceutical policy are taken from the WHO publication "How to develop and implement national drug policy" (http://apps.who.int/medicinedocs/en/d/Js2283e/). Information about the capacity for manufacturing medicines and the legal provisions governing patents is also provided.

3.1 Policy Framework

In Papua New Guinea, a National Health Policy (NHP) exists. An associated National Health Policy implementation plan was written in 2010[12].

An official National Medicines Policy document exists in Papua New Guinea[13]. It was updated in 1998. A NMP implementation plan also exists. Policies addressing pharmaceuticals exist, as detailed in Table 3. However, pharmaceutical policy implementation is not regularly monitored or assessed. Implementation is being monitored by the Pharmaceutical Services at the National Department of Health.

Table 3: The group of policies covered[13]

Aspect of policy	Covered
Selection of essential medicines	Yes
Medicines financing	Yes
Medicines pricing	Yes
Medicines Procurement	Yes
Medicines Distribution	Yes
Medicines Regulation	Yes
Pharmacovigilance	Yes
Rational use of medicines	Yes

Human Resource Development	Yes
Research	No
Monitoring and evaluation	Yes
Traditional Medicine	No

A policy or group of policies relating to clinical laboratories exists. An associated National clinical laboratory policy implementation plan also exists. Access to essential medicines/technologies as part of the fulfillment of the right to health, is recognized in the constitution or national legislation[14]. There is an official written guideline on medicines donations[15]. There is no national good governance policy in Papua New Guinea.

A policy is not in place to manage and sanction conflict of interest issues in pharmaceutical affairs. There is a formal code of conduct for public officials[16]. A whistle-blowing mechanism that allows individuals to raise concerns about wrongdoing occurring in the pharmaceutical sector of Papua New Guinea does not exist.

Section 4 – Medicines Trade and Production

4.1 Intellectual Property Laws and Medicines

Papua New Guinea is a member of the World Trade Organization[17]. Legal provisions granting patents exist. These cover pharmaceuticals, laboratory supplies, medical supplies and medical equipment[18].

Intellectual Property Rights are managed and enforced by the Ministry of Trade and Industry, http://www.ipopng.gov.pg/[19].

National Legislation has been modified to implement the TRIPS Agreement and contains TRIPS-specific flexibilities and safeguards, presented in Table 4[18]. Papua New Guinea is not eligible for the transitional period to 2016.

Table 4: TRIPS flexibilities and safeguards are present in the national law

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

[iv] Many countries use this provision of the TRIPS Agreement to advance science and technology. They allow researchers to use a patented invention for research, in order to understand the invention more fully.
In addition, some countries allow manufacturers of generic drugs to use the patented invention to obtain marketing approval (for example from public health authorities) without the patent owner's permission and before the patent protection expires. The generic producers can then market their versions as soon as the patent expires. This provision is sometimes called the "regulatory exception" or "Bolar" provision. *Article 30*
This has been upheld as conforming with the TRIPS Agreement in a WTO dispute ruling. In its report adopted on 7 April 2000, a WTO dispute settlement panel said Canadian law conforms with the TRIPS Agreement in allowing manufacturers to do this. (The case was titled "Canada - Patent Protection for Pharmaceutical Products")
[In: WTO OMC Fact sheet: TRIPS and pharmaceutical patents, can be found on line at: http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf]

There are no legal provisions for data exclusivity for pharmaceuticals, patent term extension or linkage between patent status and marketing authorization.

4.2 Manufacturing

There are no licensed pharmaceutical manufacturers in Papua New Guinea. Manufacturing capabilities are presented in Table 5 below.

Table 5: Papua New Guinea manufacturing capabilities[18]

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

No multinational pharmaceutical companies currently manufacture medicines locally and no manufacturers are Good Manufacturing Practice (GMP) certified.

Section 5 – Medicines Regulation

This section details the pharmaceutical regulatory framework, resources, governing institutions and practices in Papua New Guinea.

5.1 Regulatory Framework

In Papua New Guinea, there are legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA). The MRA is a part of the National Department of Health with a number of functions outlined in Table 6. The MRA does not have its own website[20].

Table 6: Functions of the national MRA[20]

Function	
Marketing authorisation / registration	Yes
Inspection	Yes
Import control	Yes
Licensing	Yes
Market control	Yes
Quality control	Yes
Medicines advertising and promotion	Yes
Clinical trials control	Yes
Pharmacovigilance	Yes
Other - registration of pharmacists and pharmacy technicians and revision of Essential Medicines List	Yes

As of 2011, there were 6 permanent staff members working for the MRA. The MRA receives external technical assistance from the World Health Organization to support its activities. The MRA is not involved in harmonization/collaboration initiatives. An assessment of the medicines regulatory system has not been conducted in the last five years. Funding for the MRA is provided through the

regular government budget, as well as through additional sources, including development partners. The Regulatory Authority is not funded from fees for services provided and does not retain revenues derived from regulatory activities. The MRA utilizes a computerized information management system to store and retrieve information on processes that include registrations, inspection etc. This body uses Drug Registration and Information System since 2000[18,20].

