Republic of Fiji

Pharmaceutical Sector Strategic Plan

for implementing the

the

Fiji National Medicinal Products Policy 2013-2018

Fiji Pharmaceutical and Biomedical Services Centre
Ministry of Health
Fiji

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Acknowledgments

The first strategic plan of the pharmaceutical sector is a significant achievement for Fiji. There is high expectation from all major stakeholders that this plan will be used as a dynamic document for guiding improvement and focusing donors' technical and financial support.

Many people played a valuable role in the planning process, assisting in the refinement of ideas and in the production of the final document. We believe the strategic plan is stronger because of this combined effort and enthusiasm.

Particular thanks are given to senior management of the Fiji Pharmaceutical and Biomedical Services Centre for taking leadership of the task and seeing the job through to completion. Valuable assistance from the World Health Organization and other supporters is also acknowledged with thanks.

Although the plan is very valuable, its goal can only be achieved through actual implementation. Quality change must come about in a logical progression, before the planning process begins again. With small steps, we hope we will be well placed to climb to higher levels of quality, commitment and service. Our quest is for sustainable, quality improvement in Fiji pharmaceutical services.

Suva June 2013

Abbreviations

ACTD	ASEAN Common Technical Dossier
A&E	Accident and Emergency
AIDS	Acquired Immune Deficiency Syndrome
AMR	Adverse Medicine Reaction
AMU	Asset Management Unit
ASEAN	Association of South East Asian Nations
BPS	Bulk Purchase Scheme
CCF	Consumer Council of Fiji
CIOMS	Council of International Organisations of Medical Science
CITES	Convention on International Trade in Endangered Species
CM	Complementary medicine
CPD	Continuing Professional Development
CSN	Clinical Services Network
CT	Clinical Trial
DHIRA	Directorate of Health Information & Research Analysis
DIEFPIC	Drug Information Exchange for Pacific island Countries
DMTC	Divisional Medicines and Therapeutics Committee
DTCA	Direct to Consumer Advertising
EMA	Essential Medicines Authority
EML	Essential Medicines List
EOI	Expression of Interest
EPI	Expanded Program on Immunisation
FCGP	Fiji College of General Practitioners
FEFO	'First Expired First Out'
FMC	Fiji Medical Council
FNU	Fiji National University
FPBSC	Fiji Pharmaceutical and Biomedical Services Centre
FPO	Fiji Procurement Office
FPS	Fiji Pharmaceutical Society
FRCA	Fiji Revenue and Customs Authority
FSM	Fiji School of Medicine
GDP	Good Distribution Practices
GF	Global Fund
GMP	Good Manufacturing Practice
GMU	Grant Management Unit (Global Fund)
GPP	Good Pharmacy Practice

HIV	Human Immunodeficiency Virus
HR	Human Resources
HRD	Human Resources Development
IEC	Information, Education, Communication
IMCI	Integrated Management of Childhood Illness
INCB	International Narcotics Control Board
IPR	Intellectual Property Rights
IT	Information Technology
IU	Investigation Unit
LMU	Logistics Management Unit
M&E	Monitoring and Evaluation
MIU	Medicines Information Unit
MLO	Media Liaison Officer
MoF	Ministry of Finance
MoH	Ministry of Health
MOU	Memorandum of Understanding
MPB	Medicinal Products Board
MRA	Medicines Regulatory Authority
MRU	Medicines Registration Unit
MUE	Medicines Use Evaluation
NDMO	National Disaster Management Office
NGO	Non Government Organisation
NMPP	National Medicinal Products Policy
NMTC	National Medicines and Therapeutics Committee
OTC	Over the counter
PATIS	Patient Information System
PIC	Pacific Island Country
PEA	Pharmaceutical Expenditure Assessment
PPB	Pharmacy Professions Board
PPO	Principal Pharmacy Officer
PR 2010	Procurement Regulations 2010
PSC	Public Services Commission
PSSP	Pharmaceutical Sector Strategic Plan (PSSP)
PU	Purchasing Unit
PVU	Pharmacovigilance Unit
RUM	Rational Use of Medicines
SGO	Solicitor General's Office
SOP	Standard Operating Procedures

SPC	Secretariat of the Pacific Community
STG	Standard Treatment Guidelines
STI	Sexually Transmitted Infections
TB	Tuberculosis
TM	Traditional Medicine
TMA	Traditional Medicines Association
TNA	Training Needs Assessment
TOR	Terms of Reference
TRIPS	Trade Related Aspects of Intellectual Property Rights
UMC	Uppsala Monitoring Centre
USP	United States Pharmacopoeia
WHO	World Health Organisation

Foreword

The first national Pharmaceutical Sector Strategic Plan provides direction for implementation of activities that will fulfill the objectives of the Fiji National Medicinal Products Policy and the development of the pharmaceutical sector (public and private). It provides guidance to donors interested in supporting the sector development in Fiji for the period 2013-2018. The Planning process, for the preparation of this strategy, was overseen by the Ministry of Health and undertaken by the Fiji Pharmaceutical Services Centre with participation from all components of the Pharmaceutical Sector and all relevant stakeholders.

Financial and technical assistance was provided by the World Health Organization (WHO).

The Ministry of Health (MoH) is committed to creating an environment of ongoing quality improvement in the pharmaceutical sector. The goal is to provide effective health care of good quality for the people of Fiji, especially those living in the remote areas.

Truly, by constantly improving the quality of services and products in the pharmaceutical sector, morbidity and mortality rates can be reduced. Accordingly, this improvement will have positive impact on the development of the Fiji people, the economy and the overall nation of Fiji.

The Ministry of Health commitment to improve the quality of the pharmaceutical sector is reflected in the strategic actions and outcomes to be achieved as described in this 5-year strategic plan. The plan includes an implementation framework consisting of clear and practical actions, which, if implemented (step-by-step) over the next five years, are likely to yield desired improvements, both in the sector and the country as a whole. However, these expected outcomes cannot be achieved by the pharmaceutical sector alone. Pharmaceuticals are an important part of the entire health sector. Therefore, the MoH, other government ministries and Non-Government Organizations (NGO) must continue to support all the dedicated workers in the sector. Continuing technical and financial assistance from donors is essential and most graciously appreciated to attain the outcomes indicated in this plan.

A midterm review to assess the progress of implementation of the Plan will be conducted in 2015.

In 2018 the progress of the Plan will be re-assessed and an extension may be needed to fulfill the aims of the Plan.

The Fiji Ministry of Health

Vision

A healthy population in Fiji that is driven by a caring Health Care Delivery System

Mission

To provide a high quality Health Care Delivery Service by a caring and committed workforce working with strategic partners through good governance, appropriate technology and appropriate risk management facilitating a focus on patient safety and best health status for the citizens of Fiji

Values

Customer Focus

Being genuinely concerned that health service is focused on the people/patient receiving high quality health care delivery

Respect for Human Dignity

We respect the sanctity and dignity of all we serve

Quality

We will always pursue high quality outcomes in all our activities and dealings

Equity

We will strive for equitable health care and observe fair dealings with our customers in all activities at all times irrespective of race, color, ethnicity or creed

Integrity

We will commit ourselves to the highest ethical and professional standards in all we do

Responsiveness

We will be responsive to the needs of the people in a timely manner delivering our services in an efficient manner

Faithfulness

We will faithfully uphold the principles of love, tolerance and understanding in all our dealings with the people we serve.

Executive Summary

The first national Pharmaceutical Sector Strategic Plan provides direction for implementation of activities that will fulfill the objectives of the Fiji National Medicinal Products Policy (2012) and the development of the pharmaceutical sector (public and private).

A policy, no matter how carefully formulated, has no value if it is not implemented. Therefore, this detailed strategic plan is developed to link with the revised National Medicinal Products Policy (2012) and include short- medium- and long-term strategies and plans to be implemented in the next 5 years and has two parts.

The first part sets the context for the plan. It identifies the current strengths in the pharmaceutical sector and key issues to be addressed, and the expected outcomes of development activities to be implemented in the sector within that time frame. The second section provides an implementation plan.

This Implementation Plan, 2013 – 2018 is arranged according to the flow of the pharmaceutical supply system as it is addressed in the National Medicinal Products Policy (2012).

Pharmaceutical sector situation analysis

Strengths and challenges in the pharmaceutical sector

Strengths

The new Fiji Pharmaceutical Services Centre (FPSC) was opened in May 2004 for procurement, storage and distribution of pharmaceuticals in line with regulatory and essential medicines concepts for a total of 221 Fiji MoH health facilities, three small island states and 125 retail outlets. The name was changed in 2008 to Fiji Pharmaceuticals and Biomedical Services Centre (FPBSC) to reflect activities more accurately. Since 2006 the organisation has been working under $FJ15 million which is a complete government distribution within the Health Budget.

Framework for supporting the National Medicines and Medicinal Products Policy (NMPP)

The Legal framework covers laws and procedures for selection of medicines, procurement procedures, quality assurance, registration, licensing, storage, distribution, sale and prescription of medicines, and education concerning rational use of medicines, behaviour of health professionals. The national medicines regulatory authority includes sections responsible for registration of medicines, medical devices and cosmetics; issuing of licenses for import/export and for pharmaceutical facilities; for the regulation of any business pertaining to the pharmaceutical practices; and the management of essential medicines.

Investigators (Inspectors) are being trained to understand the areas of pharmaceutical management and they are undertaking investigations.

Advertising and Promotion

Regulation on medicine promotion to cover all aspects of medicines, cosmetics and medical devices promotion and advertisement is in place but needs to be strengthened.

Funding

Fiji is committed to a relatively high level of Government financial resources on health. In addition, there are national programs that are supported by funds from external donor sources and their funds are added to the funding for health programs.

FPBSC has a total of 80 staff with multiple cadres including pharmacists, stores officers, warehouse staff and support staff in Corporate Services under the leadership of the Chief Pharmacist of the FPBSC.

A strong National Medicine and Therapeutics Committee (NMTC)exists and there are Treatment Guidelines and a Fiji Essential Medicines List that are reviewed regularly. The list includes medicines that are safe and cost-effective.

Human Resources

There is a strong and committed Faculty of Pharmacy at the Fiji National University and a large number of students keen to study pharmacy. The Public Service Commission is placing sufficient pharmacy staff in clinical settings but human resources for other categories of pharmacy work need to be strengthened.

The Faculty of Pharmacy has a competency based curriculum. The Pharmacy Profession Board registers qualified pharmacists and ensures their ongoing competence

Nurses undertake many pharmacy-related roles and the principles of medicines management and rational use of medicines are included in the nursing curriculum.

Selection of Medicines for use in Fiji

Medicines are selected by the NMTC on the basis of their validity for treating the most common problems in Fiji safely and affordably. The selected medicines make up the Fiji Essential Medicines List. Medicines are all identified by their INN (International Non-proprietary Name), also known as the generic name. All essential medicines available in Fiji must comply with the quality control standards required for registration.

There is strong understanding in the public sector concerning essential medicines and their place in the system

Classification of potentially toxic pharmaceutical substances exists and there is good awareness of restrictions on their distribution and use in both the public and private sectors. Only registered medicines may be distributed and/or offered for sale in Fiji.

Procurement

FPBSC has an experienced procurement section. However, in a remote small island nation, the service faces enormous challenges associated with lack of economy of scale and the huge distances from suppliers and distances within the nation that affect communication and distribution. It is understood that adherence to standard prescribing guidelines, good stock management practices and timely and appropriate re-ordering from the central store can make a big contribution to accurate forecasting for procurement and to maintaining stock levels in health services throughout the Fiji Islands, as well as in the central Warehouse.

