THE

NATIONAL MEDICINAL PRODUCTS POLICY

OF

THE REPUBLIC OF FIJI 2013

Reaching Out. Inspiring Life.
FIJIPHARMAC

MINISTRY of Health
Shaping Fiji's Health

FOREWORD

Medicines are required for prevention, control and treatment of illness. When a medicine is required, the rational use of medicines demands that the appropriate medicine be prescribed, that it be available at the right time at a price people can afford, that it can be dispensed correctly, and that it be taken in the right dose at the right intervals for the right length of time. The appropriate medicine must also be effective and of acceptable quality and safety.

The World Health Organisation states that the formulation and implementation by the Government, of the National Medicinal Products Policy, is fundamental in ensuring rational medicine use. Our National Medicinal Products Policy thus has various objectives, including:

(i) To ensure the ***ready*** and ***reliable availability*** of good ***quality, acceptably safe*** and ***proven effective medicines*** at a price the individual and the community can ***afford.***

(ii) To rationalise the use of medicines through the provision of improved medicine utilisation information and training of health professionals, and through education of the public in appropriate medicine use and storage with the aim of rationalising medicine supply management, prescribing and dispensing, and improving patient compliance.

(iii) To define the national goals and objectives, set priorities, and medium- to long-term commitments of the Government.

ACKNOWLEDGEMENT

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Acknowledgement also goes to stakeholders who have contributed in the review of this policy.

TABLE OF CONTENTS

INTRODUCTION

This edition arises out of the revisions of the 1994 Fiji National Drug Policy which has now been retitled as the National Medicinal Products Policy (2013).

The National Medicinal Products Policy has been developed to define a philosophy in Fiji which will guide the many public and private sector individuals and organisations involved in the medicine supply process.

Medicines may be overprescribed, or prescribed in ways that are not consistent with the currently accepted management guidelines. Such inappropriate use of medicines can lead to shortages, even when a sufficient quantity has been made available by the government.

The Cabinet approved the revised Policy in June 2012 and this document will be officially launched in 2013 aligning to the enactment of the 2 new laws, Fiji Pharmacy Profession Decree [April 2012] and Fiji Medicinal Products Decree [January 2013].

CONTEXTUAL FRAMEWORK

1 CONTEXT

The National Medicinal Products Policy (NMP) is part and parcel of the country's national health policy and has been conceived within the overall national development policy. The review of the policy has been a consultative process over a period of time and this text reflects the consensus reached but has been updated to accommodate essential developments. These developments include, for instance, the provisions contained in the Pharmacy Profession Decree 2011; the need to reorient program implementation to meet the Millennium Development Goals; and the need to ensure stricter measures of regulation to prevent the possible infiltration of sub-standard or counterfeit medicinal products.

Unless the context otherwise requires, throughout the document the terms "medicinal products", "drugs", "medicines" etc. have been used to connote the same range of products. The Policy, however, covers poisons, devices, dangerous drugs, herbal medicines etc.

2 OVERALL GOAL, OBJECTIVES AND APPROACHES OF THE NMP

The overall goal of the Policy is:

The development, within the available resources, of the potential that medicines have - to control diseases and alleviate suffering through comprehensive and integrated preventative and curative health services.

The **three main aims** of the Policy are:

1. To ensure the ready and reliable availability of good quality, acceptably safe, and proven effective medicines at a price the individual and the community can afford.

2. To rationalise the use of medicines through the provision of improved medicine utilisation information and training of health professionals, and through education of the public in appropriate medicine use and storage with

the aim of rationalising medicine supply management, prescribing and dispensing, and improving patient compliance.

3. To define the national goals and objectives, set priorities, and medium- to long-term commitments of the Government.

3 KEY OBJECTIVES

- The development and maintenance of appropriate medicine Laws and regulations to ensure full implementation of the National Medicinal Products Policy
- Ensuring adequate allocation in the health budget and development of a relevant financing policy to maintain the budget
- Development and maintenance of an appropriate work force
- Enhanced management capacity at all levels
- The establishment and maintenance of improved quality control and registration procedures
- The improvement of medicine procurement procedures through better governance and tender systems
- The selection, procurement and availability of essential medicines
- The establishment of an appropriate medicine pricing policy
- Strengthened medicine management practices
- Streamlined medicine distribution systems and logistics
- Promotion of rational prescribing, dispensing and use
- The maintenance of information and continuing education programs to improve medicine use

4 APPROACHES

- In developing and implementing the National Medicinal Products Policy, the main approaches will be:

  Effective networking involving partnership between the major players: the Government including other Ministries, eg Finance, Foreign Affairs and External Trade and Commerce, Finance (including Customs); health personnel and professional associations; academics; community leaders; private sector, non-State organisations and faith based organisations; patient groups etc.

- Increased coordination within the health sector: public, private, non-government and faith based organisations*. (It is to be noted that non-government and Faith-based Organisation referred in this Policy are licensed or approved by the Ministry of Health to provide specified health care services or Ministry of Health recognised institutions providing specified health care services in Fiji from time to time – Annex I)*

- Enhanced inter-sectoral cooperation with other sectors such as Legal, Customs, Transport, Finance, Education, Personnel Management, Provincial Authorities.

- Promotion of technical cooperation with other countries and international agencies in such fields as evaluation of medicines, exchange of information, quality control, transfer of technology, training and human resources development for medicines management systems, etc.

5 FOCAL POINT

- The Ministry of Health will be the responsible agency for overseeing the implementation, monitoring and updating of the National Medicinal Products Policy. However, no single ministry can be solely responsible for all aspects and hence the Ministry of Health will identify the responsibilities and tasks that come within the competence of all relevant ministries, departments, agencies, public sector and private sector institutions, the World Health Organisation and other UN agencies and development partners; non-governmental organisations; academic institutions, etc.

- Through a collaborative effort the Ministry of Health will ensure the swift resolution of outstanding issues and develop effective strategies and approaches to harness the combined resources of all relevant agencies to ensure the effective implementation of this policy.

- The aim of the policy is to ensure that the Fiji Pharmaceutical and Biomedical Services Centre (FPBSC) of the Ministry of Health is adequately staffed and suitably equipped to supervise the implementation of the National Medicinal Products Policy across all sectors – public, private, non-government and faith based organisations - in the Republic of Fiji.

- The Ministry of Health will support and facilitate the staffing of the FPBSC to enable it to effectively undertake its existing function as a medical store through Government Pharmacy and an expanded range of Specialist Units under the FPBSC in the context of the implementation of the National Medicinal Products Policy. Their services will include provision of:

    - Essential Medicine Program Management
    - Personnel Administration
    - Personnel Training in the Public Sector
    - Medicine Registration
    - Poisons Licensing
    - Devices Licensing
    - Approval of Clinical Trials
    - Narcotics Administration and Reporting
    - Medicine Inspectorate Services
    - Medicine Information Services
    - Poisons Information Service
    - Adverse Medicine Reaction Monitoring

6 INTERSECTORAL COOPERATION

The Fiji Pharmaceutical and Biomedical Services Centre (FPBSC) will establish and maintain cooperation between relevant sectors to enable the implementation of the National Medicinal Products Policy. As well as the Ministry of Health, sectors involved will include the Traditional Medicine, private, non-government and faith based organisations involved in health; and other government sectors such as the Attorney General's Office, Finance and Planning, Trade and Commerce, Foreign Affairs and Immigration, Home Affairs, and the Ministry of Education, Youth and Sport, Customs, Communications and Transport, Environment Lands and Agriculture.

