Department of Health

NATIONAL MEDICINES POLICY 2014

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Foreword

I am indeed very happy and honoured to write the foreword to the second edition of the National Medicine Policy. The first edition was developed and launched in 1998. After over a decade of its implementation, some progress has been recorded.

These include the enactment of the Medicines and Cosmetic Act 1999 and Medicines and Cosmetics Regulation 2002, registration of drugs, licensing of pharmaceutical establishments, inspection, donation of drugs, training and education and structure and functions to oversee, monitor and implement the policy.

However, many of the expectation of that edition were unrealistic due mainly to lack of political will by the past governments and the absence of an implementation plan as well as a structured monitoring and evaluation system.

This revised edition has taken care of those identified gaps together with addressing those areas that call for more positive action. This policy was developed with adequate consultation with relevant stake holders in the Pharmaceutical sector in order to ensure a sound and multispectral platform for achieving the main goals of the policy.

The launching of this edition is in line with National Health Plan 2011 - 2020 and the National Health Services Standards with the overall objective for the improvement of the people's health in Papua New Guinea. There are already in place structures and organization in the National Department of Health to oversee, monitor and administer the policy.

The goal of this policy is to highlight quality assurance, rational use and availability of medicines, medical supplies procurement and distribution, and pharmaceutical services delivery. Also this policy shall guide the development and establishment of appropriate infrastructures and strategies.

The government shall do its utmost to ensure that this revised edition is faithfully and successful implemented.

Honourable Michael Malabag, OBE, MP
Minister for Health and HIV/AIDS

Acknowledgement

The National Department of Health would like to sincerely extend its gratitude and appreciation to all stakeholders who had participated and contributed towards the review of the National Drug Policy 1998; through meetings and workshops which has resulted in the development of the National Medicines Policy 2014.

A special mention is made to the working team from the Pharmaceutical Service Standards Branch and the policy unit for the leadership and direction provided towards the review and update of this policy. Many thanks to the Senior Executive Members, Managers and Technical Advisors, the pharmacist throughout the country and the discipline of Pharmacy Training, UPNG for the research and contributions that has translated to this policy.

I also would like to thank other stakeholders, line agencies, provincial governments, non-government organizations, development partners, the private and corporate sector that have provided useful inputs, notably on cross-cutting issues and on areas where collaboration and partnership is necessary for the implementation of this policy.

Finally, sincere appreciation is extended to the World Health Organisation and Australian Aid for continued assistance to the health sector, in particular, the pharmaceutical sector.

In acknowledging the efforts of all who have contributed, I commend the National Medicines Policy 2014 for Papua New Guinea.

Pascoe Kase (Mr)
Secretary for Health

Executive Summary

Medicines and other health products are a special group of items requiring special attention and care. Unlike other goods of trade and commerce, medicines save lives, improve health and well-being of the population. Therefore, the trade, use and management of these special goods must be adequately regulated and coordinated. The National Medicine Policy 2014 is a response to this need, and therefore, intends to provide a framework and direction for coordinating activities in the pharmaceutical sector in Papua New Guinea, by actors in the public and private sectors and other interested parties.

The areas of concern which require policing and direction are categorized into those that impact on; availability, affordability, regulation, quality assurance, and rational use of medicines. Other areas that will impact on policy implementation include; human resources, organizational structure, research, monitoring and evaluation.

The National Medicines Policy 2014 is an update of the first National Drug Policy 1998. It has taken over a decade since, and this policy outlines strategies that target current situations as well as those anticipating newer challenges ahead.

An implementation plan outlining roles for stakeholders is included that requests for active partnerships in policy implementation. National Department of Health will play fewer roles in implementation and expects its partners to actively plan and budget for annual activities required to achieve the policy aims. Policy implementation will tie into key health sector priority plans and time frames, including the NDoH Corporate Plan as well as the National Health Plan 2011 - 2020, the Papua New Guinea Development Strategic Plan (DSP) 2011 - 2030 and the Government's Vision 2050 for the long term.

The National Department of Health will routinely monitor and evaluate progress of implementation and suggest appropriate adjustments necessary for improvements to facilitate achievement of policy aims. Operational researches will target main areas of concern and findings will contribute to future reviews.

CHAPTER ONE – BACKGROUND

1.1 Intent of Policy

The National Medicines Policy 2014 intends to provide a framework and direction for coordinating activities in the pharmaceutical sector in Papua New Guinea by stakeholders in the public and private sectors and other interested parties.

1.2 Historical Context

In 1975, less than half the world's population were estimated to have regular access to essential medicines. This situation prompted the World Health Assembly in resolution WHA28.66 to request the WHO to develop means to assist Member States in formulating national drug policies.

Ten years later in 1985, the World Health Organisation called a Conference of Experts on the Rational Use of Drugs, which resulted in a document known as the 'Revised Drug Strategy'.

The 39th World Health Assembly held in 1986 adopted this strategy which called on all governments to implement a National Drug Policy and Papua New Guinea in response to this call initiated consultations in 1995 and developed its first National Drug Policy in 1998. The National Drug Policy 1998 key objectives were to maintain a continuous and adequate supply of medicines and improve supply management and rational use at all levels.

With the development of Vision 2050, the overarching National Government long term plan, the medium term PNG Development Strategic Plan 2011 – 2030 and the National Health Plan 2011 - 2020, it has become necessary to review the National Drug Policy 1998 and align its priorities with that of the National Government, in particular the Health Sector medium to long term priorities.

1.3 Audience

Pharmaceutical services form an integral component of health service delivery in all levels of care, in both the public and private sectors and involve all health care professionals, policy makers, decisions makers, financers and the public including the patients.

The need to improve the quality of reach and span of pharmaceutical services within the country, calls for active collaboration between NDoH and its partners across both the public and private sectors. With affirmation of more formal relationships now backed by the National Health Sector Partnerships Policy 2014, the various partners of NDoH who are also audiences to this policy include;

- Central Government Agencies
- State Agencies and Regulatory bodies
- Provincial Governments and Provincial Health Authorities (PHA)
- Public and Private Hospitals and health facilities

- Development Partners
- Health Teaching Institutions
- Non-Government Organizations (dealing with health care and medicines)
- Church Health Services
- Importers, wholesalers and retailers of medicines, health products including veterinary medicinal products
- Non-conventional practitioners of herbal and traditional medicines
- Professional societies
- Research and Laboratory institutes
- Standards and accreditation bodies

1.4 Policy Development Process

This Policy document is the result of extensive consultations and inputs from relevant professionals from within the National Department of Health and the health sector stakeholders from various Government agencies, the private and corporate sector, Non-Governmental Organizations, Development Partners and others from the academia.