Storage and Distribution

Distribution of medicines is centralized in the Central Medical Store (Warehouse) at the FPBSC. The Warehouse has a computerized inventory control system and an improvement in the pharmaceutical supply system to public health facilities has been reported in previous years. The Warehouse has excellent capacity and storage conditions, has been assessed and has capacity for maintenance of quality and security of medicines in appropriate conditions from the time of receipt into stock until the time of issue and distribution throughout the public sector. There is capacity for continued availability of enough essential medicines at all levels of the health system. Capacity needs to be strengthened through accurate and systematic recording, monitoring and reporting of use and stock levels of all items. Inspection and Receiving Standard Operating Procedures(SOPs) for the Warehouse will be implemented

Efficient stock management and control can minimize wastage

Some national programs, like TB, HIV and Reproductive Health programs, are involved in making sure there are good practice guidelines and an adequate supply of quality medicines so treatments are readily available. However they need to be integrated with national systems.

Supply chain logistics need to reflect revisions to clinical practice and to continue to be strengthened to ensure there is no stock-out of the needed medicines where they are required.

Adequate and appropriate transportation including temperature control, maintenance and communication facilities are in place. Personnel necessary to maintain efficient operations of the public sector distribution system are important - particularly to less accessible areas of the country - for the prompt, safe and efficient delivery to appropriate destinations.

Rational Use of Medicines

Many editions of treatment guidelines have been prepared by an active Medicines and Therapeutics Committee for a wide range of conditions. Guidelines are being prepared in more categories and these will enhance prescribing and use of medicines.

University training (BPharm Fiji National University [FNU]) is in place to ensure competent pharmacy graduates. The curricula for most cadres of health workers are being upgraded and will include the Rational Use of Medicines and best practice standards of prescribing and dispensing.

Nursing training includes the concept of essential medicines management.

Monitoring, training and planning programs on rational medicine use are being implemented but require further strengthening.

Good relations with the private sector exist and there are opportunities for good collaboration.

Regional and International Collaboration

Initiatives supported by WHO and other institutes in surveillance for emerging diseases develop rapid response capacity if and when needed. Common approaches to disease management are being implemented and evaluation of medicines has been conducted on a regional bases together with exchange of information on pharmaceutical suppliers, quality assurance. Collaboration occurs with regional and other quality control laboratories.

Regional and International Initiatives are available to facilitate training and Human Resources development for all aspects of the pharmaceutical sector.

An email based network - Medicine Information Exchange for Pacific Island Countries(DIEFPIC)- is in place for sharing all aspects of pharmaceutical knowledge and for sharing assistance within the group. The network also has an online repository for resources to be shared.

Challenges

There has been significant achievement in the pharmaceutical sector but there is still a great deal to be done to strengthen the various components of the system.

Some articles of the medicines laws need to be strengthened or publicized more widely and **stock-outs must be addressed.**

Medicines Registration and Quality Control

Although there is a good medicine registration system in place, to cope with the workload, the medicine registration system needs to be strengthened in terms of skilled staff, office space and equipment.

While the role of the private sector in pharmaceutical service delivery is important, systems must be in place to ensure priority is given to the protection of people's health and welfare in the pubic sector.

Quality Assurance

The registration process is in place to ensure the quality of medicines available in Fiji but it needs to be strengthened in capacity and human resources. Investigation procedures to detect sub-quality medicines or products that have slipped through the system exist but they need to be strengthened. Marketing surveillance guidelines and procedures for the collection of medicines samples for quality control testing will be strengthened and kept up-to-date to capture best practices

Finance

Although the government is committed to good financial support of the pharmaceuticals system, some initiatives are beyond Fiji's funding capacity. Finance from donor programs and vertical programs can be included in the general income rather than being part of separate vertical programs. Mechanisms are required for donors to contribute to the Government program at the national level and then the finance cared for by the Government. Funds from external donor sources that support national programs need to be integrated with national funds to avoid fragmentation of management.

Human Resources

Although the Public Service Commission is placing sufficient pharmacy staff in clinical settings, human resources for other categories of pharmacy work need to be expanded and strengthened. There are insufficient appropriately trained pharmaceutical workers in the public and private sectors to implement all national policy tasks and procedures and achieve desired quality of work. Staff need special skills to do the wide range of tasks and formal training courses don't usually include all the necessary skills.

Experienced staff are too busy to do training and funds are needed for sending staff to training programs. At the same time staff can't be spared for going to training for long periods. However specific training is needed and training on-the-job is ideal.

Low salaries can sometimes lead to health workers leaving for private practice. Government will have limited leverage power if salaries are not dramatically increased.

Procurement and maintenance of reliable supplies

Stock-outs remain a problem. Quantification is one of the most difficult aspects of the procurement process and of the supply chain. Ongoing assistance and support will be needed to strengthen systems that will help estimate the quantities of medicines to be procured and to ensure those medicines are procured in a timely manner in the correct quantities to avoid stock-outs and to satisfy appropriate use according to clinical guidelines. The Procurement Unit in the Ministry of Health could be assisted with the stricter implementation of updated Procurement Guidelines.

Medicines Distribution and Supply

Medicines shortages in the public health system still happen. Communication between distribution centres in the public sector, and service delivery points, require strengthening to reduce stock-outs, unexpected delivery and potential storage problems. Monitoring and supervision in provincial and district health services need to be strengthened to maintain a reliable supply of medicines.

Supply chain logistics need to reflect revisions to clinical practice guidelines and to continue to be strengthened to ensure there is no stock out of medicines. The Warehouse inventory control system needs review. Efficient communication between stake-holders, but above all with procurement and service delivery counterparts, is needed. There is insufficient understanding of relevance of accurate stock records. Improved inventory control would result in fewer stock outs and less wastage of products and funds. Extra demands from donor funded programs concerning separate management and reporting procedures can be a burden for staff at health facilities. It is crucial that donor inputs are integrated with national programs and procedures.

Adherence to SOPs concerning stock management would enhance operations at health facilities and the Warehouse.

Disposal of pharmaceutical waste needs special facilities that are not available in Fiji.

Advertising and Promotion

Advertisement and promotion of medicines, cosmetics and medical devices needs appropriate control. Procedures are needed for approving and monitoring promotion and advertising of medicines, cosmetics and medical devices together with a mechanism for reporting unethical practices.

Rational Use of Medicines

Dissemination of standard treatment guidelines, together with education about their use will improve prescribing in Fiji. Monitoring, training and planning programs on rational medicine use are being implemented but require further strengthening. The importance of the use of generic products needs better understanding.

Medicines are ‘prescribed’ by a number of different health workers: doctors, dentists, nurse practitioners and pharmacists- some without knowledge of clinical guidelines or rational medicine use.

In the private sector, ways need to be explored on how to ensure the best use of medicines, especially antibiotics. Physicians and pharmacists in the private sector need to understand the value of Fiji’s Standard Treatment Guidelines. Training, and monitoring or supervision of practice needs to be introduced and maintained.

There is poor patient compliance with prescription instructions in some cases (particularly for chronic diseases) and there are many beliefs and practices that influence consumers’ behaviour. People often use medicines prescribed for somebody else. Some family members in rural and remote areas have poor access to health services, so self-prescribing is common as is sharing of medicines. More interventions to improve communication between providers and consumers, such as training and awareness campaigns, to increase the knowledge about medicines in communities are needed. Strategies to improve medicines understanding and use need to be assessed and introduced in the Fijian context.

Quality Assurance during circulation

Marketing surveillance guidelines and procedures for the collection of medicines samples for quality control testing need to be strengthened and kept up-to-date to capture best practices.

Unregistered complementary or traditional products of unsure quality are available. The quality and safety of commercially produced traditional medicines that are imported into Fiji from other countries cannot be assured. Cooperation with Regulatory Authorities needs to be encouraged to enable recognition of Fijian Traditional Medicines (TMs) and quality control of imported traditional products from other counties; and registration of products that comply with requirements.

Foreign TMs and complementary medicines must satisfy the regulatory requirements and be registered before they become available to the public.

Technical Cooperation with other countries and International Agencies

Training and staff development in all aspects of medicines management including upgrading and maintaining communication facilities, and transfer of appropriate technology can be enhanced though technical cooperation with other countries and International Agencies**.** Opportunities should be sought actively.

Where appropriate, common approaches to disease management, evaluation of medicines, exchange of information on pharmaceutical suppliers, quality assurance and collaboration with regional and other quality control laboratories should be encouraged.

Monitoring and Evaluation

Regional sharing and collaboration with regionally developed initiatives, for example in counterfeit and substandard medicines, laboratory testing, etc. could be beneficial.

Few Monitoring and Evaluation (M&E) initiatives are in place at present and situation analyses are rarely undertaken and assessment of the impact of interventions is not routinely undertaken. Indicators need to be developed

Expected Outcomes of the Strategic Implementation Plan

The following are the expected outcomes of this plan:

- Improved pharmaceutical sector service management nationwide contributing to achievement of public health goals and improved consumer access to essential medicines and supplies at all levels
- Health workers and consumers will understand and comply with strengthened medicine laws and regulations which reflect selection, registration, quality management and control requirements for all medicines and medical devices
- Adequate funds available for all strategic actions and activities to fully implement the medicines policy with improved work place, improved management, adequate resources allocation, work performance and follow-up in compliance with MoH guidelines
- An appropriate number of adequately trained personnel with improved career prospects and opportunities for upgrading and refresher courses to maintain a good human resources base to meet the needs of the NMPP. Increased capacity of pharmaceutical sector staff to develop, implement and monitor quality control standards for service based on MoH standards; resulting in disciplined, professional and ethical pharmaceutical sector health workers complying with quality work practices
- A medicines and medical devices registration system continuing to operate promptly and efficiently to ensure quality of products and protect the health of the public
- Strengthened procurement, storage, management and distribution of essential supplies nationwide
- Improved prescribing and dispensing of appropriate medicines
- Strengthened management, surveillance, monitoring and follow-up to maintain medicines safety.

Key issues for priority attention during 2013-2018

There is need for strengthened medicine policies, laws and regulations.

There is also need to:

- strengthen planning, management and discipline within the pharmaceutical sector
- increase awareness of the need for improved education, training, skills/expertise of the pharmaceutical workforce and to support the workforce with appropriate salaries and incentives
- improve availability of pharmaceuticals in the public and the private sector
- strengthen programs aimed at improving the rational use of medicines
- secure adequate financial resources and technical assistance to focus on priority issues in the pharmaceutical sector
- provide quality management and services in all areas in order to increase reliable access to essential medicines, especially in the remote communities.

Overall expected outcomes

A strengthened pharmaceutical sector that is an integral part of health sector development to improve the health of the people in Fiji, thereby contributing to poverty alleviation and socio-economic development; it includes the provision of:

- A more efficient and effective health system with quality management, financial support and service provision in the pharmaceutical sector guided by strong laws and regulations
- Sustainable skilled human resources in the pharmaceutical sector
- Improved access and availability to affordable pharmaceutical and other health care products that are of good quality and are safe and effective
- Rational prescribing, dispensing and use of medicines
- Effective governance of the pharmaceutical sector to encourage sustainable private and public partnerships in pharmaceutical service delivery.

Realization of these outcomes will be achieved through the implementation of proposed strategic activities outlined in the Pharmaceutical Sector Strategic Plan of Action.

Introduction to the Pharmaceutical Sector Strategic Plan

This Pharmaceutical Sector Strategic Plan identifies key issues for development.

The plan recommends activities to be undertaken to achieve the aims of the NMPP. The plans provide the timing requirements, means of verification of activities undertaken, monitoring and evaluation criteria and reporting mechanisms.

The FPBSC management team will prioritise activities and monitor and evaluate the implementation of strategic plan, and include a midterm review in 2015. This team is an integral part of the Ministry of Health's monitoring and evaluation framework. At the end of the time-frame the implementation plan will be re-evaluated and extended as needed for achievement of the aims.