5.2 Marketing Authorization (Registration)

In Papua New Guinea, legal provisions require marketing authorization (registration) for all pharmaceutical products on the market. Exceptions/waivers for registration do not exist[18,20]. Mutual recognition mechanisms are in place that includes SRAs, PIC/S members, and WHO-Prequalification. Explicit and publicly available criteria for assessing applications for marketing authorization of pharmaceutical products do not exist. As of 2011, there were 37 pharmaceutical products registered in Papua New Guinea[8]. There are legal provisions requiring the MRA to make the list of registered pharmaceutical products publicly available, this however does not happen on regular basis. Medicines are always registered by their International Non-proprietary Names (INN) or Brand name + INN. Legal provisions require a fee to be paid for Medicines Market Authorization (registration) based on applications[18,20].

Marketing Authorization holders are required by law to provide information about variations to the existing Marketing Authorization[21]. Legally, a Summary of Product Characteristics (SPC) of the medicines that are registered is not required to be published. However, legal provisions requiring the establishment of an expert committee involved in the Marketing Authorization process are in place. Possession of a Certificate for Pharmaceutical Products (that accords with the WHO Certification scheme) is required as part of the Marketing Authorization application[18]. By law, potential conflict of interests for experts involved in the assessment and decision-making for registration need not be declared.

Applicants may legally appeal against MRA decisions[21]. The registration fee (per application) for a generic pharmaceutical product is PNG Kina 20 (US$ 8.26).

5.3 Regulatory Inspection

In Papua New Guinea, legal provisions allowing for appointment of government pharmaceutical inspectors exist[21]. Legal provisions permitting inspectors to inspect premises where pharmaceutical activities are performed exist; such inspections are required by law and are a pre-requisite for the licensing of private, but not public facilities[18,20]. Where inspections are legal requirements, these are not the same for public and private facilities. Inspections are carried out on a number of entities, outlined in Table 7.

Table 7: Local entities inspected for GMP compliance[20]

Entity	Inspection	Frequency
Local manufacturers	No	N/A
Private wholesalers	Yes	Once in 2-3 years
Retail distributors	Yes	Once in 2-3 years
Public pharmacies and stores	Yes[v]	
Pharmacies and dispensing points if health facilities	No	N/A

N/A: not applicable

5.4 Import Control

Legal provisions requiring authorization to import medicines exist. Laws exist that allow the sampling of imported products for testing. Legal provisions requiring importation of medicines through authorized ports of entry do not exist. Regulations or laws to allow for inspection of imported pharmaceutical products at authorized ports of entry exist[21].

5.5 Licensing

[v] Public facilities are usually not inspected

In Papua New Guinea, legal provisions requiring manufacturers to be licensed exist[18]. Legal provisions requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP) also exist[21]. Good Manufacturing Practices are not published by the government.

Legal provisions requiring importers, wholesalers and distributors to be licensed exist[18]. Legal provisions requiring wholesalers and distributors to comply with Good Distributing Practices do not exist.

Table 8: Legal provisions pertaining to licensing

Entity requiring licensing	
Importers	Yes
Wholesalers	Yes
Distributors	Yes

Good Distribution Practices are not published by the government. Legal provisions requiring pharmacists to be registered exist. Legal provisions requiring private and public pharmacies to be licensed exist[21,22]. National Good Pharmacy Practice Guidelines are not published by the government. By law, a list of all licensed pharmaceutical facilities is required to be published[21].

5.6 Market Control and Quality Control

In Papua New Guinea, legal provisions for controlling the pharmaceutical market exist[21]. A laboratory for Quality Control testing does not exist in Papua New Guinea. The regulatory authority contracts services elsewhere. The National Department of Health has a MOU with TGA in Australia for quality testing of medicines, however, infrequently used.

There are no national laboratory facilities that have been accepted for collaboration with the WHO pre-qualification Programme. Table 9 summarises reasons for which medicines are tested.

Table 9: Reason for medicines testing

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

Samples are not collected by government inspectors for undertaking post-marketing surveillance testing. Results of quality testing are not publicly available.