The initial external consultation was held on the 10th of September 2012 at NDOH Conference room which set the stage for the review of the National Drug Policy 1998. The consultation was attended by several important partners who were instrumental in the generation of issues currently facing the pharmaceutical sector and suggestions for the review and development of this policy as a means to address the status quo. Prior to the first external consultation, there were numerous internal meetings organised by the Pharmaceutical Services Standards Branch with support from the NDoH's Policy Unit who did the desktop review of the 1998 National Drug Policy.

Following the first external consultation, continuous internal meetings were held from the second half of 2012, between the Pharmaceutical Service Standards, the Medical Supplies Procurement & Distribution Branch and Policy and Partnership Branches to formulate a draft based on the harmonization of Government of Papua New Guinea and World Health Organisation policy templates. The first draft was presented in mid 2013 at three Health Partnerships workshops attended by churches and government participants from the four respective regions. Three of these consultations were held in Port Moresby and one in Goroka, Eastern Highlands Province. Overwhelming inputs were received from all those that were consulted.

A final external consultation was convened on the 19th of July 2013 at the National Research Institute in Port Moresby. A significant number of key stakeholders attended, and their valuable contributions including further one to one stakeholder consultations with ICCC, IRC, PNG Customs, NAQIA, IPA/IPO and DAL thereafter, led to the final development and compilation of this document.

CHAPTER TWO – POLICY CONTEXT AND DIRECTIONS

2.1 Goal

The goal of the policy is to ensure that high quality medicines are accessible and affordable to the entire population at all times and that they are used rationally.

2.2 Vision and Mission

Vision: A healthy and prosperous nation, that is able to enjoy equity of access to quality pharmaceutical products and services

Mission: Improve, transform and provide quality pharmaceutical products and services to the people of Papua New Guinea

2.3 Objectives

1. To ensure adequate and continuous availability of safe, effective and good quality medicines to the entire population at all times
2. To ensure that essential medicines are affordable to all those who need them
3. To ensure available medicines are safe, efficacious and of high quality
4. To promote rational prescribing and dispensing of medicines by health professionals and the appropriate use of medicines by the patients
5. To develop and deploy human resources to support the successful and effective implementation of this policy and related legislation and regulations
6. To improve and strengthen management and delivery of Pharmaceutical Services through reforms, restructuring, streamlining, better role delineation, and partnership
7. To monitor and evaluate regularly the performance and achievements of the National Medicine Policy 2014

2.4 Principles

The following principles will serve as the underlying values that will provide the inspiration and guidance towards the implementation of the National Medicines Policy 2014:

- **Responsibility for Policy** - coordination of its implementation, monitoring, evaluation and technical oversight remains with the National Department of Health.
- **Equity** - fairness in access to pharmaceutical service and products
- **Efficiency –** deliver maximum outcomes with available resources
- **Embrace NDOH PLICIT value's** maintain Professionalism, Loyalty, Integrity, Courage, Innovation and Team work in the discharge of duties
- **Transparency –** demonstrate a complete accountability for actions and decisions taken
- **Health and Safety –** be health and safety conscious, and ensure adherence to minimum safety standards at the workplace
- **Informed Consent –** take action with prior informed agreement from clients
- **Confidentiality** - Respect and maintain the rights of others to privacy
- **Partnership** - embrace the potential of working with others for a common good
- **Sustainability –** maintain benefits into the future without external support

2.5 Core Government Legislation and Policies

The following key Government policies and standards, legislations and regulations will have both direct and indirect relevance to the achievement of National Medicines Policy 2014.

The implementation of the policy may require making reference to the following different policies and legislations, particularly, in cross-cutting areas and areas of shared concern.

2.5.1 Policies, Standards and Guidelines

- Government of Papua New Guinea Vision 2050
- Papua New Guinea Development Strategic Plan 2011-2030
- National Health Plan 2011-2020
- Traditional Medicines Policy 2007
- Health Sector Research Policy 2010

- National Health Service Standards 2011
- Medium Term Development Plan 2011-2015
- Health Human Resource Policy 2012
- Free Primary Health Care and Subsidized Specialized Services Policy 2013
- Community Health Post Policy 2013
- Health Sector Partnership Policy 2014

2.5.2 Acts and Regulations

- Poisons and Dangerous Substance Act 1952
- Animals Act 1952
- Income Tax Act 1959
- Customs Prohibited Exports Regulation 1963
- Veterinary Surgeons Act 1966
- Public Health Act 1973
- Customs Prohibited Imports Regulation 1973
- National Constitution of Papua New Guinea 1974
- Medical Registration Act 1980
- Infant Baby Feeding and Control Act 1984
- Customs and Tariff Act 1990
- National Narcotics Control Board Act 1992
- Investment Promotion Act 1992
- Public Hospital Act 1994
- Organic Law on Provincial and Local Level Government 1995
- Public Finance Management Act 1995
- Public Services Management Act 1995
- National Health Administration Act 1997
- National Agriculture Quarantine & Inspection Authority Act 1997
- Companies Act 1997
- Medicines and Cosmetic Act 1999
- Environmental Act 2000
- PNG Non Citizenship Act 2000
- Patent and Industrial Designs Act 2000
- Prices Regulation Act (Chapter 320)
- Independent Consumer & Competition Commission Act 2002
- Provincial Health Authority Act 2007
- Revised Public Hospital Charges Regulation 2013
- Revised Dental Charges Regulation 2013

CHAPTER THREE – POLICIES AND STRATEGIES

3.1 Current Situation and Analysis of Issues

The National Drug Policy 1998 provided the first policy framework and direction for effective delivery of pharmaceutical services in Papua New Guinea. Implementation of this policy has seen advances in the provision and regulation of pharmaceutical services in both the public and private sectors. A number of policy objectives however, have not been fully achieved due to limited resources and over the years emerging issues and challenges have limited effective delivery of pharmaceutical services. This has necessitated review of the policy to address the current challenges and provide policy direction to; ensure the availability and affordability of medicines, improve regulation of the pharmaceutical sector and quality assurance systems for medicines circulating in the country, promote rational use of medicines and also to address human resource development and good governance within the pharmaceutical sector.

Over the last few years, continuous shortage of essential medicines in public health facilities has led to national outcry. This has been attributed mainly to poor forecasting, quantification and procurement planning at the national level, and poor inventory management and reporting at the health facility level. The increase in population and increasing cost of medicines has meant that increased funding is required from Government for procurement of medicines and medical devices for the public health facilities and within the private pharmaceutical sector, there is a need to introduce mechanisms for controlling and regulating the price of medicines to ensure affordability for the average Papua New Guinean.

The pharmaceutical sector in PNG has grown steadily over the last decade and with the increasing global circulation of counterfeit and substandard medicines there is an urgent need to effectively regulate medicines circulating in the country to ensure that they are safe, effective and of good quality. This includes improving requirements and processes for issuing of licenses for importation and sale of conventional and complimentary medicines, fast-tracking product registration and strengthening collaboration with stakeholders to ensure compliance.