PHARMACEUTICAL SECTOR STRATEGIC ACTION PLANS 2013 – 2018

for implementation of National Medicinal Products Policy

PHARMACEUTICAL SECTOR STRATEGIC ACTION PLANS 2013 – 2018
for implementation of Fiji National Medicinal Products Policy 2013

Introduction:

- Strengths and opportunities have been identified over the past and recent years and have facilitated the development of this Pharmaceutical Sector Strategic Plan of action which is intended to overcome existing challenges in the sector through the presentation of feasible activities to be implemented over the coming years (2013-2018). Responsible units and individuals to implement the activities are indicated in the matrix below. Technical assistance and funding may be needed to implement some of the activities. Where such need arises responsible units should seek assistance from relevant organizations.
- To ensure timely implementation of proposed activities below, it is recommended that at least three reliable and enthusiastic officials be appointed to serve as patrons (champions, respected opinion leaders, etc.) to continuously prompt responsible units specified in the plan to implement the indicated activities.

Framework

- The Plan is set in a context of the NMPP that explains the Context, Goals, Objectives, Approaches, Key Focal Points and the role of the Ministry of Health and the Fiji Pharmaceutical and Biomedical Services Centre.

(Note: For the meaning of abbreviations used in the Plan refer to page 4 of the Plan)

1. Legal and Regulatory Framework

Refers to the legal context, overall goals and objectives, Regulatory Framework, responsible agencies and the existence of Laws, Regulations, Decrees and Proclamations to guide regulate and control players, operations and activities in the pharmaceutical sector

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Legal Framework **Legislation and regulation** ***Legislation relating to the practice of pharmacy***	1	Without exceptions enforce the existing law, and develop and enforce regulations and guidelines to the fullest extent possible.	Increased adherence to the law in the sector Increased number of investigation visits and prosecution as appropriate	Pharmaceutical sector players complying with laws	MRA Investigation Unit	x	x	x	x	x	□□□□□ Investigation and prosecutions reports. Reduction in the number of incidences of violation of the Laws, Decrees & guidelines
	2	Publicise to health professionals and the general public, the laws and licensing conditions that control the sale of medicinal products in the private sector.	Workshops and publicity campaigns to explain law on pharmacists' responsibilities of selling medicines & dispensing prescription only medicines.	Understanding about unlawful dispensing of prescription only medicines by pharmacists.	MRA IU	**x**	**x**	**x**	**x**	**x**	□□□□□ Inspection shows ceased OTC sale of prescription only medicines by pharmacists

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Legal Framework **Intellectual Property Rights Laws and Pharmaceuticals**	3	Maintain current collaboration between Ministry of Health and other relevant agencies and ministries to sustain awareness of the legal framework (Patent Law) to allow compulsory licensing, parallel importation, Government Use and any other TRIPS flexibilities. and anything having impact on health services	A strong collaboration resulting in sound legal framework and awareness to allow compulsory licensing and all other TRIPS flexibilities	Advantages of TRIPS flexibilities available	MRU FPBSC Patent Office	**x**	**x**	**x**	**x**	**x**	☐☐☐☐☐ TRIPS compliant health friendly legislation in place
	4	Examine any proposed international treaties and conventions related to trade and or proposed free trade Agreements in detail to ensure that flexibilities available under the TRIPS agreement are not affected.	Any proposed International treaties and conventions related to trade and/or proposed Free Trade Agreements examined to ensure TRIPS agreements are not affected	Effective TRIPS compliant, public health sensitive legislation in place to enable access to affordable medicines	FPBSC MRU MoH Policy Unit	**x**	**x**	**x**	**x**	**x**	☐☐☐☐☐ Reports on examination of treaties etc
Medicinal Products Board& Pharmacy Profession Board	5	Establish the 2 Boards for the Decrees and the necessary administrative requirements for the Boards to review legislation and develop relevant regulation to strengthen implementation of the law	1.Boards established with TORs and criteria for membership 2. Inadequate areas of he pharmaceutical legislation identified and strengthened	1. Fully fledged MPB and PPB operating 2. Updated pharmaceutical legislation	MPB MRA MRU	x	x	x	x	x	☐☐☐☐☐ 1. Fully fledged MPB and PPB operating 2. Revised and updated pharmaceutical legislation
	6	Develop annual action plan for the Boards	Action plans	Action plans guide activities of the 2 Boards	MPB and PPB	x	x	x	x	x	☐☐☐☐☐ Action plans in place and used the PPB and MPB
	7	Publicise to health professionals and the general public, the laws, Decrees and licensing conditions that control the pharmaceutical sector	Workshops and publicity campaigns to explain the law regarding the responsibilities of pharmacists and heath professionals	Understanding about Decrees controlling the practice of pharmacy	MRA MIU	x	x	x	x	x	☐☐☐☐☐ Audit /survey shows increased understanding by heath professionals and the public of the Decrees
Pharmacy Professions Board	8	Expand the role of the PPB to (a) carry out registration of pharmacists; (b) control of pharmacists' conduct and CPD (consider the need for technical assistance) . See also #55, 56, 115)	Agreement on the registration and continuing education of pharmacists and control of their conduct by the PPB.	PPB registers pharmacists, manages standards for CPD and controls pharmacists' conduct	PPB	x	x	x	x	x	☐☐☐☐☐ Accredited CPD activities available and used to re-register pharmacists
	9	Develop CPD Program for Registered Pharmacists (consider the need for technical assistance)(see also # 55, 56, 115)	Providers of suitable CPD activities	Maintenance of pharmacist CPD	PPB FPS	x	x	x	x	x	☐☐☐☐☐

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
Legal Framework **Medicines Regulatory Authority** ***Registration, licensing and Investigation***		To establish the Unit with the delegated role of carrying activities for the Board									
	10	Increase trained staff with skills to expedite medicines dossier evaluation (for evidence based medicines registration based on ACTD standards) and improve equipment and facilities for licensing and Investigation (Refer # 17)	More staff available and skilled in best practices for reviewing dossiers for the registration of health products	A faster and evidence based system for the registration of pharmaceutical products	MRA MRU	x	x	x	x	x	☐☐☐☐☐ Sufficient staff trained; efficient registration
	11	Explore and install appropriate software to facilitate the medicinal products registration procedure. *(mSupply worth considering – (see also #12 below, 15)*	Software identified and installed	Registration procedure facilitated	MRU IT WHO		x			x	☐☐☐☐☐ Procedure developed
Registration of manufacturers and distributors	12	Develop a registration procedure for registration of manufacturers that satisfy international GMP standards. It will involve standardized documentation matched with appropriate assessment software. *(see also #11 above, 15)*	Procedure for registration of manufacturers and suppliers who satisfy conditions	Registration of manufacturers and suppliers who satisfy conditions	MRU IT	x	x	x	x	x	☐☐☐☐☐ Procedure developed
	13	Maintain a list of prequalified suppliers including a system for review and renewal of registration every two years	Prequal Suppliers listed. Software flags time for review and renewal	Updated registration maintained	MRU IT	**x**	**x**	**x**	**x**	**x**	☐☐☐☐☐ Prequal suppliers list in place with review and renewal system in place
Good Manufacturing Practice	14	Organize regular meetings with regulatory authorities.	Information about GMP conditions and provisions for registration and licensing available to local producers	Local producers attempt to reach appropriate standards for registration and licensing for the Fiji health sector	MRA MRU	**x**	**x**	**x**	**x**	**x**	☐☐☐☐☐ Meetings with local manufacturers to explain details of GMP and provide encouragement to achieve GMP standards.
Registration of medicinal products	15	Develop registration program for medicinal products (including complementary and traditional medicines, devices) in Fiji(see # 11,12)	Specifications developed and publicized to relevant agencies	Knowledge of specifications for registration of medicinal products in Fiji	MRU MIU	x	x	x	x	x	☐☐☐☐☐ Specifications for registration produced and disseminated
	16	Develop a list of strong regulatory authorities whose standards can be used to facilitate evaluation	Product standards accepted by strong regulatory authorities	Facilitated assurance of quality for registration	MRU WHO	x	x	x	x	x	☐☐☐☐☐ List available and updated

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Legal Framework *Registration of medicinal products (continued)*	17	Develop procedure for registration and conditions for other products such as medical devices, Traditional Medicines and health supplements, based on ASEAN or other appropriate harmonized standards. (*See # 10).* Collaborate with Regulatory mechanisms to regulate that labels on foreign medicinal products include English language*(See Domain 11. Technical cooperation with other countries and international agencies #s 150, 151*)	Procedure for registration and labeling of medical devices, Traditional Medicines and health supplements, based on ASEAN harmonized standards.	Registration and labeling of medical devices, Traditional Medicines and health supplements, based on ASEAN harmonized standards.	MRA MRU	x	x	x	x	x	□□□□□ Registration system in place and operating
	18	Make the list of registered products public through the MoH website	List of registered products and publicly available	List of registered products easily available on request from MoH website	MoH MRU MIU	**x**	**x**	**x**	**x**	**x**	□□□□□ List of registered products available on request from MoH or MoH website
Narcotic control	19	Prepare an SOP and checklist to ensure that the import and management of narcotics and psychotropic substances are in line with licenses and all aspects of the INCB and Fiji Law	SOP and Checklist in place to conform with INCB protocols and National laws	Import/management in line with INCB & National Law	IU FRCA	**x**	**x**	**x**	**x**	**x**	□□□□□ SOP and Checklist in place and being used
Schedules of medicinal products and restrictions on distribution and use	20	Develop Medicine scheduling system in Fiji	Reviewed approved list/schedules of – General sale medicines, OTCs, Pharmacist only, Prescription only medicines, and special category controlled medicines (e.g. narcotic)	Clear categories for better management of pharmaceutical substances and conditions for their sale and distribution	PPB MPB MRA NMTC	**x**	**x**	**x**	**x**	**x**	□□□□□ Approved schedules of medicines by their level of restriction for sale and distribution
Licensing	21	Issue licenses to persons based on qualification of the seller or the distributor, the permitted category of schedules and the permitted scope of practice.	Licenses issued based on qualification of the seller /distributor &permitted category of schedules	Seller and/or distributors only operating according to their qualification and permitted categories	MRU IU PPB MPB	**x**	**x**	**x**	**x**	**x**	□□□□□ Internal audit reports

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Legal Framework ***Investigation Unit*** *Investigations*	22	Develop check-lists / SOPs and increase the number of monitoring visits to licensed individuals and premises to ensure possession of licenses and compliance with license conditions concerning medicines and to remove licenses if necessary	Increased visits by medicine investigators equipped with relevant SOPs and checklists and investigation reports	Monitoring capacity and licenses removed if appropriate. Sellers and/or distributors only operating according to their qualification and permitted categories	MRA IU FPBS	x	x	x	x	x	□□□□□ Report on investigators' visits& action taken when necessary
Investigation Unit *Investigations (continued)*	23	Develop legal instruments to prosecute and penalise individuals who contravene license conditions for the sale or distribution of the restricted substances	Legal instrument in place	Contraveners punished	MRU IU FRCA	x	x	x	x	x	□□□□□ Penalties for contraventions in place and operational
Customs Authority relationship	24	Continue to collaborate with FRCA to facilitate their role at all border posts in checking consignments' compliance with import licensing requirements, including providing regular training to update on recent changes, if needed.	FRCA Officials regularly supported by Drug Investigators Minutes of Meetings	Continuing good collaboration with FRCA concerning Border control	MRU IU FRCA	x	x	x	x	x	□□□□□ Reports of FRCA Officials Minutes of meetings
	25	Provide a continually updated list of ALL registered importers, exporters, suppliers and products to FRCA	List to FRCA	Expedited Border Control	MRU FRCA	x	x	x	x	x	□□□□□ Updated lists supplied
Import of medicinal products	26	1. Develop and disseminate guidelines (to be listed) to potential importers to assist them to comply with all necessary regulations and requirements. 2. Ensure by Investigation that importers comply with all licensing and registration conditions	1. Guidelines 2. Investigations to premises and at Borders	Knowledge by potential importers of regulations /requirements and compliance with law	MRU/IU FRCA	x	x	x	x	x	□□□□□ 1. Guidelines developed and disseminated 2. Reports of IU and FRCA
	27	Ensure, by enforcing without exceptions, the relevant provision of the legislation requiring that all companies, organisations & NGOs involved in importing medicines for use in Fiji have appropriate licenses for the import of medicines.(*See also # 82)*	A list of credible and compliant import companies and NGOs operating in the country.	Only credible and compliant import companies and NGOs operating in the country.	MRA	x	x	x	x	x	□□□□□ A list of licensed, credible and law-abiding import companies & NGOs operating in the country
	28	Ensure that all companies, organisations & NGOs involved in importing medicines for use in Fiji have appropriate documentation of quality assurance for the products such as the WHO certification scheme	Evidence of quality assurance for all products imported.	Only quality assured products will be imported by companies and NGOs operating in the country.	MRA	x	x	x	x	x	□□□□□ Evidence of quality assurance for products by import companies & NGOs operating in the country
	29	Strengthen relationship with National Disaster Management Office with other relevant agencies concerning specific medical supplies related needs and develop and disseminate the response list appropriately eg to Foreign Missions and relevant agencies	Collaboration with NDMC and relevant agencies concerning medical supplies disaster and emergency response	Only appropriate medical supplies response to disaster or emergencies in line with NMMP	NDMO FPBSC Other Technical Agencies	x	x	x	x	x	□□□□□ Established collaboration. Published list of disaster requirements