1. REGULATORY FRAMEWORK

Based on a review of the existing regulatory framework, new laws have been finalised to regulate:

- medicinal products;
- poisons;
- therapeutic devices; and
- narcotic medicines

1.1 MEDICINAL PRODUCTS DECREE AND PHARMACY PROFESSION DECREE

Provision has been made for the above to be regulated under a new Medicinal Products Decree. The new Laws as well as new regulations deal with the licensing and regulation of importation, exportation, manufacture, sale, supply, storage, advertising, promotion, etc. Products together with institutions and individuals handling them will be regulated through a registration/licensing/authorisation process. Regulations to deal with clinical trials have also been drafted.

- The new Medicinal Products Decree covers all medicinal products including herbal medicines. There is provision to enact detailed regulations to regulate any such product.
- The new Pharmacy Profession Decree deals with the registration of pharmacists, pharmaceutical chemists and technicians by the Pharmacy Profession Board; as well as pharmacy premises.
- The enactment of the necessary decrees and regulations will reflect the political commitment required for the allocation of adequate resources for implementation.

1.2 INTELLECTUAL PROPERTY RIGHTS, LAWS AND PHARMACEUTICALS

- Trade Related Intellectual Property Rights (TRIPS) compliant, health sensitive Laws will be developed to enable access to affordable medicines for the treatment of HIV-related infection, and other expensive patented medicines that are needed to address the health problems of Fiji.

- The Government shall take advantage of all the flexibilities and safeguards within the TRIPS Agreement for the promotion of public health and ensuring access to pharmaceuticals.

- The harm and benefits of international trade and other treaties will be studied so as to safeguard the national interest concerning public health and ensure access to pharmaceuticals. In particular, any potential Free Trade Agreements will be examined in detail to ensure that flexibilities available under the TRIPS agreement are not affected.

- The Ministry of Health shall collaborate with the Ministries of Trade and Commerce, Foreign Affairs and External Trade, Justice (including the Intellectual Property office) and other relevant agencies in the area of Intellectual Property Rights in developing a legal framework that enhances access to essential medicines including grant of compulsory licensing and parallel importation and Government Use. Public health and access to pharmaceuticals must remain in the forefront while undertaking and signing any bilateral or international treaties or agreements.

1.3 Regulatory and Administrative Mechanisms

1.3.1 Medicinal Products Board and Pharmacy Professions Board

- Legislative provisions have been made for the appointment of a Medicinal Products Board and a Pharmacy Profession Board to control medicinal products and all aspects of pharmacy practice respectively. Both boards will have a mix of public and private sector representatives. The two boards will be headed by the Permanent Secretary to the Ministry of Health. Provision has also been made for a Medicinal Products Board Secretariat and a Pharmacy Professions Board Secretariat. The Chief Pharmacist will serve to oversee the Registrar of both Boards and will supervise the day to day operations of both secretariats. The Chief Pharmacist will be required to liaise with the Minister of Health and other senior officers on all matters pertaining to the work and functions of the two boards.

- The Medicinal Products Board as well as the Pharmacy Profession Board will be empowered to oversee technical matters concerning medicinal products and all aspects of pharmacy professional activities respectively, as well as to provide advice, as and when required. The Pharmacy Professions Board

is responsible for registration of pharmacy personnel and for maintaining standards of practice. By out-sourcing certain matters, both Boards can benefit from the inputs from specialists in different areas who cannot otherwise be accommodated as members on the main boards. Working through a committee structure instead of setting up a multiplicity of institutional bodies is the best approach for small medicines regulatory authorities. Provision has been made for the boards to function within an environment of good governance, accountability and transparency.

1.3.2. THE NATIONAL MEDICINES REGULATORY AUTHORITY

1. Relevant units of the National Medicines Regulatory Authority (MRA) will continue to be responsible for registration of medicinal products and devices, and issuing of licences as proscribed by the Legislation. The MRA will be strengthened structurally and organisationally and empowered to implement its mandate effectively and efficiently.
2. Licences or permits issued will indicate the conditions for which they are issued.
3. Schedules (classes) of medicinal products will be determined in order to control the sale and supply of medicinal products which may be prescribed or distributed over-the-counter and at different levels in the public, private and non-government sectors. The MRA will compile, publish and update as required, a list of the schedules and the medicines included in each schedule.

1.3.2.1 REGISTRATION, QUALITY ASSURANCE, LICENCING FOR SALE OF MEDICINES AND INVESTIGATION

The aim of Medicine Registration and Licensing for Sale is to facilitate the management, control and monitoring of medicines throughout the system, including public, private, non-government and faith based organisations, and will include investigation within different phases of importation, quality control, distribution and use of medicines.

- All companies (local and international) and their products must comply with proscribed national and international standards before they can be registered in Fiji. The Medicines Registration Unit (MRU) will be consulted by all manufacturers intending to import medicinal products to Fiji.
- Quality of imported products will be assured by registration by the MRU and procurement practices in accordance with the Policy; and monitoring of

these practices. Only medicines registered in Fiji will be permitted to be procured and distributed in the country.

- Importers of medicinal products are required to provide evidence of GMP at the manufacturing site and of the product submitted for import. They may make use of the *WHO Certification Scheme on the Quality of Pharmaceuticals Moving in International Commerce*, as this scheme is designed to provide assurance regarding the quality of the product. Arrangements will be made for the independent analysis of medicines samples. The recommendations and procedures of the WHO/UN Prequalification of Medicines Program will be used to the extent feasible.

- Appropriate data and information must be provided with the application for registration of companies and products. All data will be evaluated by the Medicines Registration Unit (MRU). Medicines will be registered only after sufficient proof of satisfactory quality, safety and efficacy has been provided. Registration data from countries with developed regulatory systems will be used as a benchmark.

- Those manufacturers who meet the requirements for registration by the MRU will be eligible to submit products for registration as long as the products comply with national or international quality requirements as specified by the MRU.

- Registration will be harmonised with the registration procedures in other Pacific Island Nations, in line with international standards.

- Registration will be by generic name (INN).

- Registration will be re-evaluated, revised and revalidated every 5 years.

- Medicines proved to be unsafe, ineffective, of greater harm than benefit, of inadequate therapeutic value, withdrawn from the market in some countries, must be considered for withdrawal.

- Medicines will only be handled by registered persons in registered premises licensed by the Board.

- Herbal and complementary medicines will satisfy the same registration requirements as other medicinal products. The details will be spelled out in the Law and/or regulations.

- New medicines, which are in the process of registration or assessment for their safety, efficacy and quality, may be only distributed through places authorised and licensed by the Medicinal Products Board on the advice of the National Medicines and Therapeutics Committee for a specified period.
- The MRU will issue ***Import Licences*** to individuals who are authorised to import medicinal products and medical supplies to Fiji.
- The customs authority will only permit entry of products with valid Import Licences.

The Pharmacy Medicinal Products Board and Pharmacy Professions Board will authorise Pharmacy Investigators under the guidance of the Fiji Pharmaceutical and Biomedical Services Centre (FPBSC) for the purposes of monitoring the implementation of and enforcing all the provisions of the Laws concerning the management of medicinal products as well as pharmacy premises.

- Investigators will liaise closely with officers of the Fiji Revenue and Customs Authority in the monitoring of medicine importation. An authorised Inspector will accompany the customs officers to meet incoming shipments at the Port and at the Airport as required in collaboration with the Customs Office.