The illegal sale of prescription medicines in market places and unlicensed outlets together with public ignorance about the dangers of medicines leads to self-prescribing by patients and irrational use of medicines. This can lead to serious long term outcomes such as antimicrobial resistance which poses a greater burden on the public health care system. The use of antibiotics for veterinary purposes and in animal husbandry does add to antimicrobial resistance. Irrational prescribing practices by health professionals also contribute to the irrational use of medicines and this can be addressed through awareness and adequate training.

The lack of qualified pharmacy professionals in key strategic positions within the healthcare delivery system was a major limiting factor to full implementation of the National Drug Policy 1998. A consistent number of national pharmacists have been

trained over the years to address this challenge and in recent years the recruitment of pharmacists into the public health system has been a positive achievement. There is still a need for recruitment of more pharmacy professionals at all levels of the public health system and for adequate training of other health professionals for effective delivery of pharmaceutical services. Improved human resource planning including consideration of incentives such as adequate remuneration and continued professional education is required.

In order to effectively implement this policy, relevant legislation and regulations must be updated and enforced. Close collaboration with partners and stakeholders is required and good governance and management must be practiced at all levels. Ultimately, the National Department of Health should work towards establishing a National Medicines Regulatory Authority to effectively regulate the pharmaceutical sector in PNG.

3.2 Policies and Strategies

3.2.1 Medicines Availability

There are important determinants that are considered when ensuring availability of medicines. These include i) evidence based selection ii) effective and transparent procurement processes iii) reliable inventory systems iv) and an effective storage and distribution system.

A sound functioning system that performs well will be able to ensure adequate and continuous availability of safe, effective and good quality medicines to the entire population at all times.

i) Selection

Medicines shall be rationally selected for use in the country in accordance with the "essential medicines" concept and prioritized by generic names

Strategies:

a) The NDoH Pharmaceutical Advisory Committee (PAC) will review the Medical and Dental Catalogue in line with changes in standard treatment guidelines and clinical practice.

b) The Pharmaceutical Advisory Committee (PAC) will ensure selection of medicines included in the Medical and Dental Catalogue will be by generic names.

c) Request for purchase and use of non-catalogued medicines will be coordinated through the established Medicines Therapeutic Committees (MTC) in all hospitals.

d) The NDOH will advocate and ensure private pharmaceutical providers support and implement the essential medicines concept.

ii) Procurement

Medicines procurement for the public health system shall remain a centralized function of Government. NDoH as the steward of the Health System shall take carriage of this function and ensure Vital, Essential and Non-Essential medicines are available in adequate quantities at all times

Strategies:

a) The NDoH will work with provinces, PHA, hospitals and districts to strengthen processes for determining correct quantities of medicines for procurement based on consumption and morbidity trends

b) The NDoH will collaborate with partners to strengthen public sector procurement systems in accordance with the Public Finance Management Act 1995, Good Procurement Practice Guidelines and Vital, Essential and Non-Essential (VEN) Classification

c) Advocate for private pharmaceutical sector involvement in supporting the NDoH initiatives in promoting availability of VEN medicines

d) The NDoH will liaise with Central Agencies to reinstate the powers of the Pharmaceutical Supplies and Tenders Board (PSTB) as enshrined in the Public Finance Management Act 1995.

e) The NDOH will advocate for "green procurement" initiatives to all relevant stakeholders

iii) Storage

All Medicines should be appropriately stored and secured in accordance with good storage practices

Strategies:

a) All stakeholders will enforce compliance to good storage practices set out in the Good Storage Practice Guidelines

b) All Pharmaceutical establishment will adapt and design storage premises to minimum standards that would ensure good storage conditions as set out in the National Health Services Standards and other relevant standards

c) The number of Area Medical Stores will be rationalized and the capacity of provincial transit stores strengthened as per the Medical Supplies reform plan.

d) Appropriate security measures will be introduced by all relevant stakeholders to prevent theft and misuse of medicines.

iv) Inventory Management

A centralized Stock Inventory Management information system will be used to support management decision making

Strategies:

a) A suitable computerized inventory system in line with Health Sector ICT Policy, will be deployed linking the Central (National) level, Area Medical Stores, Provincial Transit Stores and Provincial Hospitals

b) The NDOH will work with provinces, Provincial Health Authorities (PHA) and hospitals to ensure correct, complete and timely reporting of stock management information are processed through their respective Medicines Therapeutic Committees (MTC) to the Central level for appropriate action

v) Distribution

Vital, Essential and Non-Essential medicines shall be made available andaccessible to all health facilities including the remotest ones at all times

Strategies:

a) All relevant stakeholders are to ensure Good Storage Practice and Good Distribution Practice guidelines are adhered to along the supply chain.

b) A National Medical Supplies Distribution plan considering specific geographic conditions and routes of transportation will be developed and implemented

c) The NDoH will engage with all partners where possible in the delivery of medicines and outsource logistics management functions where applicable in line with the relevant objective in the NHP 2011-2020

d) Mandatory requirements for compliance to good storage and distribution practices will be built into distribution contracts, and contractors' performance will be monitored against set indicators on a regular basis.

e) The NDoH will work with partners and other relevant stakeholders to strengthen "pull systems" for resupply of medicines to health facilities and build capacity of provinces and districts to implement this system

vi) Local production

Local production of generic medicines and natural health products will be promoted and encouraged and will be subjected to product registration

Strategies:

a) The NDoH will work with other state agencies to encourage locally manufactured generic medicines and natural health products for local use and exports.

b) A set of criteria for good manufacturing practice for production will be developed, enforced and compliance monitored.

vii) Disposal of expired and unwanted medicines

Expired and unwanted medicines shall be disposed safely to minimize hazard to the community and environment

Strategies:

a) Expired and unwanted medicines will be disposed-off in accordance with safe and environmentally friendly disposal methods as outlined in the National Stock Management System Handbook

b) The NDoH will work with other relevant stakeholders to promote through public education the correct and safe disposal of expired or unwanted medicines

c) Medicines and other health products which are imported illegally and those that do not meet relevant national laws for imports will be seized at entry points, detained and destroyed under PNG Customs laws.

d) The NDOH will collaborate with Provinces, Provincial Health Authorities, Public Hospitals and other Regulatory and Enforcement Agencies to plan, procure and install at least one incinerator each in all provinces either at the Regional Area Medical Stores, Provincial Transit Stores or major sea/land ports of entries in the country

e) The NDoH will work in partnerships with relevant law enforcement and border surveillance agencies to carry out border surveillance on illegal medicinal imports

3.2.2 Medicines Affordability

The ability to afford medicines can impact on whether a patient receives a full course of treatment or no treatment at all. The Government's "Free Primary Health Care and Subsidized Specialist Care Policy" intends to ensure minimal costs for those accessing primary and specialist health services in the public sector. This attempt should be complemented by exploring other options for financing, including insurance and endowment schemes.