		(See also # 82, 86)									

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Table					Indicator / Verification/year
						1	2	3	4	5	
Legal Framework *Export of medicinal products*	30	Develop regulations if needed to ensure it reflects best pharmaceutical export practice.	Result of review and recommendations for updating	Legislation remains current	MoH – FPBSC FRCA	x	x	x	x	x	□□□□□ Updated export legislation
	31	Conduct education and awareness activities to ensure understanding among exporters, staff and the public	Education activities organised	Awareness among exporters, staff and the public	MOH - FPBS	X	x	x	x	x	□□□□□ Report on education activity
	32	Conduct monitoring visits to licensed individuals and premises to ensure compliance with license conditions and to remove licenses if necessary	Visits by medicine investigators equipped with relevant SOPs and checklists	Monitoring capacity and licenses removed if appropriate	MRA / MOH - FPBSC	X	x	x	x	x	□□□□□ Report on medicine investigators visit & action taken when necessary
Internet supply of pharmaceuticals	33	Develop appropriate regulation to control internet pharmacy activities associated with import/export or sale of medical supplies. Determine and impose penalties	Regulation and penalties in place	Internet activities associated with import /export or sale of medical supplies prohibited	MPB	x	x	x	x	x	□□□□□ Internet activities controlled. Penalties imposed
Management of Medicinal Products	34	Increase the number of monitoring visits by investigators with checklists and SOPS to licensed individuals and premises to ensure compliance with license conditions concerning medicines management and to remove licenses if necessary	Increase visits by medicine investigators equipped with relevant SOPs and checklists	Monitoring capacity and licenses removed if appropriate	MRA IU	X	x	x	x	x	□□□□□ Report on medicine investigators visit & action taken when necessary

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Table					Indicator / Verification/year
						1	2	3	4	5	
Legal Framework ***Advertising and Promotion of Medicinal Products*** *Refers to ensuring that advertising and promotion of medicines are of a high professional standard and conform to the requirements of the medicines laws, decrees and regulations.*	35	Review and strengthen as needed, regulation on promotion to cover all aspects of medicines, cosmetics and medical devices promotion and advertisement to ensure that there is compliance with WHO *Ethical criteria for medicinal drug promotion* for advertising and promotion	Up-to-date regulations on medicines promotion, information and advertisement covering Ethical Criteria to control advertising and promotion	Unbiased and safe promotion, information and advertisement to health professions and the general public	FPBSC/MRU NMB	x	x	x	x	x	☐☐☐☐☐ Revised and strengthened regulation on medicine promotion, information and advertisement, in place and implemented; special guidelines for advertising medicines for children included
	36	Develop and publish a mechanism for monitoring advertising and promotional activities to ensure that they conform with the relevant ethical criteria; and for reporting unethical practices (by advertisers, health professions and the general public) Leaflets for distribution in pharmacies and health services?	Checklist circulated to relevant people with reporting instructions	Reports received and acted on	MIU CCF FPS FMA	x	x	x	x	x	☐☐☐☐☐ Checklist developed and circulated to appropriate people with instructions for use
	37	Develop and implement programs for empowering the general public to minimize self-medication, eg with schools, Consumer Council, faith-based organisations	Programs for educating and empowering the general public to minimize self-medication developed and implemented	Decline in self-medication by the general public	PPB MIU CCF	x	x	x	x	x	☐☐☐☐☐ Programs for empowering the general public to minimize self-medication developed, in place & implemented
National Medicines and Therapeutics Management ***Essential Medicines Management Authority (EMA)***	38	Develop TOR for the EMA in line with its role in overseeing the management and use of essential medicines including training and Medicine Use Evaluation (MUE) in collaboration with the NMTC. Map and justify HR and equipment requirements.	EMA role and needs defined and submitted	Well functioning and resourced EMA	PBBSC EMA NMTC	x	x	x	x	x	☐☐☐☐☐ MRA defined, resourced and functioning
National Medicines and Therapeutics Committee	39	Review and Strengthen the role of the NMTC *(see also Domain 4. Selection)*	NMTC established with clear TORs	Improved coordination and oversight of best use of medicines	FPBSC NMTC	x	x	x	x	x	☐☐☐☐☐ NMTC with clear TORs in place
Clinical Trials	40	Develop regulations to control clinical trials and the medicines for use in the trials together with guidelines for conduct of clinical trials of medicines in accordance with the NMPP and circulate widely to relevant stakeholders.	Guidelines for conduct of clinical trials.	Clinical trials only conducted in accordance with Fiji Guidelines and WHO/CIOMS	MPB NMTC	x	x	x	x	x	☐☐☐☐☐ Clinical trial guidelines prepared and disseminated.

2. Financial Resources

Refers to the assurance of availability of sufficient funding to provideadequatequantitiesofappropriatequalityessentialmedicinesatthe 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.

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Financial Resources	41	Advocate for increased financial resources from government, donors and other health partners to provide adequate quantities of quality essential medicines for the public sector to be procured cost-effectively and managed efficiently and for implementing all components of the NMPP.	Justified submission	Additional funds will be available if needed	MoH FPBSC	x	x	x	x	x	□□□□□ Submission for funds that satisfy identified needs
	42	Conduct Pharmaceutical Expenditure Assessment covering all areas of the pharmaceutical sector every 2 years for Public & Private sectors	2 yearly Pharmaceutical Expenditure Assessment	Pharmaceutical Expenditure known	FBBSC	x	x	x	x	x	□□□□□ 2 yearly Pharmaceutical Expenditure Assessment

3. Human Resources

Refers to ensuring that an appropriate number of adequately trained personnel are available to meet the needs of the National Medicinal Products Policy.

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Human Resources ***Human Resources needs and competencies***	43	Map and justify human resources position needs for all categories of pharmacy workers in all components of the pharmaceutical sector and develop HR master plan to include extended and new services. Review the pharmaceuticals system to ensure the appropriate role delineation	A map of current human Resource position needs and master plan for the sector and review	Needs are known	FPBS All facilities	x	x	x	x	x	□□□□□ Map of Human Resources position needs
	44	Make Human Resource needs recommendations and submit to PSC	HR Recommendations made and submitted	Recommended HR needs. Appropriate pharmacy workforce to meet the current and future services	MoH / FPBSC PSC - DHR	x	x	x	x	x	□□□□□ Map of Human Resources position needs submitted to PSC and addressed
	45	Develop National Competencies for all levels of the system and strengthen competency based curriculum at all institutions of higher learning. Include the concept of Essential Medicines and the role of Standard Treatment Guidelines.	National Competencies for the whole system developed and reviewed Curriculum conforming with Competency Standards	Appropriately trained Pharmacists available in the sector to perform a range of pharmacy related roles	MoH-Personnel Dept/ Institutes of Higher Learning/ FPBSC	x	x	x	x	x	□□□□□ National Competencies and Reviewed Curriculum
Expansion and maintenance of human resources	46	1. Establish the Pharmacy Services Policy for the Public Sector. 2.Conduct a Training Needs Assessment (TNA) for pharmacists and other pharmacy staff related to strengthening capacity in the whole sector to identify key functions (in all areas of the pharmacy system) and training needs – organizational, occupational and individual level assessments (in both in the private and public sectors)	Results of TNA	Knowledge to inform what is needed to improve staff capacity	MoH- PSC FSM FPBSC etc	x	x	x	x	x	□□□□□ TNA Report
	47	Develop and implement training plans based on TNA for the sector (number, skills, career opportunities) in the short-, medium-, and long term to improve staff capacity in the sector (pharmacists and other pharmacy staff)	Training Plans and programs	Adequate trained and skilled staff in place, both in the public and private sectors, to implement national medicines policy components	MoH PSC FSM FPBSC etc	x	x	x	x	x	□□□□□ Status reports on the implementation of training plan and programs

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Human Resources *Expansion and maintenance of human resources (continued)*	48	Collaborate with donor supported disease focused programs to ensure that their training is integrated with national training	Collaboration between donor programs and MoH programs to ensure integration and minimal disruption to services.	Health service delivery enriched by good collaboration	MoH FPBSC Donors	x	x	x	x	x	□□□□□ Guidelines on integration of special focus programs developed and used
	49	Prepare and implement an SOP that requires staff who have undertaken training e.g. attended conferences, workshops, seminars and meetings, in-country or abroad, to share what they have learned with other relevant staff and discuss how the new knowledge acquired can be used to improve the quality of services provided and outcomes	SOP outlining procedure for sharing knowledge gained after training workshops, conferences, etc.	Knowledge gained after training workshop, conferences, etc. used to improve the quality of services	FPBSC	x	x	x	x	x	□□□□□ Reports of meeting held to share knowledge gained from training opportunities
	50	Strengthen monitoring and evaluation capacity at all levels to ensure efficient and effective management of medicines and medical devices *(see also Domain 12. Monitoring & Evaluation#163-165)*	Ideas submitted to strengthen support and M&E	Quality of work will be enhanced and work satisfaction improved	FPBSC	x	x	x	x	x	□□□□□ HR Capacity evaluation tools developed
	51	Develop accredited system in collaboration with PPB and FNU (*See also PPB # 8.)*	CPD system place	Quality of work will be enhanced and work satisfaction improved	PPB	x	x	x	x	x	□□□□□ CPD system in place
Improved career prospects	52	Explore and identify ways to reward staff based on their performance and CDP	Ways to reward staff based on their performance identified	A motivated workforce	MoH/HRD PSC FPBSC	x	x	x	x	x	□□□□□ Reward system in place and operational
	53	Seek consensus and accordingly recommend salary structures for pharmacy staff (along with other staff as necessary) – to motivate staff to remain in service	Appropriate Salary Structure approved	Motivated staff remaining in the public sector without the need for second jobs	MoH/PSC	x	x	x	x	x	□□□□□ Satisfactory salary structure developed, approved & implemented
Facilitating achievement of tasks	54	Explore options for outsourcing workforce or specific tasks at certain levels of services	List of possible 'outsource' options	Facilitated achievement of tasks	EMA	x	x	x	x	x	□□□□□ List of options for outsourcing tasks

4. Selection

Refers to the choice of medicines for treatment of the most common conditions in Fiji, based on their evidence of safety, quality, effectiveness, availability in the market from reliable suppliers at affordable prices