1.4 MANUFACTURE

- Legislative provision has been made to regulate the manufacture of medicinal products.
- Manufacturers will be required to conform to international standards and to take due note of revisions of the International Pharmacopeia and related monographs. Procedures will be established for the prequalification of active pharmaceutical ingredients and for their conformance with a certification scheme for pharmaceutical starting materials moving in international commerce.
- Manufacturing plants and processes will be designed to conform to acceptable international requirements such as WHO Good Manufacturing Practices. The Medicinal Products Board will address the need to develop in-country capability for inspection; until adequate resources are available, the Board will utilise the services of qualified personnel from regulatory agencies

and laboratories other countries through technical cooperation agreements. Guidelines on inspection of pharmaceutical manufacturers will be adapted.

1.5 EXPORT

- Exports will increase with an increase in domestic manufacture so Legislative provision will regulate exports. Legislation will prohibit use of Fiji as a transit point for the export and transshipment of prohibited or dangerous medicines or counterfeit medicinal products.
- Products for export must conform to the *WHO Scheme for the Export of Medicinal Products Moving in International Commerce* as well as applicable International Conventions relating to dangerous medical supplies to which Fiji is a Party.

1.5.1 EXPORT OF MEDICINAL PRODUCTS

- Licence to export any medicinal products must be obtained from the Medicinal Products Board. Investigators will liaise closely with officers of the Fiji Revenue and Customs Authority in the monitoring of medicine export.
- Medicines can only be exported by way of wholesale dealing to authorised persons (Wholesalers and Pharmacies) as per conditions of the Wholesale Licence issued by the Medicinal Products Board. Exporting of medicines to individual patients are prohibited.

1.5.2 INTERNET SUPPLY OF MEDICINES PROHIBITED

- All procurement of medicines into Fiji must be in line with the National Medicinal Products Policy and medicines procured will be primarily for the use of Fijian citizens. Procurement for the purpose of satisfying internet demand by export or for providing medicines outside Fiji on request by email order is prohibited.
- Supply of medicines on foreign prescriptions of Medical Practitioners not registered in Fiji is illegal and therefore prohibited.

1.6 ADVERTISING AND PROMOTION

The aim of the policy is to ensure that advertising and promotion of medicines are of a high professional standard and conform to the requirements of the medicines Laws and regulations. Prior approval for advertising will need to be granted by the Medicinal Products Board. An application form will be available from Fiji Pharmaceutical and Biomedical Services Centre (FPBSC).

The new Medicinal Products Decree and the Medicinal Products Regulations specify the necessary requirements relating to labels and product information as well as advertising and promotion.

- The use of International Nonproprietary Names will be mandated.
- The Medicinal Products Board has established ethical criteria and guidelines for medicine promotion and will advertise and publish these guidelines for distribution to all interested parties. Ethical criteria for medicine promotion will be published for distribution to all interested parties.
- All medicine promotional and advertising materials must conform to the ethical criteria and guidelines developed by the Fiji Pharmaceutical and Biomedical Services Centre (FPBSC).
- Labelling and advertising for medicines must be based on scientifically established evidence and be in good taste and must not claim properties that have not been scientifically proven. Advertising must be objective, educational in purpose.
- In Fiji, direct to consumer advertising of medicines is not permitted.
- Medicine advertising aimed at or involving the inappropriate use for children will not be permitted.
- Medicine promotional activities will be in line with National Medicinal Products Policy objectives. In this respect, whenever the brand name of a medicine is used in any form of promotional or educational material the generic name of the medicine must be given due prominence.
- Promotion and advertising of pharmacy-only and prescription-only medicines will be restricted to professional medical, pharmaceutical, dental, veterinary or nursing publications. Advertising concerning traditional medicines will be controlled by an appropriate body representing the Traditional Medicines sector.

- Guidelines will be developed for the support of the government's educational activities and publications by the pharmaceutical industry, that will proscribe the use of such initiatives for commercial advertising.
- Medicine advertising and promotional activities will be carefully monitored to ensure that they conform to the relevant ethical criteria.

1.7 NATIONAL MEDICINES AND THERAPEUTICS MANAGEMENT

- A Committee of the Medicinal Products Board will function as a National Medicines and Therapeutics Committee.

2. FINANCIAL RESOURCES

The aim of the policy is to ensure that sufficient funding is made available to provide adequate quantities of appropriate quality essential medicines at the lowest possible cost to all those who need them in the public sector as well for the implementation of all components of the National Medicinal Products Policy.

- Within the total health budget, suitable provision will be made for the implementation of the national medicines policy strategies and for support of the necessary workforce.

- Financial resources for purchasing medicines will be based on the careful estimation of the total quantities of medicines and medical supplies needed in the country using data from all available sources including the MOH, hospitals and dispensaries. Efforts will be made to enable appropriate quantification to be made using demand-morbidity methodology based on the use of medicines according to the standard treatment guidelines.

- The MOH will work in close collaboration with the Ministry of Finance and National Planning and Customs, so that due priority is given to the financing and importation of essential medicines for the country.

- Essential Medicines will be exempt from import tax.

- Non-State actors and faith based organisations involved in the delivery of health services should provide their own finance but all operations will be in line with the Policy.

- Cost recovery may be introduced to fund certain activities of the FPBSC administration, for example registration of medicines, inspection of premises. Mechanisms to generate funding with a view to sustainability will be explored.

2.1 AFFORDABILITY

- Currently prescribed essential medicines are available free to all patients in public facilities. A fair and equitable pricing policy will be considered in collaboration with all affected parties in all sectors. Appropriate exemptions would be put in place for patients who cannot afford minimum fees. TB and HIV medication will be free of charge to registered TB and HIV patients.

3. HUMAN RESOURCES

The aim of the policy is to ensure that an appropriate number of adequately trained personnel are available and supported financially to meet the needs of the National Medicinal Products Policy.

- In the context of the implementation of the new Laws on pharmacists and medicinal products, the Ministry will undertake an assessment of the role, functions and level of expertise of the existing personnel connected with different aspects of the pharmaceutical sector. An attempt will be made to identify the needs over the next 5-10 years and accordingly the Ministry will initiate discussions with relevant academic and professional institutions and organisations as to how best such needs can be met.

- Strategic planning for the expansion and maintenance of the services needed to implement the National Medicinal Products Policy will be undertaken. This planning will enable Human Resources needs to be identified so that strategies can be developed through collaboration between the Fiji Pharmacy Services and the Fiji School of Medicine for the selection and training of future staff required by the National Medicinal Products Policy. Continuing education will be developed as part of ongoing accreditation.

- Sufficient financial resources will be ensured to support the Human Resources needed to implement the components of this NMPP.

- The FPBSC will develop an interim plan to provide adequate training for implementing components of the National Medicinal Products Policy as well as technical expertise in the distribution and dispensing of medicines and other medical stores tasks until such time as the required number of trained staff is available

- The FPBSC will strive to improve the career prospects of all pharmaceutical personnel in the public sector and will encourage and support opportunities for upgrading and refresher courses and continuing professional development for existing personnel, in order to secure their positions and develop a good human resources team.

- A suitable career structure including incentives will be designed to retain such staff and their skills will be regularly improved and updated by a continuing education and refresher training program.
- Ancillary and support personnel will be provided with basic and periodic training to ensure satisfactory performance of support duties. They may be supplied with additional on-the-job training for permanent positions within the system.
- Further education and training of dispensing personnel in the private sector as appropriate under this National Medicinal Products Policy may be provided collaboratively through the Professional Associations.
- The Ministry will address the issue of technical cooperation for exchange programs involving qualified personnel from other countries whose services can be utilised for a period of time to address unmet training and service delivery needs. Training programs will include those relating to inspection and examination of counterfeit products.
- Fiji will actively participate in relevant international conferences including those on Harmonisation; and training programs.