The Government also has a policy incentive in force on tax exemption for all medicines and health goods imported into the country for all sectors. The impact of this policy on pricing structures, especially in the private sector is unclear. With a free passage into the market, it is necessary that the Government introduce price control measures to allow for fair pricing structures across the private sector for the sale of medicines.

Government interventions in financing schemes as well as pricing control for medicines are necessary to limit out-of pocket spending on medicines and improve access to medicines for all.

i) Financing of medicines

Sufficient funding based on evidence shall be made available for the procurement and distribution of adequate quantities of Vital, Essential and Non-Essential medicines

Strategies:

a) The NDoH will continue to provide evidence based budgeting and advocate for Government to continue its commitment to provide funds for Essential medicines through annual budget and increase according to population growth, morbidity trends and market forces

b) Medicines be provided free of charge or against a minimal fee in alignment with the "Free Primary Health Care and Subsidized Specialist Health Care Policy 2013" for the public health system

c) The Government will explore other options for health financing such as health insurance schemes as an additional means to finance medicines

ii) Price of Medicines

Quality Essential Medicines prices shall be regulated to promote accessibility and affordability

Strategies:

a) The NDoH will advocate for the establishment of a Pricing Committee with clear terms of reference and membership from relevant stakeholders to set pricing for medicines and monitor its implementation.

b) The NDoH will coordinate with pharmaceutical manufacturers, importers, wholesalers, retailers, dispensaries, private clinics and hospitals to ensure medicine pricing structures are shared among all relevant stakeholders via Pricing committee and other state price regulatory bodies.

c) The NDoH will continue to advocate with relevant government agencies for imports of medicines to continue to be exempted from tax in line with Government policy.

d) The NDoH will advocate for the introduction of a non-discriminatory wholesale and retail percentage markup system and other applicable pricing policies for essential medicines.

e) Medicines pricing information will be collected, analyzed and disseminated to guide public health procurements; and consumers buying medicines from the private sector.

f) Procurement of essential medicines for the public health system will be through competitive tendering processes with specifications for generic products.

iii) Compulsory license and parallel import

The government shall use, to full, the provisions in the TRIPS Agreement (Doha Declaration 2001) to protect public health, in particular to promote access to medicines for all

Strategies:

a) The NDoH will liaise with IPA and IPO in implementing regulations related to Intellectual Property Rights (IPR), and take advantage of the provisions and flexibilities within the TRIPS agreement for the promotion of public health and to ensure access to medicines

b) The Government, through NDoH in consultation with other regulatory agencies be at liberty to determine what constitutes a national public health emergency and establish its own regime for IPR limits without challenge

c) The Government will exercise its freedom to implement the Research Exception and Bolar Provisions under TRIPS agreement for access to patent medicines for purpose of research, ethical clearance and other regulatory requirements as needed by the government to facilitate improvement in medicine quality and to regulate its supply and use within PNG.

d) The Government through its stakeholders will be allowed to implement and utilize legal provisions to remedy anti-competitiveness and non-use (or non-work) of patent medicine and equipment in PNG through non-voluntary license and/or compulsory license and/or parallel importation for purpose of addressing public health issues.

3.2.3 Regulation and Quality Assurance

The National Department of Health must ensure that public health is secured through the establishment of a comprehensive quality assurance system for medicines that are imported into the country for public use. This calls for improved regulatory and quality assurance frameworks to counter any threat of exposure to low quality medicines by the population.

The procedures and interventions must target both pre-marketing and post marketing surveillance including; product registrations, personnel and establishment licensing, improved inspection services, routine testing, enforcement of good storage and distribution practices, rational use and reporting or recall programs. A robust functioning regulatory and quality assurance system supported by competent legislation, will ensure available medicines are safe, efficacious and of high quality.

i) Registration of medicines

Only medicines duly registered by the National Regulatory Authority (Pharmacy Board) shall be allowed to be marketed and used in the country

Strategies:

a) Product registration guidelines with inputs for assessment turnaround times, license duration, renewal requirements and technical expertise for assessments will be reviewed.

b) Registration procedures for essential medicines will be prioritized and fast tracked

c) Registration will be waivered for medicines which will be used for clinical trial purposes upon provision of clinical trial certificate issued by the Pharmacy Board of PNG.

d) The NDOH via Pharmaceutical Services Standards Branch will liaise with ICT branch and WHO to ensure product registration database is improved and capable of hosting online product registration and other features that will allow ease of access to information by users

e) The NDoH will ensure that only registered medicines are procured and imported into the country and also provide post marketing surveillance to ensure medicines on the market maintained quality standards

ii) Pharmaceutical premises

Only licensed pharmaceutical establishments, shall conduct import, export, wholesale, production and retail of medicines

Strategies:

a) Granting and renewal of licenses will be upon satisfactory compliance to minimum standards set out in the Medicines and Cosmetic Act, the Regulation and the National Health Service Standards

b) All pharmaceutical establishments will be encouraged to register trading names with the Investment Promotion Authority (IPA) with specific intentions only for pharmaceutical business and must employ registered pharmacists.

c) All premises used for wholesaling of medicines must be designed, arranged and operated in a manner that must not allow other activities to compromise the quality of medicines and in line with Good Storage and Good Distribution Practice Guideline.

d) The NDoH will work with relevant authorities to ensure retail pharmacies are segregated from other businesses with only a limited number of secondary retail activities allowed within the confines of the premises, as outline in the Good Pharmacy Practice Guideline.

e) The NDoH will advocate for pharmacy premises to be designed to meet standard requirements such as; space, temperature, humidity, staffing and location in accordance with Good Pharmacy Practice Guidelines.

f) The Pharmacy Board will review and impose new licensing fee schedules for manufacturers, importers, wholesaler and retailers

g) The Pharmacy Board will ensure that only qualified pharmacists, and other relevant health professionals that will be determined, be licensed to retail and wholesale medicines and other medical supplies

h) In line with Government priorities to promote the SME sector, and encourage indigenous participation, NDoH will advocate for wholesale and retail pharmacy ventures to be considered for inclusion in reserve list and restricted only to partnerships with nationals.

iii) Personnel

Only qualified pharmacists shall be licensed by the Pharmacy Board to practice in the country

Strategies:

a) The Pharmacy Board in collaboration with NDoH will advocate for all employers and recruiting agencies to ensure their employee pharmacists register annually with the Pharmacy Board in-order to practice

b) The Pharmacy Board in consultation with relevant stakeholders will revise and update the licensing criteria for foreign pharmacists on regular basis

c) The Pharmacy Board will engage with relevant professional bodies for the development and coordination of activities required for registration of national intern pharmacists

iv) Inspection

Pharmaceutical Inspections function of NDoH will be strengthened and improved to ensure compliance to policies, standards and legislations.