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Selection ***The role of the NMTC***	55	The NMTC will publicise its roles as an Advisory Committee to the MoH on all matters related to the use of medicines at all levels of the health services as described in the NMPP. The role includes development or collaboration in development of Standard Treatment Guidelines that generate an Essential Medicines List; as well as providing a formal mechanism for interaction with Hospital Medicine & Therapeutic Committees and the CSNs; and Technical cooperation with other countries and international agencies	Clear role of NMTC and CSNs Records of deliberations of NMTC. Products such as STGs and EMLs and other guidelines.	Improved coordination and oversight of best use of medicines by all players including donors.	NMTC EMA	x	x	x	x	x	☐☐☐☐☐ Publicised role of NMTC Records of deliberations of NMTC
	56	Review and develop a collaborative role between NMTC and the Clinical Service Network (CSN) in STG development. *(#s59 & 60to be done together)*	Recommendation and Role of CSN/NMTC defined	Clarified system in place on the development of STGs	MoH – Policy Unit FPBSC, NMTC/CSN EMA	x	x	x	x	x	☐☐☐☐☐ Publicised role of CSN and NMTC in STG development Records of deliberations of NMTC
	57	Review and disseminate Procedures and criteria for recommending the inclusion or deletion of a product in the STGs and National Essential Medicines List *(See also #140)*	Procedure in place and disseminated (Forms)	Clear procedure for inclusion and deletion of items	NMTC CSNs	x	x	x	x	x	☐☐☐☐☐ Procedure in place and disseminated (Forms)
	58	Review and disseminate procedures for coordinating with donor programs in which the use of medicines is a significant component in the Public Sector.	Clear procedures for donors supporting programs in which the use of medicines is a component	Harmonisation between donor funded and national programs	NMTC CSNs Donors EMA	x	x	x	x	x	☐☐☐☐☐ Clear procedure in place and used for donors supporting programs in which the use of medicines is a component
Treatment Guidelines and the EML	59	Disseminate immediately and nationwide new editions of STGs and addendums and/or errata to STGs and/or EML as they become available. *(Addenda or errata may be circulated between new editions of STGs and EML). (See also # 140).*	New editions, Addendums and/or errata to STGs and/or EML	Contents of the EML harmonized with STGs and any changes circulated promptly	FPBSC NMTC EMA	x	x	x	x	x	☐☐☐☐☐ A report on new editions and extent of harmonization of the EML with STG and circulation of information

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Selection *Treatment Guidelines and the EML (continued)*	60	Conduct trainings to address targets identified in the above evaluation and to assist understanding throughout the sector.	Trainings developed	Improvement in understanding of cost benefits	NMTC CSN MIU/ EMA Training institutions	x	x	x	x	x	□□□□□ Training to address targets developed and implemented

5. Procurement of medicines and medical supplies

Refers to ensuring the necessary quality and quantity of medicines to meet the health needs of the Fiji population, at the lowest possible cost in a timely manner.

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Procurement ***Medicines and medical supplies for the public sector***	61	Review current guidelines and strengthen guidelines and procedures for all aspects of the procurement cycle Develop and strengthen a comprehensive procedures Manual for all aspect at procurement cycle in conjunction with the PR 2010.	Specific guidelines and procedures for procurement produced by a competent team	Increased efficiencies in public sector procurement	FPBSC Procurement PU	x	x	x	x	x	☐☐☐☐☐ Monitoring and evaluation of procurement
	62	Include pharmacist trained person in Customer Service to evaluate and advise on orders from facilities and provide information concerning any changes in treatment or distribution policies,	Pharmacy trained person in Customer Service	Appropriate and efficient medicines dispatch and enhanced relationship with facilities	Warehouse FPBS	x	x	x	x	x	☐☐☐☐☐ Monitoring and evaluation of procurement
	63	***As a priority,*** review the current allocation system for distribution of supplies with an aim to capture the actual demand associated with appropriate use of the right medicines	Result of review	Knowledge of current situation and challenges	FPBS Warehouse staff LMU	x	x	x	x	x	☐☐☐☐☐ Report complete
Forecasting & Quantification of needs *Refers to the determination of quantities to be procured or ordered and the reconciliation of the needs & quantities with available funds*	64	Review requisition process from Health Facilities	Review of the outcomes of 2009 training program with a view to building on it to roll out appropriate training in maintenance of reliable medical supplies.	Appropriate training taking place	FPBSC EMA Division Health facilities	x	x	x	x	x	☐☐☐☐☐ Training to develop appropriate system for maintenance of reliable medical supplies in place NO MORE STOCKOUTS
	65	Develop appropriate order forms and matching tally sheets for each level of facility including only stock authorized for that level. Extra lines can be available for special needs eg STGs. *(Pilot forms and tally sheets were prepared at trainings in Suva & Lautoka 2009 – see above- build on those)* *(See also Domain 7 Distribution # 102)*	Appropriate order forms and tally sheets prepared	Facilitate quantification and ordering from warehouse	FPBSC EMA Health Facilities	x	x	x	x	x	☐☐☐☐☐ Appropriate forms for system for maintenance of reliable medical supplies in place NO MORE STOCKOUTS
	66	*(See above)* Increase the level of hands-on support/ supervision with focus to assist facilities to improve staff capacity to undertake accurate estimation of needs based on accurate record keeping of stock prescribed/dispensed/used appropriately. Increase appropriate training in terms of medical nursing Increase in human resources will be needed*(see Domain 3. Human Resources).*	Schedules for hands-on support supervision visits with focus on supporting facilities to improve quantification skills	Proficiency to undertake accurate quantification of pharmaceutical needs by staff at all levels of the supply system	FPBSC LMU	x	x	x	x	x	☐☐☐☐☐ Training and supervisory reports

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Procurement *Forecasting and quantification of needs (continued)*	67	Provide support to ensure records of appropriate use leading to consumption data, together with stock out days, are used to generate accurate forecasts/quantification of medicines. (*See also #91)*	Accurate appropriate consumption data and stock out days used to adjust average monthly consumption rates	Accurate quantification based on consumption method according to appropriate use	FPBSC LMU	x	x	x	x	x	☐☐☐☐☐ Training and supervisory report
Use of correct data for forecasting and quantification for national procurement	68	Use the data generated from the above processes for national forecasting and quantification for procurement	Data generated by appropriate consumption records used for national procurement	Rational procurement and reliable supplies of medicines in Fiji. No more stockouts	PU IT FPBSC	x	x	x	x	x	☐☐☐☐☐ Rational forecasting and quantification system in place for procurement
	69	Identify/explore appropriate software system to integrate Directorate Health Information and Research Analysis (DHIRA) system with FPBS procurement unit information to facilitate evaluation of whether medicines supplies are meeting health needs. *(See also Domain 12 M&E)*	Integrated DHIRA and procurement medical supplies database	Facilitated assessment of whether medical supplies match health needs	DHIRA Warehouse IT	x	x	x	x	x	☐☐☐☐☐ Integrated system planned for development
	70	Where computerized systems do not exist, discuss ways to strengthen the manual systems, such as SOPs, to assist the generation of accurate data to be used separately for the quantification of essential medicines. *(Review materials prepared for training in 2009)*	Existing manual medicine inventory database providing at all lower levels, a module for quantification of medicines	Accurate manual quantification of medicines	Logistic Management Unit	x	x	x	x	x	☐☐☐☐☐ Accurate quantification report generated directly from manual systems
Evaluation of efficiency	71	Develop a system for evaluating efficiency of procurement and supply chain management *(See also Domain 12 M&E)*	Information system about supply chain management	Targets can be identified and addressed	LMU EMA	x	x	x	x	x	☐☐☐☐☐ Information system for M&E supply chain management

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Procurement ***Cost effective procurement*** ***Choosing procurement methods, locating and appointing suppliers, contracting, monitoring of order delivery and***	72	Review and recommend new cost effective methods of procurement.	Reviewed procurement methods associated with cost	Cost-effective procurement assured	MoF – FPO MoH – FPBS WHO International Procurement Agencies	x	x	x	x	x	☐☐☐☐☐ Review undertaken and results addressed
	73	Review and update the guideline for the prequalification of suppliers. Develop/find a software system that matches the FPBSC specifications for evaluating suppliers to facilitate data entry and decision making. Explore mSupply for appropriate software.	A list of prequalified suppliers, with option for review every 3 years	Shortened tendering process. Contracts awarded to prequalified, performing, reliable suppliers	MoH – FPBS Suppliers Technical Agencies MoF - FPO	x	x	x	x	x	☐☐☐☐☐ Tender contracts are obtained from a list of prequalified suppliers

supplier performance	74	Continue cross-country and Regional comparative price information-sharing (DIEFPIC). Regional Price Information Exchange at www.piemed.cominformation provides information on medicines prices among countries in the Region and on price trends. *(See Also Domain 11 Technical cooperation with other countries, international agencies& other stake-holders.*	Update of the Regional Price Information Exchange to the WHO website, and DIEFPIC library	Regional Price Information available	FBPS WHO MIU	**x**	**x**	**x**	**x**	**x**	□□□□□ Regional Price Information Exchanged
Human Resources For Procurement	75	Review the current procurement human resources with a view to developing a specific appropriate Procurement Cadre *(See also Domain 3, Human Resources, Combine with # 80 below)*	Results of review and recommendations	Appropriately trained and resourced procurement cadre	FPBSC FPO PSC Tertiary Academic Institutions	**x**	**x**	**x**	**x**	**x**	□□□□□ Regional Price Information Exchanged
	76	Conduct a Training Needs Assessment (TNA) related to strengthening staff capacity in all needed areas in the procurement section to identify key functions and pharmacists training needs *(Combine with # 79 above)*	Results of TNA	Knowledge to inform what is needed to improve staff capacity for all aspects of procurement	MoH-FPBSC/DHR PSC MSPS – HR Unit	**x**	**x**	**x**	**x**	**x**	□□□□□ TNA Report
	77	Develop and implement training plans based on the above needs assessment for the procurement section (number, skills, career opportunities) in the short-, medium-, and long term to improve staff capacity (pharmacists and other pharmacy staff)*(see also #97)*	Training Plans and programs	Adequate trained and skilled staff in place, to implement all aspects of procurement	MoH-FPBSC/DHR PSC – HR Unit	**x**	**x**	**x**	**x**	**x**	□□□□□ Status reports on the implementation of training plan & programs
Purchase of medicines by private, NGO and faith-based organisations	78	Develop a guide, and ensure, through regular investigation visits, that all private importers are licensed, have customs permits, and only procuring products registered in Fiji. Develop penalties for non-compliance. *(see also #s 26, 27)*	Schedules of regular inspection of private importers and customs point. Penalties for importing unregistered products clearly outlined and disseminated	Only quality products registered for use in Fiji imported by the private sectors. Contraventions penalised	FPBSC MRU MRA FRCA	**x**	**x**	**x**	**x**	**x**	□□□□□ Inspection reports

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Procurement ***Medicines and medical supplies donations***	79	Disseminate to all relevant stakeholders (including the customs and foreign missions) *Fiji Medicines Donation Guidelines* for donation of medicines in the public, private and NGO sectors and conduct education sessions so that any pharmaceutical donations comply with the national guidelines approved by the MoH.	Fiji Donation Guidelines disseminated and understood	Pharmaceutical donations comply with national standards and guidelines	LMU Donors MoH MRA	**x**	**x**	**x**	**x**	**x**	□□□□□ Compliance with approved Donation Guidelines
Donations of medicines and supplies for focused or disease based programs	80	Develop and disseminate a procedure to ensure that supplies for donor funded disease focused programs are integrated with supplies procured by the FPBSC. Explore opportunity for pooled procurement Involving faith base organization for distribution of	Mechanisms for integrating special supplies with nationally procured supplies	Special programs supplies integrated with national supplies	FPBSC donors	**x**	**x**	**x**	**x**	**x**	□□□□□ Supplies from all sources integrated

		medicinal products. *(See also Domain 11, Technical Cooperation with other countries, international agencies and other stake-holders)*									
	81	Ensure that supplies provided by donors for donor funded disease based programs are not delivered directly to any health facilities. Management must remain at central level and all supplies must be integrated	Procedure for donation of focused program medical supplies to be integrated centrally	National and donors medical supplies integrated and managed centrally. Reporting to donors only from central level.	FPBSC PU Donors	**x**	**x**	**x**	**x**	**x**	☐☐☐☐☐ Management and reporting concerning all supplies from all sources integrated
Medicines procurement in emergency situations	82	Develop and circulate clear procedures for the procurement of medical and supplies by other agencies in emergency situations in collaboration with the NDMO. (*See also Customs Section #29)*	Clear procedures for procuring medicines in emergency situations.	Emergency procurement will be facilitated	FPBSC NMTC NDMO FPO	**X**	**X**	**X**	**X**	**X**	☐☐☐☐☐ Emergency procedure in place
Procurement by private wholesalers	83	Develop guideline and ensure, through regular Investigation visits, that all private importers are licensed and only procuring products registered in Fiji and by generic nomenclature according to the guideline. Develop penalties for non-compliance. *(See also #26-28).*	Guidelines and schedules of regular investigation of private wholesalers. Penalties for importing unregistered products clearly outlined and disseminated	Only quality products registered for use in Fiji wholesaled by the private sector. Contraventions punished.	MRU MPB	**x**	**x**	**x**	**x**	**x**	☐☐☐☐☐ Guidelines in place and investigation reports

6. Medicines storage and inventory control

Refers to ensuring the maintenance of quality and security of medicines in storage throughout the public, private, NGOs and faith based organizations from the time of receipt into stock until the time of issue to the patient.