4. SELECTION OF ESSENTIAL MEDICINES

The aim of the Policy is the selection of medicinal products in accordance with the essential medicines concept as defined by the World Health Organisation (WHO). Essential medicines are those that are of the utmost importance, and necessary to satisfy the health needs of the majority of the population.

4.1 ROLE OF THE NATIONAL MEDICINES AND THERAPEUTICS COMMITTEE IN THE SELECTION OF MEDICINES

- Selection of essential medicines for the Fiji Essential Medicines List is made by the National Medicines and Therapeutics Committee. It is composed of experts in all the medical and pharmaceutical fields necessary to enable informed decisions to be taken. Medicines are selected to satisfy the needs of the public sector and the National Standard Treatment Guidelines of Fiji. Where there are no Standard Treatment Guidelines in place, selection will be based on international experience and best practice and cost-effectiveness. Preference will be given to medicines for conditions contributing to the greatest burden of disease in Fiji.

- As and when necessary, additional members may be co-opted and consultations may be undertaken with interested parties including representatives of professional bodies, and any other relevant organisations. However, selection will reflect broad policy objectives and the process of medicine selection by the Committee will be carried out independently according to the Committee's mandate.

- Selection of medicines is based on a number of criteria including:

    - pattern of disease prevalence

    - safety and efficacy (based on evidence and evaluations obtained in controlled clinical trials and/or epidemiological studies)

    - cost, taking into account the following elements: the cost of the treatment rather than that of the dosage form; the cost of treatment in relation to savings made by, for example, reduction in the need for surgery or hospitalisation; different rates of treatment, success

achieved as a result of improved patient compliance; reduced loss or waste through the use of more stable products

- adherence to recognised and adequate quality control standards (including stability)
- therapeutic advantage
- the needs of operating programs such as Integrated Management of Childhood Illness (IMCI), syndromic management of sexually transmitted infections, family planning and mass campaigns such as the Pacific Program to Eliminate Lymphatic Filariasis (PacELF) and the National HIV Program.

- Where several medicines are available for a given indication, or two or more medicines are therapeutically equivalent, the product with the most favourable benefit/harm ratio will be selected. Preference will be given to:
  - medicines which have been most thoroughly investigated
  - medicines with the most favourable pharmacokinetic properties, e.g. those which improve compliance or minimise risk in various disease states
  - medicines and dosage forms with the greatest stability or for which suitable storage facilities exist.
- When considering fixed ratio combinations the following criteria will be considered:
  - the clinical condition requires the use of more than one medicine
  - the therapeutic effect of the combination is greater than the sum of the effects of each medicine
  - the cost of the combination is less than the total cost of the individual products
  - sufficient combinations are provided to allow for dosage adjustment to meet the needs of the majority of the population
  - compliance is improved.

Selection of essential medicines is by generic name or International Non-proprietary Name (INN) only.

- A Fiji Essential Medicines List (FEML) containing all the medicines selected for use will continue to be produced for use in all health institutions including training schools, and to all medical, dental, pharmacy, senior nursing, and senior health administrative personnel. New editions of this will be prepared at least once every two years and will concur with the recommendations in the Standard Treatment Guidelines. Where necessary amendments authorised by the National Medicines and Therapeutics Committee can be published as a supplement in the interim. The main list will indicate the allowed level of use, i.e. prescribing, of each item, based on the following classification:

    1. Divisional Hospitals only
    2. Divisional + Specialist hospitals only
    3. Divisional + Specialist + Sub divisional hospitals
    4. Divisional + Specialist + Sub divisional hospitals + Health Centres
    5. Divisional + Specialist + Sub divisional hospitals + Health Centres + Nursing Stations

    5a. Nursing Station with medical officer's authorisation

    Request only – Those medicines which will only be purchased on request and authorised according to this Policy.

    Other special programs for example Reproductive Health Clinic and Specialty Clinic for HIV cases, IMCI program.

- Suggestions for amendments to the Fiji Standard Treatment Guidelines and the Essential Medicines List should be made in writing to the National Medicines and Therapeutics Committee, through the secretary of the committee. Full justification including literature review for each suggested amendment must be provided.

- New medicines will only be introduced if they offer distinct advantages over existing medicines. If information on existing listed medicines shows they no longer have a favourable benefit/harm ratio, they will be deleted and replaced with safer alternatives.
- Non-list medicines may be requested for specific patients in exceptional circumstances by the completion by the physician of a standard form used for this purpose, which should be sent for consideration by the Divisional Medicines and Therapeutics Committee. If there is a funding implication the request is then referred to the National Medicines and Therapeutics Committee for consideration against competing claims for funding.
- Non-list medicines may be requested for use in exceptional circumstances for emergency management of emerging diseases in compliance with a protocol developed by the National Medicines and Therapeutics Committee.
- Visiting medical specialists and medical teams will be made aware of the provisions of Fiji's National Medicinal Products Policy and Fiji Essential Medicines List [FEML] and required to comply with the above provisions.
- Patients returning from treatment in other countries with prescribed non-list medicines will be assisted as follows:
    - The patient will be referred to an appropriate specialist to decide on interim treatment. If appropriate, application can be made to the Committee for consideration of long term treatment for the patient.
- Vaccines authorised under the Expanded Program on Immunisation will be included in the FEML.
- Medicines for the treatment of HIV infection and related opportunistic infections may be included in the FEML but purchase will depend on affordability.
- A list of essential medicines for children will be developed by the Committee based on the model list compiled by WHO

4.2 CLINICAL TRIALS

- Legislative provisions have been made to ensure that clinical trials are not undertaken within the Fiji without prior approval from the National Medicines and Therapeutics Committee. Appropriate regulations have been drafted for the purpose. The new regulations require compliance, *inter alia,* with the WHO/CIOMS guidelines on Clinical Trials.

4.2.1 DONATIONS OF MEDICINES FOR USE SPECIFICALLY IN CLINICAL TRIALS

- Clinical trials promulgated in the guise of a donation of a medical product are not permitted in Fiji.
- Donations of specific medicine/s for use in a specific population for a defined time under conditions that are not determined by the Ministry of Health are not acceptable. Issues of genuine informed consent, use of placebos where alternative treatments are available, post trial treatment where the treatment is for an ongoing condition and for fair affordable access for all who would benefit from treatment are paramount.
- Donation Guidelines applicable to all medicines and medical supplies donations will be maintained for use in the Fiji.

5. PROCUREMENT OF MEDICINES AND MEDICAL SUPPLIES

The aim of the policy is to ensure the necessary quality and quantity of medicines to meet the health needs of the Fiji population, at the lowest possible cost.

5.1 Purchase of Medicines and Medical Supplies for the Public Sector

- Purchase of medicines and medical supplies for the public sector is centralised, the sole organisation responsible for this function being the Fiji Pharmaceutical and Biomedical Services Centre (FPBSC).
- Purchases of medicines and medical supplies by the FPBSC will be by means of open tender or restricted tender and all manufactures intending to participate in the tender will apply to the FPBSC Medicines Registration Unit (MRU), a unit within the Ministry of Health, for prior registration (see above Registration).
- In emergency situations, negotiated procurement or direct procurement may be used.
- Those manufacturers who meet the requirements for registration will be supplied with a Certificate of Registration allowing them to participate in the tender.

Products tendered must be accompanied by a Certificate of GMP before they can compete and successful products will be registered by the MRU.