Strategies:

a) Enforcement of standards for quality in both the public and private sectors will be advocated and strengthened.

b) Empower and capacity build Pharmaceutical Inspectors and relevant law enforcement and border surveillance agencies to effectively deliver inspection services as required to ensure compliance to the National Medicines Policy 2014, Medicines and Cosmetics Act and its related Regulation

c) Promote professional conduct in line of duties for inspectors and ensure inspections are carried out according to guidelines and law

d) The NDoH will pursue active partnerships with relevant government authorities for inspection and enforcement of legislation through MoUs

v) Quality Control

All medicines marketed in the country should meet acceptable quality standards

Strategies:

a) A national quality control laboratory for testing of medicines will be established and a continuous program of sampling and testing of selected medicinal products marketed in the country will be undertaken

b) Formal cooperation/partnerships will be explored and existing agreements maintained with relevant partners and recognized laboratories within the region for quality testing of medicines regularly and on needs basis and also with other regional accreditation bodies

c) Global measures to counter circulation of counterfeit and substandard medicines will be adopted including enacting new laws

d) The NDoH will work with front line Government Agencies and train them on simple screening methods to detect counterfeit and banned medicines

vi) Medicine donations

The National Guideline for Medicines Donations shall guide all donations of medicines into the country. Any donations not meeting the requirements shall be detained and destroyed at the point of entry into the country.

Strategies:

a) The National Guideline on donations will be widely distributed and awareness with key messages advocated on for public interest.

b) Unapproved imported donations of medicines and medical devices will be seized at entry points, detained and destroyed under PNG Customs laws

c) Regulations to allow mandatory issue of import permits for all donations of medicines and medical supplies will be developed and implemented according to the Operational Guideline with PNG Customs Services.

vii) Regulation of narcotic drugs and psychotropic substances

All Narcotic drugs and Psychotropic substances shall be restricted for therapeutic use and purposes only

Strategies:

a) All licensing, import and export of controlled substances will be in accordance with the Poisons and Dangerous Drug Act 1952, National Narcotic Control Board Act and Customs Prohibited Imports Regulation 1973 and Exports Regulation 1963

b) All Narcotic Drugs and Psychotropic substances will continue to be listed as controlled medicines requiring appropriate handling, storage, inventory and documentation

c) All imports will continue to be controlled through issue of import permits per consignment.

d) Access to narcotic drugs, psychotropic substances and other medicines with potential for abuse will be restricted to only needs based requisition (pull system) from health facilities.

e) Reports on national utilization of narcotic drugs and psychotropic substances in both the public and private sectors will be regularly updated and reported on.

viii) Regulation of natural health products

The use of natural health products in complementary and alternative medicine shall be regulated.

Strategies:

a) All natural products used in complementary and alternative medicine will be listed with the Pharmacy Board and regulated according to their risks
b) All importers and wholesalers of natural health products will register with the Pharmacy Board of PNG
c) The NDoH will advocate to ensure the public is made aware that advertising of natural products do not carry therapeutic claims or exaggerated or mislead on benefits and risks.
d) Post marketing surveillance and adverse events reporting mechanism will be strengthened and improved
e) The NDoH will ensure the public have access to safe and effective natural products by investigating their safety, efficacy and quality
f) All natural health products with therapeutic indications manufactured domestically for commercial use will be subject to product registration

ix) Regulation of cosmetics with therapeutic indications

The use of cosmetic products with therapeutic indications shall be regulated

Strategies:

a) All cosmetic preparations with active pharmaceutical ingredients that require prescription or advice from a clinician or pharmacist will be registered
b) The Pharmacy Board of PNG will work with relevant stakeholders to ensure cosmetics with minimal risk to public health and safety are listed
c) All establishments intending to manufacture, import and sell cosmetics with therapeutic indications will be licensed by Pharmacy Board of Papua New Guinea

3.2.4 Rational Use of Medicines

The Conference of Experts on the Rational Use of Medicines, convened by the WHO in 1985 defined rational use as follows; "The rational use of medicines requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time and at the lowest cost to them and their community".

There are critical negative feedbacks associated with irrational use such as side-effects, treatment failure, deteriorating health conditions, resistance development etc. Use of medicines in veterinary sector adds to antimicrobial resistance problems worldwide.

This policy therefore, aims to achieve rational use by advocating for rational prescribing and dispensing of medicines by health professionals and the appropriate use of medicines by the public. The NDOH will collaborate with Statutory veterinary

regulatory authority to ensure use of medicines in veterinary sector and animal husbandry is rational in order to achieve favorable health outcomes.

i) Education and training

All Health professionals shall be trained and made aware of "essential medicines" concept and rational use of medicines

Strategies:

a) Curricula for training of health professionals involved in diagnosis, prescribing and dispensing will include components on essential medicines concept, rational use of medicines, patient counseling and stock management

b) The NDoH will work with provinces, PHAs and hospitals and conduct continued pharmacy education to health professionals on rational drug use

c) The NDoH will continue to advocate and promote prescribing and dispensing of generic medicines in the public and private sectors in accordance with standard treatment guidelines and essential medicine lists

ii) Medicines Information

Information on medicines safety, effectiveness and efficiency shall be promoted

Strategies:

a) The National Medicines Information and Pharmacovigilance Center will be strengthened to promote safe, effective and efficient use of medicines by providing evidence based information on therapeutic use of medicines to health care professionals and the public

b) The NDOH will liaise with Medicines Therapeutic Committee from provinces, hospitals and PHAs to monitor adverse drug reactions and provide report on a timely manner for appropriate action and advice for correction

c) The NDoH will conduct awareness to encourage public reporting of adverse events and for timely and appropriate action

iii) Public Education

Correct information on medicines and their use shall be made available to the general public

Strategies:

a) The NDoH will advocate and promote safe and effective use of medicines through various channels including the use of all public media

b) The NDoH will engage all partners to drive messages across to the public on rational use of medicines and the consequences of irrational use

iv) Medicines Therapeutic Committees

All levels of health care system shall be encourage to establish governance processes in their establishments for good pharmaceutical management practices and services

Strategies:

a) All provincial hospitals in the country will be encouraged to establish the Medicine Therapeutic Committee (MTC).

b) The NDOH through Pharmaceutical Services Standards Branch (PSSB) will provide advice and technical support for the formation and functioning of the MTC

c) Reporting of adverse drug reactions will be in line with reporting arrangements in the MTC Guideline

v) Advertisement and Promotion

All advertisements relating to medicines or products which therapeutic claims are made shall be approved by the Pharmacy Board of PNG before advertisement.