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Medicines Storage *Storage facilities*	84	Conduct a Needs Assessment related to strengthening storage facilities at all levels to identify needs for upgrading or expanding facilities to comply with best practices for storage conditions (temperature, humidity, security, air conditioning, lighting, floor and ceilings, drainage systems, etc)	Results of needs assessment	Knowledge to inform what is needed to improve storage capacity at all levels	FPBSC/ Warehouse AMU / LMU PPO for all hospitals/ health facilities	x	x	x	x	x	□□□□□ Needs assessment Report
	85	On the basis of the needs assessment seek funding (government or donor) to improve the storage conditions at Warehouses (all stores), including peripheral stores and health facility stores (referral and health centres) to comply with best practices for storage conditions (temperature, humidity, security, air conditioning, lighting, floor and ceilings, drainage systems, etc) Donors must comply with MoH specifications for construction	Costed plans for Improving storage facilities where needed and funding sources identified	Medicines and related products at all level of the supply system stored appropriately	FPBSC/ Warehouse AMU/LMU EMA	x	x	x	x	x	□□□□□ Reports on (improved) storage conditions for medicines and related products at all level of the supply system
Record keeping and stock management at all levels	86	Identify a suitable Medical Storage and Maintenance Guideline with Checklist for immediate use. In the longer term develop Fiji context guidelines for all levels (standardize in terms of storing – FPBS/Divisional/Health centres/Nursing stations	Guidelines for good storage, stock care and management,	Best practice storage, stock care and management	FPBSC Warehouse EMA	x	x	x	x	x	□□□□□ Storage and stock management guidelines available and being used
	87	Maintain and update training modules, train staff and increase support / supervision to encourage good stock management with emphasis on record keeping. Conduct training as needed. *(Ref also#71)*	Stock management training modules, Trained staff on modules, Supervision schedules and appointed supervision staff.	Better stock management and record keeping. Enhanced morale and performance, especially at peripheral facilities, due to on-the-job contact	FPBSC/ Warehouse Supervisor LMU GMU ? Procurement PPO	x	x	x	x	x	□□□□□ Training modules prepared and staff trained. Supervision /support/ happening
Inventory control	88	Develop and circulate policies on regular stock counts	Reports of physical stock checks and reconciliation by all facilities submitted to FPBSC on regular basis according to agreed schedules	Physical stock checks & reconciliation of records undertaken & reported to central level by all facilities regularly based on agreed schedules	FPBSC/ Warehouse Supervisor LMU Procurement PPO	x	x	x	x	x	□□□□□ Reports of regular physical stock checks and reconciliations by all facilities

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Medicines Storage *Inventory control (continued)*	89	Develop an inventory control manual that can be used as a supervisory check list. Supervisory visits/Checklist/Time	Inventory control manual	Assurance that inventory control is accurate	FPBSC Warehouse Procurement PPO	x	x	x	x	x	□□□□□ Inventory control manual in place and being used
Disposal of expired and unwanted pharmaceutics	90	Develop and disseminate comprehensive guidelines for minimisation of waste and the safe disposal of unusable and unserviceable pharmaceutical products and hospital waste. Link with Department of the Environment Establish public awareness campaign to promote good medicine disposal (Advertise – Safe disposable of medicine awareness) Suggest that communities bring unused medical products back to the hospitals or pharmacies from where they will be disposed of appropriately.	Approved and disseminated Guidelines for the disposal of unusable and unserviceable pharmaceutical waste products	Timely and safe disposal of unwanted pharmaceutical waste	FPBSC Dept of Environment Acting Chief Health Inspector (MoH) MLO Infection Control CCF	x	x	x	x	x	□□□□□ Approved, disseminated and utilized Guidelines for the disposal of unusable and unserviceable pharmaceutical waste products

7. Distribution of Medicines

Refers to ensuring the prompt, safe and efficient distribution of medicines to authorised end-users throughout the public, private, NGO and faith based organizations, so that the quality of the products is maintained throughout the process and medicines are available when needed.

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Distribution of Medicines ***Distribution in the public sector***	91	Assess and prioritise infrastructure needed to improve the overall distribution performance of the FPBSC Warehouse	Report of assessment	Good warehouse management and distribution practices	Warehouse, FPBSC	x	x	x	x	x	□□□□□ Report of assessment
	92	Develop and enforce guidelines /training to address gaps detected above and for ensuring compliance with Good Distribution Practices (GDP). Include guidelines for distribution during cyclones and other disasters.	Approved Good Distribution Practice guidelines	Good Distribution Practices at all times	FPBSC Warehouse	x	x	x	x	x	□□□□□ Guidelines developed and enforced Verification
Appropriate transport, logistics, stock management and storage	93	Conduct a Needs Assessment related to strengthening distribution practices at all levels to identify needs for upgrading equipment to comply with best practices for storage conditions during transit (temperature, humidity, security, etc	Results of needs assessment	Knowledge to inform what is needed to improve distribution systems at all levels	FPBSC/ LMU AMU	x	x	x	x	x	□□□□□ Needs assessment Report
	94	On the basis of the needs assessment improve distribution practices including to peripheral stores and health facility stores (referral and health centres) to comply with best practices for distribution (temperature, humidity, security, air conditioning, etc)	Improved distribution practices where needed and funding sources identified	Medicines and related products at all level of the supply system transported appropriately. Timely delivery/receiving of medicine stocks at facility level	FPBSC/ Warehouse AMU LMU	x	x	x	x	x	□□□□□ Reports on (improved) distribution conditions for medicines and related products at all level of the supply system
	95	Develop Distribution Manual and ensure it includes ▪ Good transportation planning is needed for islands and remote areas so that stocks reach centres/users in time. ▪ Allocation of fuel for distribution e.g. boat fuel ▪ Need for regular in-house training on stock management ▪ Relocation of storage rooms at the health facilities Short expiry /near-expiry medicines must not be distributed to islands and remote areas health facilities	Distribution Manual	Best practice Distribution	FPBSC LMU EMA	x	x	x	x	x	□□□□□ Manual prepared
	96	Establish Distribution Performance indicators for 2-way monitoring of practice at user facilities/hospitals/warehouses for the whole system	Indicators to monitoring the performance cycle of the Warehouse agreed upon	The performance of the Warehouse monitored regularly and timely remedial measures taken as needed	FPBSC/ Warehouse	x	x	x	x	x	□□□□□ Reports of performance of the Warehouse as measured by agreed indicators

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Distribution ***Appropriate transport, logistics, stock management and storage (continued)***	97	Through appropriate training,strengthen LMU role to review and confirm the rationale for order quantities. Report on incidents to Chief Pharmacist	Training undertaken and Rational orders placed with the Warehouse	Orders are placed based on actual and confirmed needs	FPBSC Warehouse LMU, EMA User facilities	x	x	x	x	x	☐☐☐☐☐ Report on ordering habits of user facilities
	98	Develop and implement a regular schedule of visits by LMU to facilities to strengthen understanding of requisition procedures Review and update schedule of visits as needed.*(see also Domain 5, Procurement # 69)*	Regular coordinated communication between LMU and facilities	Improved understanding of procedures and availability of supplies at user facility	FPBSC/ Warehouse, User facilities	x	x	x	x	x	☐☐☐☐☐ Communication visits happening
Subpopulations with special therapeutic needs	99	Identify sub-populations with special needs and in collaboration with CSNs develop guidelines to ensure their access according to national policies, to the medicines they need. Approval and endorsement for the policy and guidelines is required from the NMTC.	Policy detailing sub-populations with special needs and mechanisms to ensure their access to their needed medicines	Sub-populations with special needs having access to needed medicines	FPBSC NMTC	X	X	X	X	X	☐☐☐☐☐ Policy complete, accepted and circulated
Medicine supply to foreign nationals	100	Ensure that all health personnel in the public system are aware of the policy concerning foreign nationals by providing a circular to health facilities that is clearly described in the NMPP.	Circular to health personnel concerning policy	Awareness of policy	FPBSC	X	X	X	X	X	☐☐☐☐☐ Circular prepared and circulated
	101	Maintain communication with HIV and TB programs who also have guidelines for medicines supply to foreign nationals.	Policies from HIV, TB and other relevant programs	Policy in place for harmonization of all donor funded programs with national programs	FPBSC Special Programs	X	X	X	X	X	☐☐☐☐☐ Circular prepared and circulated

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Distribution ***Quality assurance process for medicines in circulation***	102	Strengthen mechanisms (SOPs) to monitor and evaluate the quality of medicines circulating in the public and private supply system by training staff and providing tools and processes for reporting substandard or suspect counterfeit medicines. Mechanisms are already in place, but there is need for strengthening by identifying loopholes/gaps in implementation.	Training modules and tools	Improved capacity to monitor the quality of medicines in the public and private sectors	FPBSC MRU EMA	x	x	x	x	x	☐☐☐☐☐ Training and M&E reports and additional tools supporting effort to combat substandard and suspect counterfeit medicines
	103	Maintain investigation, sample collection and testing program to ensure adherence to pharmaceutical regulations and to combat counterfeit and substandard medicines in the public and private sectors Mechanisms are already in place, but there is need for strengthening by identifying loopholes/gaps in implementation.	Harmonized investigation schedules	Fiji free of substandard and counterfeit medicines	FPBS MRU IU	x	x	x	x	x	☐☐☐☐☐ Inspection and QC testing reports
	104	Strengthen regulation to provide for harsh penalties to medicines counterfeiters and their distributors Mechanisms are already in place, but there is need for strengthening by identifying loopholes/gaps in implementation.	Regulations amended to provide harsh penalties to counterfeiters and their distributors	Effective deterrence to the contemplation of preparation and distribution of counterfeit medicines	MRA IU MPB	x	x	x	x	x	☐☐☐☐☐ Regulation in place on penalties to medicines counterfeiters and distributors
	105	Develop an incident reporting system that captures all aspects of distribution errors and as well as quality control, together with a system to respond to reports	Incident reporting and response system	Incident reporting and response system in place and operating	FPBSC LMU	x	x	x	x	x	☐☐☐☐☐ Incident Reports and responses
Quality Control Laboratory	106	Develop a university-based laboratory that can be used for basic medical product quality control and as a training institution and facility Mechanisms are already in place, but there is need for strengthening by identifying loopholes/gaps in implementation.	University QC Laboratory	Basic QC facility and training in Fiji	FPBSC FNU	x	x	x	x	x	☐☐☐☐☐ QC training and testing Laboratory in place
International distribution by private wholesalers	107	Develop guideline and ensure, through regular investigation visits, that all private wholesalers wishing to export are licensed and only distributing internationally, products they are licensed to distribute and according to the conditions of their license. Develop penalties for non-compliance.	Guidelines and schedules of regular investigation of private international distributors. Penalties for contravention of license conditions clearly outlined & disseminated	International distribution only according to the conditions of licenses. Contraventions penalised.	MRU MPB	x	x	x	x	x	☐☐☐☐☐ Guidelines and Investigation reports

8. Rational Use of Medicines

Refers to ensuring that medicines are prescribed, dispensed, and used rationally throughout the public, private, NGOs and faith based orgnizations in order to maximise the therapeutic benefit to the patient and reduce loss, wastage and hazards arising from irrational practices, including theft and misappropriation.