- Medicines are procured by generic name (INN)
- Medicines are procured according to the Fiji Essential Medicines List
- Medicine procurement procedures will be completed in a timely manner to allow surface transport as far as possible to ensure the most appropriate use of financial resources
- In order to make the best possible use of available funds, procurement will continue to be aimed at securing the lowest available price for a product of acceptable quality. Whenever possible, medicines will be

purchased in bulk quantities and repackaged locally in order to maximise savings obtained through bulk discounts.

- Procurement of medicines will be restricted to items registered in Fiji and registered for use and currently marketed in their country of origin with the exception of certain medicines for treatment of specified locally endemic diseases.

5.1.1 Generic Nomenclature

- Foreign suppliers of branded medicines will be requested to label their product packages and containers in English with the generic name of the medicine at least one third the size of, and displayed adjacent to, the trade name.

5.1.2 Human Resources for Procurement

- The MOH will actively encourage the improvement of procurement efficiency by ensuring the adequate provision of suitably qualified personnel and facilities for the procurement section of the Fiji Pharmaceutical and Biomedical Services Centre (FPBSC) and by supporting the computerisation of procurement operations. This process will include the development of a market intelligence capability. The MOH will encourage technical support from WHO or other appropriate bodies to build procurement capacity and expertise.

5.2 Purchase of Medicines by Private, Non-government, and Faith-based Organisations

- The private, non-government and faith based organisations may conduct their own procurement provided it complies with the Policy in all aspects including registration and quality. A permit to import must be obtained from the MRU and this permit must be presented to Customs for clearance of goods. In cases where no permit covers imported goods they will be withheld by Customs and returned to the sender at the sender's expense.

5.2.1 Medicine and Medical Supplies Donations

Medicines and medical supplies must only be donated in response to a request that is signed by the Chief Pharmacist and in compliance with the applicable laws and guidelines. Points of entry to Fiji will be aware of this policy and the

Donation Guidelines and will put in place procedures to prevent the entry of unauthorised donations.

- Provincial Councils will be made aware of this policy so they can control the admission of donations in remote areas of Fiji. Unsolicited donations that contravene the requirements will be confiscated at the point of entry and returned to the sender at the sender's expense. Under the legislation, penalties will be enforced for contravention of the policies.
- Foreign diplomatic missions will be notified concerning the policy on donations.
- Donated medicines that have been approved must comply with all the following criteria:
  - Be registered for use in the Republic of Fiji
  - Be included in the Fiji Essential Medicines List
  - Have at least 18 months shelf life remaining after delivery to Fiji
  - Be labelled in English
- Any approved donations must be directed to the FPBSC, not to individual health facilities.
- Organisations, including faith based organisations; working in Fiji shall not donate their excess medicines from the stock for their own use to health services in Fiji. Requests to donate stock, in exceptional circumstances, must be accompanied by details of the proposed donation including generic name, strength, quantity and expiry dates. These organisations must take care to avoid importing excess medicines to minimise waste. Disposal of any waste is their own responsibility but must be in accordance with this Policy.

5.2.2 Medicine Procurement in Emergency Situations

- In times of emergency such as natural or man-made disasters, the government should immediately establish a coordinating body to assess needs and articulate any appeals for assistance. The FPBSC must be included in the coordinating body to assess medical supplies needs, advise the coordinating body about medical supplies-related issues, approve

donations if donations are needed, and coordinate their receipt and distribution. The requirement to comply with the applicable laws and guidelines and the National Policy on donations of medicines and medical supplies will be made known. Unsolicited donations that contravene the requirements will be confiscated at the point of entry and returned to the sender at the sender's expense.

- Additional guidelines for donations of single-source products will be formulated as necessary.

5.3 PROCUREMENT BY FIJI PRIVATE WHOLESALERS

5.3.1 DISTRIBUTION WITHIN FIJI

- Fiji private wholesalers, procuring medicines for sale to the private sector in Fiji will comply with the provisions of this National Medicinal Products Policy. Only medicines registered in Fiji by the Medicinal Products Board may be imported, using generic nomenclature, for distribution in Fiji to duly licensed outlets.

5.3.2 INTERNATIONAL DISTRIBUTION

- Fiji wholesale licence holders may sell products internationally to authorised agencies only upon approval by Medicinal Products Board as per their Wholesale Licence conditions, which is reviewed every 5 years and in compliance with all the standards determined by the National Medicinal Products Policy including good manufacturing practice, quality assurance from manufacturer to end user and conditions associated with the scheduled status of the medicines.

6. MEDICINE STORAGE AND INVENTORY CONTROL

The aim of the policy is to ensure the maintenance of quality and security of medicines in storage throughout the public, private, non-government and faith based organisations from the time of receipt into stock until the time of issue to the patient.

6.1 MEDICINE STORAGE

- The Ministry of Health will endeavour to ensure the provision and regular maintenance of adequately sized, suitably constructed and equipped storage facilities at every level in the public sector medicine distribution system. Where necessary, new stores will be constructed or existing stores modernised and refurbished in order to ensure that medicines are stored in a systematic, secure and safe way, so that losses due to deterioration, expiry or theft are minimised. Where appropriate, storage facilities will include air-conditioning and/or a properly maintained refrigerator to protect heat-sensitive products during the period of storage.

- Regular checks will be carried out by Pharmacy Investigators or stores personnel on the quality of stored medicines at all levels to ensure that they have not deteriorated under the storage conditions prevailing at each location.

- Private, non-government and faith based organisations' medicine storage facilities will be regularly checked, in order to ascertain adequacy and suitability of the facilities and conditions. Checks will be performed by Investigators authorised by the Medicinal Products Board.

- The professional skills of pharmacists, pharmacy technicians, pharmacy assistants and store managers are vital to the efficient and successful operation of a medicine storage and distribution system. The government will therefore ensure that adequate numbers of pharmaceutical and stores management personnel are recruited and suitably trained to run and maintain the stores of public, private, non-government and faith based organisations.

- The MOH should encourage technical and financial support from WHO or suitable bodies to upgrade training in medicine management including

inventory control (see below) for medical store staff including health centre and dispensary staff from outer islands.

- In order to encourage the correct maintenance and organisation of medicine stores throughout the country, the FPBSC will develop a stores procedures manual containing practical guidelines on the required procedures for all medicine storekeepers. This development may need the assistance of a WHO consultant or other appropriate recruit.

6.2 Inventory Control

The aim of the policy is to ensure the continued availability of sufficient quantities of the required essential medicines at all levels of the health system, through the accurate and systematic recording, monitoring and reporting of stock levels of all items.

- The Ministry of Health will strive to improve and standardise inventory control procedures at all levels of the public medicine supply system to ensure the availability of all essential medicines in order to satisfy the specific needs of the health services. Special attention will be directed at maintaining a reliable supply of medicines and buffer stocks of vital medicines will be maintained. Minimum and maximum stock levels will be reviewed regularly, systematic stock rotation ensured, dead stocks and expired stocks will be identified and either disposed of, or, in the case of non-expired useable items, redistributed.
- Buffer stocks will be maintained to address possible emergencies.

6.2.1 Inventory Systems

- Efficient manual inventory control procedures should supplement the use of financial management information system software, for health service levels inaccessible to the MOH network. Continuous training for software users should be ensured and the equipment must be maintained at all times. Technical support and services for management software is critical for the well functioning of the software so that the MOH will have minimum system downtime or delays.
- The Ministry of Health will support the introduction and maintenance of systematic, practical and accurate procedures for the estimation and regular

reporting of medicine consumption at all levels so that the FPBSC can use this data in the compilation of correct estimates for national medicine procurement needs. Adherence to Standard Treatment Guidelines and maintenance of treatment records are essential to facilitate estimation of medicine needs to sustain good stock levels.