Strategies:

a) The NDoH will regulate and advocate for advertisement of medicinal products or products with therapeutic claims gets approval to encourage rational use and should not be misleading nor should claims be exaggerated

b) An ethical criteria for promotion of medicinal products based on the "WHO ethical criteria for medicinal drug promotion" will be developed and included in legislation to provide a legal base for control of advertising

c) Regulations to lay out different requirements for advertising to the health professionals and the public will be developed and circulated.

d) The Pharmacy Board of PNG in collaboration with NDoH will encourage reporting of advertisements which are deemed unethical and complaints investigated.

vi) Appropriate prescribing

Prescribing of medicines shall only be by duly registered practitioners in accordance with good prescribing practice and in-line with Standard Treatment Guidelines

Strategies:

a) The NDoH will ensure there is generic prescribing in the public sector and pro-actively promote generic prescribing in the private sector

b) The NDoH will advocate for the provision of clinical pharmacy service to support rational use of medicines be taken up by major hospitals in line with National Health Service Standards charter for doctor-pharmacist ratios

vii) Dispensing

All medicines shall be labelled and dispensed using generic names

Strategies:

a) Adherence to good dispensing practices as detailed in the Good Pharmacy Practice Standards guideline will be promoted through the Medicine Therapeutic Committee at health facility level.

b) All medicines are to be dispensed only by duly registered pharmacist.

viii) Combating antimicrobial resistance (AMR)

Global measures to mitigate emergence of resistance to anti-microbials shall be adopted and promoted to achieve favourable public health outcomes

Strategies:

a) The NDoH will work with relevant stakeholders to ensure continuous access to essential quality assured anti-microbials

b) Rational use of anti-microbials will be advocated through established MTCs in all health facility levels.

c) The NDoH will work with DAL and NAQIA and other relevant government agencies for the control of anti-microbial use in veterinary medicine and animal husbandry

d) Partnerships with relevant domestic and international laboratories for antimicrobial surveillance and sensitivity testing will be undertaken and strengthened.

3.2.5 Human Resource Development

Human resource is critical and central to the delivery of government priorities and services. Papua New Guinea has an ongoing issue with lack of educated professional and technical staff to contribute to national development. The Health Sector Work Force Crisis Review Report 2011, by the World Bank, highlighted shortfalls in human resources for health, and recommended for accelerated efforts to address this problem. The NDoH is formulating several response plans, including the Health Human Resource Enhancement Plan 2014-2016 and the Health Human Resource Policy 2012. In line with the NDoH response, this policy aims to ensure the Department of Health in collaboration with key stakeholders, develop and deploy adequately trained human resources for health, in particular for the pharmaceutical sector.

i) Human Resource Planning

There shall be sufficient quality human resources in the pharmaceutical sector for effective service delivery

Strategies:

a) The Pharmaceutical Standards Branch and the Medical Supplies Procurement and Distribution Branch will work with the Human Resources Branch of NDoH to develop a human resource plan that will ensure that appropriately trained and

well-motivated pharmacy personnel are available in the health sector to provide effective pharmaceutical services

b) In line with the National Health Service Standards 2011 charter on role delineation, NDoH will advocate to Provinces, Provincial Health Authorities and Public Hospitals to ensure pharmacy professionals are placed at all levels of health care system to effectively implement this policy

c) The NDoH, Hospitals and Provincial Health Authorities will create opportunities and incentives for placement of pharmacy personnel at health centers levels to national referral hospitals (Levels 3-7) in the public sector

d) The NDoH will advocate for clinical pharmacists to be recruited in major health facilities to support rational use of medicines in line with National Health Service Standards charter for doctor-pharmacist ratios

ii) Human Resource Training

Health professionals shall be appropriately skilled and knowledgeable in management and use of medicines

Strategies:

a) The NDoH will collaborate with health training institutions to incorporate curriculum on the appropriate skills in management and use of medicines for all health care professionals

b) Curriculum for pharmacy technicians and assistants will be developed in collaboration with health training institutions

c) The NDoH will collaborate with all partners to ensure the continued motivation and retention through the provision of proper incentives, including; regular in-service training, continued professional education and post graduate training

d) The NDoH will plan and budget for pharmacist working in the public sector to undertake post graduate training

3.2.6 Good Governance and Management Framework

This policy aims to improve organizational structure and optimize performance in the delivery of pharmaceutical services in the country. This requires the Government through Central Agencies and the NDoH to plan for better organizational performance through reforms and streamlining with better role definition and delineation to achieve efficiency in delivering pharmaceutical services.

Additionally, operational researches must be financed and conducted to measure key policy areas in the National Medicines Policy 2014. Findings from the researches can be used to review approaches and redesign policies for way forward. Supported by competent legislation and utilizing partnerships, the National Medicines Policy 2014 key objectives can be fully realized in the medium term.

i) Structure and functions

Medicines Quality Assurance system performance shall be promoted through better alignment of organisational structures to achieving department and sector functional goals and objectives

Strategies:

a) The NDoH will do review and provide options to Minister for Health and HIV/AIDS to establish an autonomous body (National Medicines Regulatory Authority) reporting directly to the Ministry to regulate pharmaceutical affairs of the country

b) The Medical Supplies Procurement and Distribution Branch will be reformed to increase staff ceiling and streamlining roles and job descriptions

c) The NDoH will absorb the Pharmacy Board Secretariat into its organizational structure

d) Organizational work culture that thrives on the principles of transparency, accountability and fair participation for all will be promoted for efficient and effective services

e) Domestic and international partnerships for technical co-operation in areas of good governance and management will be enhanced and established.

f) Independent systems and regulatory audits will be encouraged and supported to ensure optimal organizational performance and conformance to standards and good practices

ii) Research

All research and studies concerning medicines and the system in PNG shall comply with the National Health Research Policy and as prioritized under the Health research agendas

Strategies:

a) The NDoH will plan and budget for funding to support and conduct research prioritized under the national health research agendas.

b) Operational research and other studies supporting the monitoring and evaluation of this policy will be promoted by the health sector organizations.

c) The NDoH will advocate and encourage provinces, hospitals and PHAs to plan, budget and conduct operational research to improve their services.

iii) Legislation

Existing legislations and regulations shall be revised to effect implementation of the National Medicines Policy

Strategies:

a) The NDoH will lead the health sector partners to update existing legislations and regulations as and when required to enforce policy directions and address changes affecting the pharmaceutical sector

iv) Approaches

There is only one Health system and partnerships with the Public and Private sector shall be led and undertaken by the NDoH in implementing this policy.