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Rational Use of Medicines ***Training***	108	strengthen RUM in collaboration with training institutions and NMTC /CSN decisions	Reviewed and approved Curricula for health workers inservice training that include RUM	RUM included in training	FPBSC/FNU	x	x	x	x	x	□□□□□ Inservice RUM included in curricula
	109	Use Divisional Plus meetings and similar forums to share information about RUM, STGs… with all medical practitioners	Include RUM, STG news etc on Divisional Plus meetings agendas	RUM, STG news etc on Divisional Plus meetings agendas	Divisions NMTC DMTC	x	x	x	x	x	□□□□□ Report on Divisional Plus meetings
	110	Encourage and promote the sharing of information and experiences among countries on successful interventions to promote rational use of medicines. *(See also 11. Technical Cooperation with other countries, International Agencies& other stakeholders)*	Electronic or other information sharing network established	Improved decision making through timely sharing of information on RUM	FPBSC	x	x	x	x	x	□□□□□ Network described above being used to share information
	111	Develop refresher courses on RUM and other suitable continuing education activities that will be maintained in collaboration with other relevant bodies and that can be accredited for CPD. *(See also # 8)*	A range of refresher training courses	Rational use of medicines by health professionals	FPBSC/FNU/ FPS/relevant Professional Bodies	x	x	x	x	x	□□□□□ Appropriate refresher courses developed and implemented
	112	Provide suitable training in counseling that will be maintained for health workers so they can help patients understand the use of their medicines as well as appropriate care and storage of medicines to avoid deterioration and waste. This training can be linked to other training on Good Pharmacy Practice - in particular good dispensing procedures (*See also # 47, 128/29)*	Medicines Counseling training modules	Improved patients understanding and compliance with prescribed medicines and their proper storage	FPBSC	x	x	x	x	x	□□□□□ Survey report on medicines understanding and use by patients

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Rational Use of Medicines ***Prescribing***	113	Review the scope of staff prescribing responsibilities as determined by authorization to prescribe at different levels of health facilities; and authorization to prescribe in specific areas such as HIV treatment. Inform staff and universities of approved prescribing authorisation.	Documentation of scope of staff prescribing responsibilities at different health service levels and for specific conditions	Scope of prescribing responsibilities defined	FPBSC/ Dept Hosp Services, Universities	x	x	x	x	x	□□□□□ Circulation to relevant parties of scope of prescribing responsibilities
	114	Conduct awareness activities for prescribers in all sectors, public, private, and NGOs, visiting specialists, so they are familiar with the STGs and EML and the list of medicines determined for the level of prescriber and according to the directions of the Ministry of Health. Authorized personal should prescribe according to STG	Education and awareness activities	All health personnel aware of STGs and EML and the medicines specified for use at their particular level of service	PPB FMC	x	x	x	x	x	□□□□□ Report on education and awareness campaigns Audit of prescribing
	115	Strengthen policies and Implement mechanisms that encourage generic prescribing in both the public, private and other sectors.	IEC materials and campaigns	Generic prescribing accepted and used (in the public, private and other sectors)	PPBoard NMTC FMC	x	x	x	x	x	□□□□□ Reports on the extent of prescribing by INN/generic in the sector
	116	Monitor and assess prescribing practices in the country and collaborate with other sections of the national MRA to ensure appropriate, efficient, and cost-effective prescribing for all diseases *(See also Monitoring and Evaluation Domain 12)*	Tool for conducting survey on prescribing practices developed	Prescribing practices monitored	FPBSC Hosp/NMTCs	x	x	x	x	x	□□□□□ Survey reports on prescribing practices
	117	Conduct and/or support studies to generate evidence on health and economic impacts of irrational prescribing and on the effectiveness of interventions implemented in the country *(See also Monitoring and Evaluation Domain 12)*	Economic studies	Positive economic impacts of interventions are influential in gaining further support	FPBSC NMTC (Appropriate body contracted by FPBSC)	x	x	x	x	x	□□□□□ Studies undertaken
	118	Review legislation to ensure that legislation prohibits channeling of prescriptions from all prescribers to specific Pharmacies (which stock specific products) and provides penalties for contravention.	Clear law to prohibit prescribers channeling prescriptions to specific pharmacies	Business links between Private prescribers and dispensers prohibited. Penalties imposed	PPB	x	x	x	x	x	□□□□□ Clear law and penalties for contraventions
	119	By issuing a circular and following up with investigation, ensure Doctors prescribe rationally and according to STGs and not according to what is available in the local pharmacy	Circulars to Doctors re appropriate prescribing plus investigation	Appropriate prescribing	MIU NMTC FCGP	x	x	x	x	x	□□□□□ Circulars and reports of investigations/audits
	120	Develop mechanism to notice anomalies in prescribing – report to NMTC and consider audit	Routine mechanisms Periodic audits	Prescribing errors / anomalies noticed and addressed	Hospital pharmacists Facility staff	x	x	x	x	x	□□□□□ Mechanisms in place and being used

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Rational Use of Medicines ***Dispensing***	121	Develop or strengthen dispensing practice code including appropriate counseling, as part of Good Pharmacy Practice (GPP) and make use mandatory. *(See also # 47)*	Dispensing Practice Code Guidelines Assurance that STG is available in all therapeutic areas	Good dispensing and counseling practices both in the private and public sectors STG for all therapeutic areas	FPBSC NMTC CSN FNU	x	x	x	x	x	□□□□□ Survey report on GPP
	122	Include Good Dispensing Procedures and Practices in the training curricula for all ***other*** categories of staff who are authorized to dispense to ensure that medicines are will be dispensed efficiently and correctly throughout the public sector. Encourage the same principles in the private and NGO sectors. *(See also Human Resources Domain 3. See also # 47,48)*	Comprehensive dispensing modules routine part of training curricula for relevant health staff. Curriculum and continuing education (Include an orientation program)	Good dispensing practices by all categories of health staff	FPBSC Training institutions	x	x	x	x	x	□□□□□ Reviewed and revised training curricula as needed
	123	Ensure through regular investigation of premises, where dispensing operations are performed, that the provisions of the law in relation to the dispensing practices are being satisfied in all respects	Schedule of investigation visits to ensure compliance to Good Dispensing Practices	Compliance with Good Dispensing Practices nationwide	FPBSC/ MRA CCF MoH Commerce Commission	x	x	x	x	x	□□□□□ Investigation report highlighting dispensing practices
	124	Ensure facilities for counselling for special cases in privacy – eg special space to share medication information - by addition to guidelines for pharmacy practice concerning special counseling space.*(See also Human Resources Domain 3. # 47)*	Privacy space allocated in dispensing area	Private confidential counselling available	FPS Pharmacists PPB	x	x	x	x	x	□□□□□ Investigators' report on counseling facilities available and used
	125	Improve Pharmacy practice – enforce ***pharmacists*** in private sector to carry out medication counselling to customers; not assistant. Conduct investigation visits. *(See also Human Resources Domain 3. # 47,48)*	Guideline on counseling produced and disseminated. Investigation visits to pharmacies	Routine counseling by pharmacists	FPS PPB IU	x	x	x	x	x	□□□□□ Investigation Report on sources of information available at health facilities
	126	Collaborate with the Fiji Commerce Commission to support pricing policy for privately dispensed medicines.	Pricing policy developed.	Harmonised dispensed medicines prices for Private pharmacies	FPBSC PPB/FPS Commerce Commission	x	x	x	x	x	□□□□□ Report

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Rational Use of Medicines ***Patient compliance and self-medication***	127	Gradually develop and distribute unbiased and practical information on use of medicines and treatment for the public beginning with priority information such as use of antibiotics, diabetic medication; and other special issues such as self-medication as determined by studies of community needs. In the longer term consider development of a free information line.	Good examples of priority information Direct free line where people can call regarding medicines	Priority areas e.g. antibiotic and diabetic prescribing addressed and improved	FPBSC MIU	x	x	x	x	x	□□□□□ Appropriate IEC materials produced and distributed
	128	Conduct appropriate community based training and/or the use public media to improve understanding about medicines and self-medication	Community focused IEC materials and campaigns and programs	Communities have better understanding about RUM, self medication etc	FPNS MIU MLO MoH CCF	x	x	x	x	x	□□□□□ Appropriate IEC materials, CBIA programs implemented
Adverse medicine reaction (AMR) reporting *(See Medicines Information #8)*	129	Develop an operational PV centre and TORs with the capacity to monitor medicines quality in circulation and AMRs. Review AMR Forms and make them readily available for both private & public sector health professionals and to consumers. Explore integration with Medicines Information Unit. *(see Domain 9, #142 Medicines Information)*	PV centre with TORs	QC of medicines in circulation and reporting of AMRs	FPBSC MIU CCF	x	x	x	x	x	□□□□□ PV centre with TORs AMR forms readily available
	130	Conduct an advocacy meeting with Consumers Council and health professionals and prepare material for circulation with a view to strengthening AMR reporting through the preparation, training and implementation of relevant SOPs and/or guidelines to improve the collection of medicines adverse reactions, medication errors and reports on lack of effectiveness of medicines sector. More reporting has to be done by public & private sectors.	1. Tools for collecting information and trained focus staff 2. Survey to detect common error AMRS that occur	Routine collection of AMRs, medication errors, ineffective medicines reports	FPBSC MIU FCGP FMA FNA FPS CCF	x	x	x	x	x	□□□□□ Meeting held, AMR reporting system strengthened together strengthened AMR reporting. Results of survey
	131	Establish close contacts with national programs (focal points for HIV, TB and others) to obtain related information on quality of medicines, AMRs, adverse events due to a medication itself, inappropriate use of a medicine, including associated medication errors, if any) Vaccines to be included in collaboration with EPI	Contacts established with national programs' focal points	AMRs, medication errors and ineffective medication documented and appropriate actions taken to prevent their recurrence	FPBSC MIU National focal programs EPI	x	x	x	x	x	□□□□□ Reports submitted to MIU by national programs
	132	Enter reported and confirmed AMRs into the global monitoring database maintained by Uppsala Monitoring Centre (UMC)	List of AMR reported to UMC	Global consolidation and analysis of AMR reactions specific to identified medicines	FPBSC MIU	x	x	x	x	x	□□□□□ List of AMR reported to UMC

9. Medicines Information

Refers to ensuring 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.