- Physical inspection (stocktaking) of medicine stocks by local personnel should take place at least twice yearly to check for mistakes. A weekly stock-take of vital medicines should be maintained.

6.3 Quality Assurance Processes for Medicines in Circulation

The aim of the policy is to ensure maintenance of quality of all aspects of the implementation of the policy throughout the public, private, non-government and faith based organisations and to ensure that medicines reaching the patients are safe, effective and meet approved specifications and standards. The quality assurance system will include managerial, technical and legal aspects. Quality will be assured throughout the process from procurement to use.

- Quality medicines management practice will be assured by medicines receipt, management and dispensing in accordance with the Policy. FPBSC will set up and maintain an efficient and adequate Investigation Unit to ensure that quality assurance policies are implemented in all aspects and at all levels of the medicine supply system.

6.3.1 Maintenance of Quality of Products in Circulation

- The Ministry of Health will develop a strategic plan for the testing of medicinal products moving through the medicine supply system (for example of suspect items, or those liable to rapid deterioration), using internationally recognised quality control procedures. If necessary, laboratories in other countries in the region may carry out the required tests.

- The Ministry of Health will institute a system for withdrawal of medicinal products from circulation which have been shown by testing or

demonstrated otherwise to be of unacceptable quality and the use of expired medicines will not be permitted.

6.3.2 Quality Medicines Management Practice

- Quality medicines management practice will be assured by medicines receipt, management and dispensing in accordance with the Policy. The Fiji Pharmaceutical and Biomedical Services Centre will set up and maintain an efficient and adequate Medicine Investigation Unit to ensure that quality assurance policies are implemented in all aspects and at all levels of the medicine supply system.

6.4 Disposal of Expired and Unwanted Pharmaceuticals

The aim of the policy is to ensure minimum pharmaceuticals waste through efficient procurement, record keeping and stock control and where disposal is needed, ensure it is conducted in a safe and environmentally sound manner.

- The Ministry of Health will develop a specific policy for the disposal of pharmaceutical waste.
- Before the disposal of any waste, permission must be sought from the Ministry of Finance and National Planning.
- It is important that pharmaceuticals waste is minimised through:
  - Adherence to Standard Treatment Guidelines based on the Fiji Essential Medicines List. This practice will facilitate calculation of required needs and subsequent rational procurement and minimise waste
  - Good stock management
  - Prevention of unsolicited donations of pharmaceuticals
  - Donors' compliance with Donation Guidelines when donations are required.
  - A policy of sound procurement, management and use of pharmaceuticals with the aim of minimising waste. Where waste is unavoidable, it will be disposed of safely and in an environmentally sound manner in line with the WHO Guidelines for Safe Disposal of

Unwanted Pharmaceuticals and with the health investigators in collaboration with Ministry of Environment.

6.4.1 Incineration at Appropriate High Temperature

- All waste can be disposed of in appropriately built high temperature incinerators. Where appropriate incinerators are available, pharmaceutical waste should be appropriately and securely packed and sent to those incinerators for disposal.
- In remote communities, consignment to the nearest appropriate incinerator is recommended but where appropriate incineration is not possible, in the short term, pharmaceutical waste will be disposed of safely using the land fill method.

6.4.1.1 Sorting for Disposal by Land Fill

Sorting is needed to separate the pharmaceuticals into separate categories for which different disposal methods are required. Controlled medicines (narcotics and psychotropics), antineoplastic medicines and antibiotics require special methods such as encapsulation.

- Unwanted (expired, non-formulary and sub-standard) narcotics may only be disposed of after written permission has been obtained from the Chief Pharmacist. Unwanted narcotics from Sub-Divisional health facilities must be recorded in the narcotics register and sent to the nearest base hospital. Destruction must be recorded in the narcotics register and in the presence of two pharmacists who will both sign the register.
- Tight security is necessary during sorting and disposal to prevent diversion by unauthorised persons and possible pilfering. Immobilisation by encapsulation is the best method of preventing pilfering and leaching into the environment from a store or from land fill.
- If pharmaceuticals must be discarded by land fill they must be covered immediately with a large quantity of municipal waste.

6.4.1.2 Encapsulation of Hazardous Waste

- Encapsulation involves collecting waste in puncture-resistant and leak-proof containers. When the container is three quarters full, a material such as cement (mortar), sand, plastic foam or clay is poured into the container until

completely filled. After this material has dried, the container can be sealed and may be stored, land-filled, or buried.

7. DISTRIBUTION OF MEDICINES

The aim of the policy is to ensure the prompt, safe and efficient distribution of medicines to authorised end-users throughout the public, private, non-government and faith based organisations, so that the quality of the products is maintained throughout the process and medicines are available when needed.

- Only medicines registered in Fiji will be distributed in the country
  - Medicines will be distributed only according to level of approved/licensed use in health facilities
  - Pharmacy only medicines will not be distributed through unauthorised outlets
- Provincial Councils and remote health facilities will be made aware of the distribution procedures so communities will understand the policy.
- Medicines will be distributed through the public and private sector. The Fiji Pharmaceutical and Biomedical Services Centre (FPBSC) is responsible for the distribution of medicines to the public health sector.
- Medicines will be distributed in the public sector on the basis of orders supplied from the health facilities. Orders from health facilities will be prepared on the basis of accurate maintenance of patient records and documentation of medicines used according to the standard treatment guidelines.
- Medicines for the non-government and faith based organisations may be distributed through their own mechanisms but in accordance with the procedures articulated in the National Medicinal Products Policy.
- The Ministry of Health will ensure the provision of adequate and appropriate transportation, maintenance and communication facilities and the personnel necessary to maintain the efficient operation of the public sector distribution system.
- The Government will endeavour, through the Fiji Pharmaceutical and Biomedical Services Centre to maximise coordination between the different sectors in the transportation and distribution of essential medicines,

particularly to less accessible areas of the country, to facilitate prompt, safe and efficient delivery to the appropriate destination.

- The Fiji Pharmaceutical and Biomedical Services Centre and user units, will establish an efficient and practical system for inspection and identification, collection and redistribution (or disposal as required, upon the authorisation of the Finance) of excess stocks of medicines and medical supplies.

- WHO good distribution practices for pharmaceutical products as well as guidelines for inspection of medical supplies distribution channels will be adapted. For the efficient distribution of temperature sensitive vaccines, medicines and medical supplies, the state of the pharmaceutical cold-chain will be assessed and facilities will be upgraded, as required.

7.1 Appropriate Transport, Logistics, Stock Management and Storage

- Transport will include temperature control, and prompt and accurate delivery to appropriate destinations.
- Storage and stock management during transit will be in a manner to maintain the quality of products and adequate levels of stock.
- Periodic checks will be undertaken by Pharmacy Investigators to ensure that:
  - Transport and delivery are appropriately and efficiently executed
  - Pharmacy practice is carried out in accordance with policy
  - There is no deterioration of products
  - Facilities for storage and work are appropriate, for example water-proof, secure, locked.

7.2 Sub-populations with Special Therapeutic Needs

- In accordance with the National Medicinal Products Policy and identified needs, the Medicinal Products Board will initiate necessary action to secure and distribute listed medicines for example, through the Global Fund to Fight AIDS, Tuberculosis and Malaria and GAVI for immunisation of mothers and children.

- Pain relief medicines for specific patients, such as narcotic and other medicines subject to the international drug control treaties, will be made available in accordance with treaty provisions and domestic legal requirements.