Strategies:

a) The Department of Health in its stewardship role will ensure all partners involved in medicines procurement and supply on behalf of the state, operate under formal agreements and comply with relevant state policies, regulations and laws

b) There will be increased coordination within the health sector including churches and non-governmental organizations

c) Inter-sectorial cooperation with public sector such Finance, Education, Personnel Management and Provincial Administrations will be strengthen and enhanced

d) There will be increased health systems responsibility to local authorities in line with the Organic Law on Provincial Governments and Local Level Governments.

e) There will be request for Technical Cooperation with other countries and international agencies in such fields as: evaluation of drugs, exchange of drug information, quality control, transfers of technology, training and human resources development

f) The NDOH via PSSB will develop operational guidelines to effect MoUs between NDoH and front line Agencies such as PNG Customs and Royal Papua New Guinea Constabulary

g) Timely Information sharing among key stakeholder and health partners for mutual benefits will be encouraged and strengthened through established agreements

h) Use of restricted and specialized medicines at the primary health care system will be facilitated through the established referral pathways as indicated by the National Health Service Standards.

CHAPTER FOUR – IMPLEMENTATION PLAN

Health is a decentralized function of government under the Organic Law on Provincial and Local Level Government (OLPLLG) 1995. The decentralized functions are articulated in the National Health Administration Act 1997, the Public Hospitals Act 1994 and the Provincial Health Authorities Act 2007 and other complementary legislations outlined in chapter one of this policy.

The National Health Administration Act 1997 provides the NDoH the mandate to lead the health sector in developing policies to set directions for implementation. This policy is developed in fulfilment of the National Health Plan's Medical Supplies/Pharmaceutical Services Reform Agenda under Key Result Area 3.

The strategies from National Health Plan 2011-2020, the Medical Supplies Reform Plan, the Alotau Accord Priorities and the National Health Services Standards are well articulated in this policy and the NDoH Corporate Plan.

The NDoH will be implementing this policy through its Annual Implementation Planning and Budgetary process, utilizing both recurrent and Development budgets.

Like the NDoH, all Provinces, Provincial Health Authorities and the Public Hospitals will plan and budget for their implementation annually through the normal planning and budgetary process. Most of them will be revising their Provincial Strategic Implementation Plans, the Provincial Development Plans, the Hospital Strategic Implementation Plan or their Corporate Plans in alignment to the National Health Plan Midterm review in 2015. This will be the opportunity for them to incorporate related strategies from the National Medicine Policy 2014 into their plans.

The private sector including the Non-Government Organisations will implement this policy within their own jurisdiction taking into account their own goals, objectives and resources, however they are encouraged to work with the local government authorities in the area which they operate from.

The government through the local and national function will work with the private sector utilizing partnership agreements as specified in the Health Sector Partnerships Policy 2014 to implement this policy. This is to ensure efforts of all stakeholders in the health system are well coordinated and reported on towards the achievements of the National Health Plan 2011-2020 priorities and the 2012 Alotau Accord Priorities. All partners brief roles in implementing this policy is listed in Annex 1.

CHAPTER FIVE – MONITORING AND EVALUATION

Establishing a monitoring and evaluation framework with regular communication between NDoH and its partners is required to continuously measure the performance of the National Medicines Policy 2014. System audits and quality checks which are part of the process will be conducted on pre-determined timeframes using approved checklists and indicators for measurement of progress. Operational researches will also be carried out and findings will be used to chart way forward. The Department of Health will;

1. Establish monitoring capacity within the Pharmaceutical Service Standards Branch and the Strategic Policy Branch to monitor implementation of this policy.

2. Develop suitable measurable key performance indicators to track progress of implementation and achievement of objectives

3. Conduct periodic monitoring of implementation progress through system performance audits and quality management checks

4. Conduct operational researches into key areas of the policy to identify gaps in implementation and propose interventions to correct problems

5. As a priority under the National Health Plan, monitoring and review of this policy will be done in consistent with the National Health Plan reviews.

ANNEX I: BRIEF ROLE OF KEY PLAYERS

In implementing this policy, NDoH will take into account the legislative requirements concerning partner's engagements with the different levels of government under the decentralised system in the following manner:

a) **Central Government Agencies –** will provide policy level support towards key policy strategies such as health financing, workforce planning etc.

b) **State Agencies and Regulatory bodies –** to provide regulatory support through joint inspection and monitoring efforts towards the control and surveillance of pharmaceutical activities within the country

c) **Provincial Governments and Provincial Health Authorities (PHA) –** to be actively involved in the implementation of the policies and strategies through formulation of achievable annual activity plans

d) **Public and Private Hospitals and health facilities –** Promote the rational use of medicines through the formation of Medicines Therapeutic Committees (MTC)

e) **Development Partners –** Provide technical assistance towards capacity building and health systems strengthening

f) **Health Teaching Institutions –** Assist the NDoH to develop human resource capacity for the health sector, specifically the pharmaceutical sector

g) **Non-Government Organizations including Church Health Services (dealing with health care and medicines) -** To align their efforts in line with NDoH priorities outlined in the policy and to ensure compliance with Government requirements

h) **Importers, wholesalers and retailers of medicines and health products –** To comply with relevant policies and laws for import, wholesale and retail of medicines and health products

i) **Non-conventional practitioners of herbal and traditional medicines –** Comply with regulations for practice and code of ethics for promotion

j) **Professional societies –** Affiliations for advocacy on professional conduct and ethics for Pharmacy professionals

k) **Research and Laboratory institutions –** Lead and support operational researches that has implications on the National Medicines Policy and other researches on medicines quality

l) **Standards and accreditation bodies –** Audits and accreditation of medicines testing facilities

ANNEX 2: LIST OF ACRONYMS

AMR	Anti-Microbial Resistance
AMS	Area Medical Store
APEC	Asia Pacific Economic Co-operation
DAL	Department of Agriculture and Livestock
GoPNG	Government of Papua New Guinea
ICCC	Independent Consumer Competition Commission
ICT	Information and Communication Technology
INN	International Non-Propriety Name
IPA	Investment Promotion Authority
IPO	Intellectual Property Office
IPR	Intellectual Property Rights
IRC	Internal Revenue Commission
MTC	Medicines Therapeutic Committee
NAQIA	National Agriculture Quarantine & Inspection Authority
NDoH	National Department of Health
NGO	Non – Governmental Organization
NHIS	National Health Information System
NHP	National Health Plan
NHSS	National Health Service Standards
NMP	National Medicines Policy
PAC	Pharmaceutical Advisory Committee
PHA	Provincial Health Authority
PSSB	Pharmaceutical Services Standards Branch
PSTB	Pharmaceutical Supplies and Tenders Board
RPNGC	Royal Papua New Guinea Constabulary
SME	Small to Medium Enterprise
TRIPS	Trade Related Intellectual Property Rights
VEN	Vital, Essential, Non - Essential
WHA	World Health Assembly
WHO	World Health Organization

ANNEX 3: DEFINITIONS

Adverse Drug Reaction (ADR) – may be defined as "any response to a drug which is noxious, unintended and occurs at doses normally used for prophylaxis, diagnosis or therapy". ADRs are therefore unwanted or unintended effects of a medicine which occur during its proper use.