5.7 Medicines Advertising and Promotion

In Papua New Guinea, legal provisions exist to control the promotion and/or advertising of prescription medicines. Pharmaceutical Services at the National Department of Health is responsible for regulating promotion and/or advertising of medicines. Legal provisions prohibit direct advertising of prescription medicines to the public and pre-approval for medicines advertisements and promotional materials is required. Guidelines and Regulations for advertising and promotion of non-prescription medicines exist[18,20]. There is no national code of conduct concerning advertising and promotion of medicines by marketing authorization holders.

5.8 Clinical Trials

[vi] Routine sampling in pharmacy stores and health facilities
[vii] Routine sampling in retail outlets

In Papua New Guinea, legal provisions requiring authorization for conducting clinical trials by the MRA exist. There are no additional laws requiring the agreement by an ethics committee or institutional review board of the clinical trials to be performed. Clinical trials are not required to be entered into an international, national and/or regional registry, by law[21].

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

5.9 Controlled Medicines

Papua New Guinea is a signatory to a number of international conventions, detailed in Table 10.

Table 10: International Conventions to which Papua New Guinea is a signatory[23]

Convention	Signatory
Single Convention on Narcotic Drugs, 1961	Yes
1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes
Convention on Psychotropic Substances 1971	Yes
United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	No

Laws for the control of narcotic and psychotropic substances and precursors exist (Dangerous Drugs Act 1973). The annual consumption of Morphine is 0.492626 mg/capita[24].

The legal provisions and regulations for the control of narcotic and psychotropic substances, and precursors have not been reviewed by a WHO International

Expert or Partner Organization to assess the balance between the prevention of abuse and access for medical need. Figures regarding the annual consumption of certain controlled substances in the country are outlined in Table 10S below.

Table 10S: Annual consumption of selected controlled substances in Papua New Guinea[24]

Controlled substance	Annual consumption (mg/capita)
Morphine	0.492626
Pethidine	1.901779

5.10 Pharmacovigilance

In Papua New Guinea, there are no legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate. Legal provisions requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA do not exist. Laws regarding the monitoring of Adverse Drug Reactions (ADRs) do not exist in Papua New Guinea. A national pharmacovigilance centre linked to the MRA does not exist.

An official standardized form for reporting ADRs is used in Papua New Guinea. Feedback is not provided to reporters. Information pertaining to ADRs is not stored in a national ADR database. ADR reports are not sent to the WHO collaborating centre in Uppsala.

There is no national ADR or pharmacovigilance advisory committee able to provide technical assistance or causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication in Papua New Guinea. A clear communication strategy for routine communication and crises communication does not exist. ADRs are not monitored in a public health program.

Medication errors (MEs) are not reported. A risk management plan is not presented as part of the product dossier submitted for Marketing Authorization.

In Table 11S below is shown who has reported ADRs in the past two years. In the last two years there has not been a regulatory decision based on local pharmacovigilance. There are no training courses in pharmacovigilance.

Table 11S: Reporting of ADRs

Reporting by:	
Doctors	Yes
Nurses	Yes
Pharmacists	Yes
Consumers	No
Pharmaceutical Companies	No
Others	No

Section 6 - Medicines Financing

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

6.1 Medicines Coverage and Exemptions

In Papua New Guinea, concessions are made for certain groups to receive medicines free of charge (see Table 12). Furthermore, the public health system or social health insurance schemes provide medicines free of charge for particular conditions (see Table 13).

Table 12: Population groups provided with medicines free of charge[18]

Patient group	Covered
Patients who cannot afford them	No
Children under 5	Yes
Pregnant women	No
Elderly persons	Yes

There is a minimal co-payment of 1 PNG Kina per medicine prescribed. Those who cannot afford usually pay 1-2 Kina per prescription.

Table 13: Medications provided publicly, at no cost[18]

Conditions	Covered
All diseases in the EML	No
Any non-communicable diseases	No
Malaria	No

Tuberculosis	Yes
Sexually transmitted diseases	Yes
HIV/AIDS	Yes
Expanded Program on Immunization (EPI) vaccines for children	Yes
Other	No

A public health service, public health insurance, social insurance or other sickness fund does not provide at least partial medicines coverage.

Private health insurance schemes provide medicines coverage. They are not required to provide at least partial coverage for medicines that are on the EML.

6.2 Patients Fees and Copayments

Co-payments or fee requirements for consultations are levied at the point of delivery. Furthermore, there are copayments or fee requirements imposed for medicines. Patients pay 10 Kina for consultation fee in the public health facilities. Revenue from fees or from the sale of medicines is used to pay the salaries or supplement the income of public health personnel in the same facility[9,18].