7.3 MEDICINE SUPPLY TO FOREIGN NATIONALS

- The overall goal of the Policy is to use available resources to ensure provision of medicines to control common diseases and alleviate suffering of Fiji citizens.

- Foreign Nationals working for private and foreign organisations in the Republic of Fiji are not entitled to medical supplies, unless there is an emergency. They will need to provide medicines for their own personal use. In the case of an emergency, a limited supply of medicines may be authorised, if available.

- Foreign Nationals working for the Government of the Republic of Fiji should organise their own personal medications from their own country for their period of employment in Fiji. However they will be eligible for supplies of medicines for acute conditions from the Fiji Essential Medicines List if they are needed. The private sector is available to foreign nationals and special medicines can be made available for purchase through the Bulk Purchase Scheme.

- The Foreign Missions will be made aware of the provisions of this National Medicinal Products Policy.

8. RATIONAL USE OF MEDICINE

The aim of the policy is to ensure that medicines are prescribed, dispensed, and used rationally throughout the public, private, non-government and faith based organisations in order to maximise the therapeutic benefit to the patient and reduce loss, wastage and hazards arising from irrational practices, including theft and misappropriation.

9.1 TRAINING

The aim of the policy is to ensure that all health workers involved in diagnosis, prescribing and dispensing of medicines receive adequate and relevant theoretical and practical training from well-trained teachers to enable them to perform these activities correctly and efficiently.

- Health workers will have access to appropriate training courses for their level of practice, for example Pharmacist, Pharmacy Technician, Pharmacy Assistant, Nurse Practitioners, with relevant curricula in diagnosis, prescribing, dispensing and management as required to ensure adequate coverage of public health and essential medicine concepts, including the rational use of medicines and the role of the Fiji National Medicinal Products Policy.

- Specialised training will be provided for selected health workers for specific circumstances, for example in the management of tuberculosis and in the management of HIV infection.

- A systematic and comprehensive program of refresher courses and other suitable continuing education activities will be made available by Professional Associations in collaboration with the Fiji National University, School of Pharmacy, and WHO or other relevant bodies and implemented for the further training and continuing professional development of practicing health workers in the above areas.

- Suitable training materials on rational medicine use will be developed in consultation with health workers at all levels for use both in initial and continuing education activities.

- Suitable training in counselling will be provided to health workers so they can help patients understand the use of their medicines as well as appropriate care and storage to avoid deterioration and waste.

8.2 PRESCRIBING

The aim of the policy is to ensure that medicines are prescribed wisely and correctly throughout the public, private, non-government and faith based organisations, according to the recommended Standard Treatment Guidelines which have been established.

- The National Medicines and Therapeutics Committee will strive to constantly monitor and assess prescribing practices in Fiji and collaborate with the FPBSC and the National and Divisional Medicines and Therapeutics Committees to ensure appropriate, efficient, and cost-effective prescribing.
- Only prescribers authorised to prescribe Tuberculosis treatment will be permitted to prescribe medicines for Tuberculosis.
- Only authorised physicians are permitted to prescribe treatment for HIV infection and opportunistic infections.
- Visiting medical specialists will be made aware of the provisions of the Fiji National Medicinal Products Policy and Fiji Essential Medicines List and required to comply with the provisions. Where they believe there is a need to use non-formulary medicines beyond the Fiji Essential Medicine List [FEML] for an individual patient for a specified duration they will apply to the National Medicines and Therapeutic Committee for permission. Funds to procure medicines under these circumstances will be determined by the National Medicines and Therapeutics Committee on a case by case basis.
- In all sectors (public, private non-government, faith based organisations), all medicines will be prescribed by generic name (INN) or Ministry of Health approved abbreviation only. However a brand name of the medicine may be included in brackets after the generic name.

8.2.1 LEVELS OF PRESCRIBING PRACTICE

- Prescribing for patients will be in accordance with the Fiji Standard Treatment Guidelines (see Rational Medicine Use) and prescribing practices will be monitored.

- Prescribers in all sectors, public, private, non-government and faith based organisations, will only prescribe within the list of medicines determined for the level of prescriber.

The scope of prescribing responsibilities in the public system will be determined by levels of authorisation to practice:

1. Divisional Hospitals only
2. Divisional + Specialist hospitals only
3. Divisional + Specialist + Sub divisional hospitals
4. Divisional + Specialist + Sub divisional hospitals + Health Centres
5. Divisional + Specialist + Sub divisional hospitals + Health Centres + Nursing Stations

5a. Nursing Station with medical officer's authorisation

Request only – Those medicines which will only be purchased on request and authorised according to this Policy.

Other programs for example Reproductive Health Clinics and Specialty Clinics for HIV cases, IMCI programs.

Others as determined the National Medicines and Therapeutics Committee

8.3 DISPENSING

The aim of the policy is to ensure that medicines are dispensed efficiently and correctly throughout the public, private, non-government and faith based organisations, according to essential medicines concepts and recommended dispensing practices.

- All medicines (except some combination products) will be dispensed and labelled using generic names. The FPBSC will strive to improve dispensing practices by ensuring the provision of adequate packaging and labeling materials and by promoting the use of pre-packaged courses of therapy for treatment of common conditions at all levels of the health services.

- The dispenser should ensure, verbally, that the patient understands the treatment. The minimum information, in a language understood by the patient, which should appear on the label should consist of:
  - the generic name of the medicine
  - the strength of the active ingredient
  - the complete dose regime in written in a language understood by the patient
  - the patient's name and National Health number
  - the date of dispensing
  - the quantity of medicine dispensed
  - appropriate cautionary labels.
- In all sectors medicines may only be dispensed by registered pharmacists or practitioners.
- All medicines will be dispensed and labeled using generic names, but the trade name of a medicine product may appear in brackets on the dispensing label after the generic name.
- Authorised officers and Pharmacy Investigators appointed under the Laws will make regular inspections of premises where dispensing operations are performed to ensure that the provisions of the Laws in relation to the practices of dispensing are being satisfied in all respects.
- The issue of dispensing by medical practitioners will be reviewed after the new Laws and policy have been operational for a period of three years.

8.4 PATIENT COMPLIANCE AND SELF-MEDICATION

The aim of the policy on patient compliance is to ensure that compliance with prescribed treatments is maximised through the implementation of rational prescribing and dispensing practices by health professionals throughout the public, private, non-government and faith based organisations and the provision of adequate information on rational medicine use to patients and the general public.

The aim of the policy on self-medication is to ensure that the public has ready access to sufficient unbiased and practical information on appropriate self-diagnosis and treatment for them to make informed decisions in these areas.

- The FPBSC will promote research on the social and cultural factors which affect the use of medicines and will endeavour through health education and provision of relevant medicine information in community media such as radio, newspaper, faith based groups and schools, to alter any attitudes and beliefs which are found to contribute to irrational medicine use or non-use.

- Health education for the public on subjects including disease prevention, limited self-diagnosis, on what constitutes appropriate and inappropriate self-medication, and on suitable alternative non-medicine treatments will be promoted through the use of all available forms of mass communication media. This education could be included as part of the family health curriculum with the provision that information on medicines be given only by people who are suitably trained for the task.

- The FPBSC will endeavour to ensure that adequate patient counselling on the use of prescribed medicines is given as part of the prescribing and dispensing process. Training curricula and continuing education programs for all health professionals will be revised where necessary to include a component on patient counselling.

- In addition to understanding the use of their medicines, patients will be counselled on the appropriate care and storage of medicines to avoid deterioration and waste.