Adverse Event – is defined as an event that led to a death, or led to a serious injury to a patient, user or to another person.

Anti-microbial resistance - Antimicrobial resistance (AMR) is resistance of a microorganism to an antimicrobial medicine to which it was originally sensitive.

Brand medicine – refers to a medicine that has a trade name and is protected by a patent. Brand name medicines are usually expensive.

Cosmetic – Means any substance or preparation, other than a medicament, intended to come into contact with the various external parts of the human body, with a view of cleaning, protecting, keeping them in good condition, changing the appearance or perfuming or correcting their odor, but does not include a soap.

Counterfeit medicine – means medicines that are 'deliberately and fraudulently mislabeled with respect to identity and/or source', and may include those with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.

Dispense – means to prepare and distribute to a patient a course of therapy on the basis of a valid prescription.

Essential (E) – Essential medicines or medical devices that are effective against less severe but significant forms of disease, but not absolutely vital for providing basic health care.

Essential medicines concept - as defined by the World Health Organization (WHO) are: "those medicines that satisfy the health care needs of the majority of the population; they should therefore be available at all times in adequate amounts and in appropriate dosage forms, at a price the community can afford".

Exporter - means the registered exporter of medicines and other health products with the Pharmacy Board of PNG.

Generic medicine – refers to any medicine marketed under its chemical name (INN). Generic medicines are usually cheaper than brand name medicines

Good distribution practice – refers to the good storage and distribution practices outlined in the Good Distribution Practice Guidelines.

Good storage practice - refers to the good storage and distribution practices outlined in the Good Distribution Practice Guidelines.

Green procurement – initiatives to source environmentally friendly products

Health training institutions – Includes higher learning institutions such as nursing schools and universities that train all cadres of health workers

Herbal medicine – includes herbs, herbal materials, herbal preparations and finished herbal products

Importer - means the importer of medicines and other health products registered with the Pharmacy Board of PNG who imports from a manufacturer and resells to buyers.

Licensing authority – Means the Departmental Head of the National Department of Health.

Medical and Dental Catalogue – A catalogue of health products which includes an essential medicines list and other medical supplies.

Medicines – Any substance in a pharmaceutical product that is used to modify or explore physiological systems or pathological states for the benefit of the recipient. In this policy the words "drug", "medicine" and "pharmaceutical" are terms used interchangeably and may denote herbal medicines and medical devices.

Medicines Therapeutic Committee – A hospital based committee that looks at the drug management cycle of selection, procurement, distribution and use.

Narcotic drugs – means medicines that have the potency to create an addiction to or are likely to be abused apart from its intended therapeutic effect

Natural products – are substances used in complementary and alternative medicine that have origins from plants or animals

Non-Essential (N) – Necessary medicines and medical devices that are necessarily used for minor or self-limited illnesses or not essential, very rarely used or not used at all overtime and should be deleted from the Medical and Dental Catalogue.

Pharmaceutical Inspector – means an officer that has been trained, and appointed by the Pharmacy Board and gazetted to conduct pharmaceutical inspections.

Pharmacovigilance – is the science of detection, assessment and prevention of adverse reactions to medicines and medicine related problems.

Pharmacy – is a retail premises registered with the Pharmacy Board of PNG for retailing of medicines and medical supplies.

Psychotropic substances – are medicines that have the potency to affect the mental state of mind.

Pull systems – a drug distribution system in which each peripheral health facility determines the medicine quantities to be requisitioned from the procurement unit or storage warehouse.

Quality medicines - refers to medicines that are safe, efficacious and of acceptable quality.

Rational use – means that patients receive medicines appropriate to their clinical needs, in doses that meet their individual requirements for adequate period of time, and the lowest cost to them and their community.

Standard Treatment Guideline – means an essential information guide which is published to guide management of common diseases.

Substandard medicine – refers to medicines that are produced with inadequate attention to good manufacturing practices and may have contents and/or dissolution times outside accepted limits, due to poor quality control.

Therapeutic - refers to healing, such as a medicine or therapy that has healing or curative capability for treatment of disease or disability.

Traditional medicine – refers to pre-western indigenous health practices, approaches, knowledge and beliefs, incorporating plants, animals, and mineral based medicines, including spiritual beliefs, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.

Veterinary Medicines – refers to medicines or antimicrobials use in veterinary and animal husbandry purposes.

Vital (V) – Vital medicines or medical devices for potentially life-saving or crucial to providing basic health services and also used frequently for first-line treatment.

Wholesaler – means the wholesaler of medicines registered with the Pharmacy Board of PNG who buys medical supplies from a manufacturer and resells to buyers.

ANNEX 4: CONTRIBUTORS TO THE POLICY DEVELOPMENT

Angau Memorial Hospital Pharmacy
Area Medical Stores, Lae
Area Medical Stores, Madang
Area Medical Stores, Mt. Hagen
Area Medical Stores, Port Moresby
Area Medical Stores, Wewak
Australian Agency for International Development (AusAID)
Borneo Pacific Pharmaceuticals
Churches Medical Council (CMC)
City Pharmacies Ltd
Clinton Health Access Initiative (CHAI)
Independent Consumer & Competition Commission (ICCC)
Intellectual Property Office (IPO)
Internal Revenue Commission (IRC)
Investment Promotion Authority (IPA)
Johnston's Pharmacies
Kimbe General Hospital Pharmacy
Medopharm (PNG) Ltd
Modilon General Hospital Pharmacy
Mt. Hagen General Hospital Pharmacy
National Agriculture Quarantine & Inspection Authority (NAQIA)
National Capital District Health Services (NCDC)
National Department of Health Program Managers and Officers
National Institute of Standards & Industrial Technology (NISIT)
National Narcotics Bureau (NCB)
Pharmaceutical Society of Papua New Guinea
PNG Customs Services
PNG PharmMedical Supplies
Popondetta General Hospital Pharmacy
Port Moresby General Hospital Pharmacy
Provincial Health Authority, Milne Bay
Provincial Health Authority, Sandaun
Provincial Health Authority, West New Britain
Provincial Health Authority, Western Highlands
Royal Papua New Guinea Constabulary (RPNGC)
Royal Society for Prevention of Cruelty to Animals (RSPCA)
University of PNG, School of Medicine & Health Sciences, Discipline of Pharmacy
World Health Organization (WHO), PNG Office

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Pharmaceutical Standards and Policy Unit of the
National Department of Health.
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of March 2014 in its special meeting number 09/2014,
NEC Decision 84/2014

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