6.3 Pricing Regulation for the Private Sector[viii]

In Papua New Guinea, there are legal or regulatory provisions affecting pricing of medicines[13]. These provisions are not aimed at the level of manufacturers, wholesalers or retailers.

The government does not run an active national medicines price monitoring system for retail prices. There are no regulations mandating that retail medicine price information should be publicly accessible.

6.4 Prices, Availability and Affordability of Key Medicines

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

WHO/HAI pricing survey has not been conducted in Papua New Guinea in the last five years.

6.5 Price Components and Affordability

No survey on medicine price components has been conducted in Papua New Guinea.

6.6 Duties and Taxes on Pharmaceuticals (Market)

Papua New Guinea does not impose duties on imported active pharmaceutical ingredients (APIs), but duties on imported finished products are imposed. Value-added tax or other taxes are imposed on finished pharmaceutical products. Provisions for tax exceptions or waivers for pharmaceuticals and health products are in place. Medicines imported by the National Department of Health are exempted from tax. API import is not known, but there is no local manufacturing facility. The value-added tax (VAT) on pharmaceutical products is 10%.

Section 7 - Pharmaceutical procurement and distribution in the public sector

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

7.1 Public Sector Procurement

Public sector procurement in Papua New Guinea is centralized under the responsibility of a procurement agency which is a part of the Ministry of Health.

Public sector request for tender documents are publicly available and public sector tender awards are publicly available. Procurement is not based on the prequalification of suppliers.

There is a written public sector procurement policy. This policy was approved in 1995[25]. Legal provisions that give priority to locally produced goods in public procurement do not exist.

The key functions of the procurement unit and those of the tender committee are clearly separated[18]. A process to ensure the quality of products that are publicly procured exists. The quality assurance process includes the pre-qualification of products. Explicit criteria and procedures for pre-qualification of suppliers does not exist[9].

Samples are accepted during the procurement process however, their quality is not tested[9]. The tender methods employed in public sector procurement include national competitive tenders and direct purchasing[18].

7.2 Public Sector Distribution

The government supply system in Papua New Guinea has a Central Medical Store (CMS) at National Level. There are 26 public warehouses in the secondary tier of the public sector distribution; 1 on state level, 5 on regional level and 20 on provincial level. There are no national guidelines on Good Distribution Practices (GDP). A licensing authority that issues GDP licenses does not exist. A list of GDP certified warehouses or distributors in the public sector does not exist.

A number of processes are in place at the CMS as detailed in Table 14S.

Table 14S: Processes employed by the Central Medical Store

Process	
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	No
Expiry dates management	Yes
Batch tracking	Yes
Reports of products out of stock	Yes

Routine procedures to track the expiry dates of medicines at the CMS exist. The Public CMS is not GDP certified by a licensing authority or ISO certified. The second tier public warehouses are not GDP certified by a licensing authority or ISO certified.

7.3 Private Sector Distribution

Legal provisions for licensing wholesalers in the private sector exist, but no legal provisions exist for licensing distributors in the private sector[21]. A list of GDP certified wholesalers or distributors does not exist in the private sector.

Section 8 - Selection and rational use of medicines

This section outlines the structures and policies governing the selection of essential medicines and promotion of rational drug use in Papua New Guinea.

8.1 National Structures

A National Essential Medicines List (EML) exists. The EML was lastly updated in 2002 and is publicly available. There are currently 423 medicines on the EML. Selection of medicines for the EML is undertaken through a written process. A mechanism aligning the EML with the Standard Treatment Guidelines is in place[9,18].

National Standard Treatment Guidelines (STGs) for most common illnesses are produced/endorsed by the Ministry of Health in Papua New Guinea. These were last updated in 2005. Specific STGs cover primary care, secondary care and paediatric conditions (updated in 2007)[9,18].

There is no public or independently funded national medicines information centre providing information on medicines to prescribers, dispensers and consumers[18]. Public education campaigns on rational medicine use have not been conducted in the last two years. A survey on rational use of medicines has not been conducted in the previous two years. There is no national programme or committee, involving government, civil society and professional bodies, to monitor and promote rational use of medicines.

A written National Strategy for containing antimicrobial resistance does not exist[18].

Papua New Guinea's EML does not include formulations specifically for children. Criteria for the selection of medicines in the EML are explicitly documented. A

formal committee or other equivalent structure for the selection of products on the EML exists. Conflict of interest declarations are not required from members of the national EML committee[9,18].