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Medicines Information ***Medicines Information Unit***	133	Map MIU needs and scope of work and submit to FPBSC for PSC to strengthen the MIU by ensuring the allocation of sufficient appropriate staff and equipment for the services and develop TORs and SOPs for its operation (*see Human Resources Domain 3)*	TORs and SOPs for MIU Submission of map to FPBSC for PSC	Adequately supported MIU with TORs and SOPs	FPBSC MIU CCF	x	x	x	x	x	☐☐☐☐☐ TORS, SOPs and report on activities of MIU result of submission
	134	Develop Central Information Unit plus individual divisional information Units that communicate fully with each other	Appropriately staffed and resourced MIU at Central and Division levels	MIU services at central and divisional levels	MoH MIU FPBS						☐☐☐☐☐ Well resourced MIU operating at central and Divisional levels
	135	Develop a mechanism for providing regular independent, unbiased and accurate information on medicines, cosmetics and medical devices to health professionals and the general public eg a regular newsletter	Mechanism for providing regularly independent, unbiased & accurate information on medicines, cosmetics and medical devices to health professionals and the general public, established eg a regular newsletter	Informed use of medicines by health professions and the general public	MIU	x	x	x	x	x	☐☐☐☐☐ Mechanisms for providing regularly independent, unbiased and accurate information on health products, in place
Medicines Information	136	Ensure, that Fiji Standard Treatment Guidelines, Essential Medicines Lists and other appropriate reference materials are available to health workers. ▪ Conduct surveys /assessment on use of STGs ▪ Conduct advocacy for use by both private and public health professionals MIU work together with FCSP/FPS/EMA – similar medicine information are shared across the FCGP *(See also # 63)*	Relevant Information available to health facilities and use evaluated	RUM through the use of good sources of information and national guidelines	FPBSC MIU	x	x	x	x	x	☐☐☐☐☐ Report on sources of information available at health facilities

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Medicines Information *Medicines Information (continued)*	137	Conduct operational and other research activities and informally collect information and data on medicines utilization and pharmacy practices to identify targets for education in the public and private sectors; or the review of pharmacy practice as necessary. Use as a guide for further education. Collaborate with Pharmacists, consumer councils and journalists to carry out operational surveys; Collaborate with NMTC to discuss and prepare medicine information	Information collection tools, collaborations and plans	Targets identified for strengthening practices and collaborations in place	MIU FPBSC CCF NMTC	x	x	x	x	x	□□□□□ System for collecting, collating and use of information in place
	138	Explore ways to extend function of MIU to become an PV and AMR centre and to include the Private Sector *(see AMR # 133, 148)*	Plans for extending operation to include PV and AMR	PV and AMR will be an integral part of the MIU	MIU FPBSC	X	X	X	X	X	□□□□□ Plans for extending operation to include PV/AMR
Poisons control and poisons information	139	In collaboration with other relevant Ministries including eg agriculture and Industry, review and prepare a list of hazardous substances and products, such as corrosives, pesticides, household chemicals, etc., and establish procedures for their registration and guidelines for handling.	(1) A list of hazardous substances & products; & (2) Procedures for their registration and guidelines for handling	A better control of harmful products	MIU MRA	x	x	x	x	x	□□□□□ (1) A list of hazardous substances & products; & (2) Procedures for their registration and guidelines for handling
Poisoning	140	In collaboration with hospitals and facilities where cases of poisoning are presented, and with the Consumer Council, develop materials to use in communities to discourage/prevent the use of poisons for attempted suicide. Explore the feasibility of establishing a staffed 24 hour hotline for poisons response.	IEC materials developed and disseminated Feasibility of 24 hour poisons hotline explored	Prevention of attempted suicide with poisons. Safe use of poisons for appropriate purposes	MIU A&E in hospitals Specialist physicians	X	X	X	X	X	□□□□□ IEC materials developed and disseminated Feasibility of 24 hour poisons hotline explored

10. Traditional Medicine

Refers to recognising 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.

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Traditional Medicine	141	Collaborate with WHO to establish an appropriate Fiji 'Traditional Medicines Association' (TMA) that will be responsible for the management of traditional and complementary medicines. Contact USP. Identify a group of people to follow up.	Plan for development of a 'Traditional Medicines Association'	Information to inform further action	MRU MIU FPBSC WHO USP	X	X	X	X	X	☐☐☐☐☐ Plans in place
	142	Appropriate group identified above to study, document and develop control procedures for traditional Fijian Medicines	Plan for documentation and control concerning Fijian TMs	Information base about Fijian TM	TMA CCF Health facilities	X	X	X	X	X	☐☐☐☐☐ Plans in place
	143	Develop legislation/regulation to prevent foreign exploitation of traditional Fiji knowledge and practices. Any commercial exploitation must be regulated to maintain knowledge and control in Fiji communities. Intellectual Property Rights to remain owned in Fiji	Regulation to prohibit foreign ownership of Fiji IPR associated with Fiji TMs	IPR of TMs remain in Fiji communities	Patent Law NMPP Attorney General	X	X	X	X	X	☐☐☐☐☐ Legislation n place
	144	Expand AMR system to include TM and CM AMRs in reporting *(see also # 133, 136, 142)*	TM and CM AMR reporting included	Knowledge of AMRs due to TMs and CMs	MIU	X	X	X	X	X	☐☐☐☐☐ TM and CM AMRs included in reporting system

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Traditional Medicine ***Registration/ regulation of TMs***	145	As a preliminary step develop a procedure that requires all imported traditional / complementary medicines to include English language names of ingredients. Attempt to List products	English language names on all imported 'traditional' and complementary medicines. Products listed	Names of ingredients known and listed	MRU	X	X	X	X	X	□□□□□ English language names on products listed
	146	Seek technical assistance to proceed towards registration to control import and availability of TMs and CMs. Include training of personnel and provision of resources	Assistance sought	Ultimate registration of TMs and CMs	MRU WHO	X	X	X	X	X	□□□□□ Assistance sought
	147	Strengthen procedures to control traditional medicines to ensure safety for public use in collaboration with the proposed TMA. Disseminate information widely.*(See also medical products registration# 15-17,18; # 148)*	Registration or control of TMs procedures in place	Traditional medicines will be controlled or used safely For public safety	MRU MIU FPBSC TMA CCF	X	X	X	X	X	□□□□□ appropriate control of traditional medicines and public awareness
	148	Ensure compliance with Treaties to ban import of endangered species parts in medicinal products (CITES - www.cites.org). Develop education materials for the public explaining the truth about use of endangered species parts eg tiger penis, rhino horn, bears paws, shark fin.	Mechanism to detect inclusion of endangered species parts in products	Compliance with CITES treaty and public awareness	WHO CITES MIU CCF	X	X	X	X	X	□□□□□ Compliance with CITES assured Public awareness

11. Technical cooperation with other countries, international agencies and other stake-holders

Refers to actively pursuing all relevant forms of technical cooperation in order to maximize the efficient utilisation of the limited resources available in implementation of the National Medicinal Products Policy.

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Technical cooperation with other countries, international agencies and other stakeholders	149	Continue the process of information-sharing among PICs through annual regional meetings sponsored by WHO to address identified issues in the PIC pharmaceutical sectors. Promote conferences and projects, web-based and email communication, and printed technical materials to enhance ongoing development.	Attendance at regional or international meetings, conferences, web-based and email communication, etc	Gained insight to improve the pharmaceutical sector in Fiji	FPBSC WHO Ministry of Foreign Affairs	x	x	x	x	x	□□□□□ Reports of interactions and developments
	150	Explore collaboration with ASEAN to make use of initiatives developed by ASEAN, if any, that could be helpful for Fiji areas of NMP implementation such as quality control for registration of products and any other areas that might be helpful.(Bench marking and capacity building)	Relationship with ASEAN to facilitate awareness of useful initiatives	Use or adaptation of prepared and tested initiatives	FPBSC MRA Ministry of Foreign Affairs	x	x	x	x	x	□□□□□ Report on communication with ASEAN on NMP implementation
	151	Develop collaboration with regional and other quality control laboratories. (See *WHO List of Prequalified Quality Control Laboratories in DIEFPIC library)* *(See also Registration #15-18; #106-110)*	List of appropriate collaborating regional QC laboratories	Improved QC testing capacity and Assistance for tests beyond national capacity or for validating local tests	FPBSC MRA WHO Other links FNU	x	x	x	x	x	□□□□□ Through WHO/WPRO collaboration and links developed
	152	Collaborate with regional initiatives supported by WHO in surveillance for emerging diseases in order to develop rapid response capacity involving medicines use.(Outbreaks/natural disasters alerts)	Maintained relationship with existing networks	Knowledge shared leads to rapid response involving medicines when needed.	FPBSC NMTC WHO SPC NDMO	x	x	x	x	x	□□□□□ Established links with WHO and relevant bodies
	153	Participate and contribute to programs that seek to ensure the quality, safety and effectiveness of medicines through either market surveillance, sampling and testing programs or any other interregional and internationally programs for combating medicine resistance, substandard and counterfeit medicines. Interpol/WPRO WHO	Participation in programs for ensuring the quality of medicines	Only quality assured, safe and effective medicines available in Fiji market	FPBSC MRA International initiatives WHO	x	x	x	x	x	□□□□□ Market surveillance reports highlighting the prevalence of substandard and counterfeit medicines in the market

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Technical cooperation with other countries, international agencies and other stakeholders	154	Use cross-country and Regional comparative information-sharing about pharmacy-related issues and prices. (i) The Medicine Information Exchange for Pacific Island Countries (DIEFPIC) supported by WHO is a model) (ii) Regional Price Information Exchange at www.piemed.cominformation provides on medicines prices among countries in the Region and on price trends.*(Refer also to Domain 5 Procurement)*	Extended network for discussing any pharmacy related matters including supplier performance and price tends - etc	Knowledge shared beneficially in the pharmaceutical sector. *(Opportunity for pool procurement Involving faith base organization for distribution of medicinal products)*	FPBSC WHO Donors	x	x	x	x	x	☐☐☐☐☐ Report or records indicating that such information exchange/sharing is happening
	155	Develop procedures such as meetings and national workshops for integrating donor programs with national programs and their management to ensure the best outcomes from support by donors for national programs at central level to avoid duplication of programs and confusion at 'lower' levels Develop SOP/Guideline for integration Strengthen existing SOP/Guideline	Meetings/workshops. SOPs/guidelines for assistance by external donors to Fiji national programs and initiatives.	Integrated assistance to Fiji National programs and initiatives	FPBSC MOH Donors	x	x	x	x	x	☐☐☐☐☐ Proceedings of meetings/workshops Donor adherence to procedures for integration wit national programs and initiatives
	156	Continue to explore avenues for Fiji to assist other PICs in areas where Fiji has significant experience and for other PICs to share successful initiatives. This is already happening through DIEFPIC.	Areas of potential sharing defined and shared	Beneficial experience sharing	FPBSC PICs MoH(Technical expertise)	x	x	x	x	x	☐☐☐☐☐ Areas of potential help defined
	157	Collaborate with the Western Pacific Pharmaceutical Forum to explore initiatives that could be beneficially implemented in Fiji.	FPS Contact with the WPF	Knowledge to inform actions	FPBS WHO	X	X	X	X	X	☐☐☐☐☐ Contact established
Regional Procurement and bulk purchasing	158	Continue to explore the possibility of regional procurement and bulk purchasing and document pros and cons of possible ventures Develop trial for certain medicines – Suggest MOU draft More dialogue between ministries	Reports of exploration of regional procurement and bulk purchasing initiatives	Knowledge to inform actions	FPBSC MoH	X	X	X	X	X	☐☐☐☐☐ Reports of exploration of regional procurement and bulk purchasing initiatives

12. Monitoring and Evaluation

Refers to ensuring 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.

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification/year
						1	2	3	4	5	
Monitoring and Evaluation	159	Conduct a evaluation workshop to review and document the progress of the implementation of this Pharmaceutical Sector Strategic Plan (2013-2018) by 2016 evaluating progress made in achieving the suggested Indicators/Means of Verifications. Review prioritization.	Evaluation workshop held and decisions to speed up implementation rate, prioritize activities or modify some activities reached	Improved implementation of the sector strategy	FPBSC and relevant authorities	x	x	x	x	x	☐☐☐☐☐ Workshop reports (Prioritisation reviewed)
	160	Undertake periodical evaluation of all aspects of the national pharmaceutical situation – and advise on their frequency – to review activities undertaken; and measure the impact of interventions on access, quality and rational use of essential medicines against indicators.	Model for assessment and analyses of results developed for periodic use in all settings	Gaps identified for further interventions	FPBSC and relevant authorities	x	x	x	x	x	☐☐☐☐☐ Assessment report on national pharmaceutical situation
	161	Use verification/indicators for each activity to assess progress in implementation and develop key Policy Domain indicators to monitor progress to measure achievements of the objectives of the NMPP. *(See also # 54)*	Indicator/verification for each activity used and Policy Domain indicators developed	Broader assessment of progress in Plan implementation	FPBSC MRA	x	x	x	x	x	☐☐☐☐☐ Assessment report on activity and Policy Domain progress