- The Consumer Council of Fiji which plays a vital role in protecting the rights of consumers in general in the country can be involved in consumer education about appropriate care and storage and use of medicines.

9. MEDICINES INFORMATION

The aim of the policy is to ensure the provision of practical, unbiased information on the correct handling and rational use of medicines to health workers at all levels and the public as well as to community leaders.

- Independent and reliable, scientifically-based literature aimed at rationalising prescribing and dispensing will be distributed to health institutions and the relevant health workers throughout both the public and private health care sectors.

- Where appropriate, the Fiji Pharmaceutical and Biomedical Services Centre (FPBSC) will organise training programs, symposia, workshops, and lectures in order to aid the dissemination and understanding of medicines information for the various groups of health personnel and the public.

- To facilitate the collection, compilation, presentation and distribution of medicines information, the MOH will establish and maintain a suitably equipped and staffed Medicines Information Unit (MIU) under the supervision of the FPBSC. This Unit will be gradually developed and expanded so that it will eventually have an Adverse Medicines Reaction Monitoring (AMRM) function and will provide a Poisons Information Service for health professionals and the public. A dedicated telephone line for direct public access will be provided.

9.1 POST-MARKETING SURVEILLANCE AND ADVERSE DRUG AND POISONS MONITORING

Manufacturers, importers, distributors, prescribers and pharmacists will be under a duty to notify the Chief Pharmacist any particular issues of concern in the use of products. The Medicinal Products Board will enlist the services of a panel of experts to develop the methodology for post-marketing surveillance.

- The Medicinal Products Board will accord priority to the establishment of a medical supplies post-marketing surveillance and adverse medicines reactions and poisons monitoring centre in association with the MIU for Fiji as well as other South Pacific nations that might wish to be associated with this activity.

- Technical assistance will be sought to establish a medicines quality control laboratory, which should ideally be developed into a regional or sub-regional medical supplies quality control laboratory. WHO good practices for national quality control laboratories will be mandated. Criteria will be developed for the prequalification of quality control laboratories in other countries and technical cooperation agreements will be drawn up.

9.2 ADVERSE MEDICINE REACTION REPORTING

- An Adverse Medicine Reaction Monitoring system, including suitable adverse medicine reporting procedures, as part of the service of the MIU, will be explored by the FPBSC in collaboration with the National Medicines and Therapeutics Committee. In establishing such a service, the experience of other countries will be carefully considered.

10. TRADITIONAL MEDICINE

The aim of the policy is to recognise the place of traditional medicines in the management of health problems in the community and to ensure only safe and appropriate use of traditional medicines.

- The FPBSC will cooperate with the Traditional Medicines sector through the appropriate body representing the Traditional Medicine sector which includes a pharmacist as a member, to develop safe and complementary practices and cooperation with the traditional Fijian sector, the Indian sector and the Chinese sector.

- As indigenous herbal and other traditional remedies are extensively used in Fiji and are widely regarded as efficacious, the Government will encourage and support research into these remedies with a view to identifying the most useful remedies for treatment of common endemic diseases, determination of the composition of these, their formulation into standardised products of reliable quality and rationalisation of their use. Research will also identify dangerous products and they will be excluded from availability in Fiji. Such research will be undertaken in association with appropriate educational and research organisations such as the University of the South Pacific and the Fiji School of Medicine.

- The traditional knowledge concerning Fijian medicines will be protected from unauthorised exploitation by Laws or Agreements that will also provide for Fijian communities to gain a majority share in any potential reward from the authorised commercial exploitation of traditional medicines derived from indigenous cultures.

11. TECHNICAL COOPERATION WITH OTHER COUNTRIES AND INTERNATIONAL AGENCIES

The aim of the policy is to actively pursue all relevant forms of technical cooperation in order to maximise the efficient utilisation of the limited resources available in implementation of the National Medicinal Products Policy.

Technical cooperation will be encouraged and supported in various areas including the following:

- Training and staff development in all aspects of medicine management, for example:
    - Registration procedures
    - Application of the WHO Certification Scheme
    - Stock management and inventory control
    - Research and studies on medicine utilisation
- Upgrading and maintaining communication facilities
- Transfer of appropriate technology
- Evaluation of medicines
- Regional procurement schemes and exchange of information on pharmaceutical suppliers
- Quality assurance and collaboration with regional and other quality control laboratories
- Exchange of medicine information.

11.1 REGIONAL COOPERATION

- As far as possible relevant elements of the Fiji National Medicinal Products Policy, for example registration and procurement procedures and development of treatment guidelines will aim to harmonies with those of other Pacific Island Nations in order to facilitate regional cooperation.

Opportunities for regional training in all aspects of pharmacy management and practice will be explored and encouraged.

11.2 REGIONAL PROCUREMENT

- The FPBSC will cooperate with other Pacific Island Nations to develop Regional Procurement Procedures so long as the procurement standards match those of the Republic of Fiji.

11.2.1 BULK PURCHASING SCHEME

- The existing Bulk Purchase Scheme will be expanded and further developed in collaboration with all relevant authorities in Fiji and interested Pacific Island countries. The functioning of the system will depend on capacity of staff in smaller island countries to provide accurate estimation of needs. Where the capacity needs strengthening, technical assistance will be sought.

- The Bulk Purchase Scheme should provide medicines to Fiji Pharmaceutical and Biomedical Services Centre (FPBSC) at cost, and to the private sector at cost plus a defined mark-up. It is proposed that the Bulk Purchase Scheme cost recovery profits will be retained in FPBSC administration to support further development.

12. MONITORING AND EVALUATION

The aim of the policy is to ensure the successful implementation of the National Medicinal Products Policy in all its aspects by the establishment of mechanisms for monitoring and evaluating performance under the policy.

- It is critically important that the implementation of the new policy and the of the laws is closely monitored from the outset. Teething problems are inevitable in attempting to implement a new set of laws and regulations within a new policy framework.
- An implementation plan that provides for the application of the requirements to be phased-in will be developed. A set of indicators that will assist in monitoring implementation will be developed.
- The FPBSC will establish and maintain a monitoring and evaluation capability with the function of following the implementation of the National Medicines Policy and defining indicators for measurement of progress towards achieving policy objectives.
- All aspects of medicine management will be monitored by FPBSC and regularly evaluated to determine progress towards achievement of stated objectives.
- Monitoring of rational medicine use will be carried out by the FPBSC in collaboration with the National Medicines and Therapeutics Committee by a variety of methods including monitoring prescribing, dispensing and patient compliance through audits or surveys, and the comparison of epidemiological data with data on medicine consumption and utilisation. Indicators will be defined to help measure trends.

ANNEX I

DEFINITIONS OF NON-GOVERNMENT AND FAITH-BASED ORGANISATION HEALTH CARE PARTNERS

Non-government and Faith-based organisations that provide limited health care services are institutions that, from time to time, provide their services as professional health care givers within their institutional mandate, for special needs of the population.

It must be noted also that the health care services are not core functions of the organisations but they are provided to supplement the services provided by the government of the day.

Examples of non-Government Organisations:

Fiji Red Cross

Saint John Ambulance

Fiji Cancer Society

Fiji Spinal Injury Association

FRIEND Fiji

Project Heaven

The faith-based Organisations depend on overseas partners or members who visit Fiji and are recognised by the appropriate regulatory professional body to practice as health care professionals in Fiji.

All above organisations are very important partners to the Ministry of Health in ensuring accessible basic services by the population of Fiji and therefore the National Medicinal Products Policy is a guide for efficient management of medicinal products under their care.