A national medicines formulary does not exist. A funded national inter-sectoral task force to coordinate the promotion of the appropriate use of antimicrobials and prevention of the spread of infection does not exist. A national reference laboratory or other institution does not have responsibility for coordinating epidemiological surveillance of antimicrobial resistance[18].

8.2 Prescribing

Legal provisions to govern the licensing and prescribing practices of prescribers exist. However, legal provisions restricting dispensing by prescribers do not exist. Prescribers in the private sector dispense medicines[9,18].

There are no regulations requiring hospitals to organize or develop Drug and Therapeutics Committees (DTCs).

The training curriculum for doctors and nurses is made up of a number of core components detailed in Table 15.

Table 15: Core aspects of the medical training curriculum[9,18]

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

Mandatory continuing education that includes pharmaceutical issues is not required for doctors, nurses or paramedical staff. Prescribing by INN is obligatory in the public, but not in the private sector[9,18].

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

8.3 Dispensing

Legal provisions in Papua New Guinea to govern dispensing practices of pharmaceutical personnel exist. The basic pharmacist training curriculum includes a spectrum of components as outlined in Table 16.

Table 16: Core aspects of the pharmacist training curriculum

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

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

Substitution of generic equivalents at the point of dispensing is allowed in public, but not in private sector facilities[18]. Sometimes, antibiotics and injectable medicines are sold over-the-counter without a prescription.

A professional association code of conduct which governs the professional behaviour of pharmacists exists. In practice, nurses, pharmacists and

paramedics do sometimes prescribe prescription-only medicines at the primary care level in the public sector (even though this may be contrary to regulations)[9,18].

Section 9 - Household data/access

This section provides information derived from past household surveys in Papua New Guinea regarding actual access to medicines by normal and poor households.

In the past 5 years, no household surveys have been undertaken to assess the access to medicines.

List of key reference documents:

[1] World Health Organization (WHO) (2010), "World Health Statistics 2010", WHO Press, Geneva. Available online: http://www.who.int/whosis/whostat/2010/en/index.html.

[2] World Health Organization (WHO) (2009), "World Health Statistics 2009", WHO Press, Geneva. Available online: http://www.who.int/whosis/whostat/2009/en/index.html.

[3] World Health Organization (WHO) (2011), "World Health Statistics 2011", WHO Press, Geneva. Available online: http://www.who.int/whosis/whostat/2011/en/index.html

[4] World Bank Data (2009). Website: http://data.worldbank.org/country/papua-new-guinea

[5] National Health Accounts (NHA), Papua New Guinea - National Expenditure on Health (Kina), 2009. Available online: http://www.who.int/nha/country/png/en/

[6] Calculated based on data provided in [3] and [5]

[7] Medium Term Expenditure Framework, 2011

[8] National Pharmacy Board, 2011

[9] National Department of Health, 2011. Website: http://www.health.gov.pg/

[10] Department of Personnel Management and Public Employment Association, 2010

[11] School of Medicine and Health Sciences, University of PNG, 2011

[12] National Health Plan 2011-2020, Back to Basics - Strengthened primary health care for all and improved service delivery for the rural majority and urban disadvantaged, Government of Papua New Guinea, June 2010. Available online: http://zanggom.files.wordpress.com/2010/10/pngnhp_vol1_final300dpi_020710.pdf

[13] National Drug Policy, 1998

[14] National Health Administration Act, Department of Health, Papua New Guinea, 1997

[15] National Stock Management System Handbook, 2007

[16] Code of Ethics for Public Sector, 2009

[17] World Trade Organization, 1996. Website: http://www.wto.org/english/thewto_e/countries_e/papua_new_guinea_e.htm

[18] World Health Organization (WHO) (2007), "WHO Level I survey", Geneva

[19] Ministry of Trade and Industry, Investment Promotion Authority (IPA), Intellectual Property Office of Papua New Guinea (IPOPNG), Level 3 Credit Corporation, Cuthbertson Street, Down Town, Port Moresby, National Capital District, PNG. Website: http://www.ipopng.gov.pg/

[20] Pharmaceutical Services, Medical Standards, National Department of Health, P.O.BOX 807, Waigani, Port Moresby, PNG

[21] Medicines and Cosmetic Act 1999, Papua New Guinea. Available online: http://www.wipo.int/wipolex/en/details.jsp?id=3422

[22] National Health Service Standards, Papua New Guinea

[23] International Narcotics Control Board (INCB). Website: http://www.incb.org/

[24] International Narcotics Control Board (INCB), 2009. Website: http://www.incb.org/

[25] The Public Finance Management Act, 29 June 1995, Department of Finance, Papua New Guinea. Available online: http://www.finance.gov.pg/Website%20Documents/public_finance_management_act.htm