

KINGDOM OF CAMBODIA

Nation-Religion-King

Pharmaceutical Sector

Strategic Plan

2013-2018

Department of Drugs and Food

Ministry of Health

Final Draft October 2012

DRAFT

Table of Contents

Acknowledgements.....	5
Abbreviations.....	6
Foreword DRAFT.....	8
Mission Statement of the Ministry of Health, Kingdom of Cambodia.....	9
Values of the Ministry of Health.....	9
Working Principles of the Ministry of Health.....	9
Policy Statement 2013 - 2018.....	10
Executive Summary.....	12
Pharmaceutical sector situation analysis.....	13
Context.....	14
Strengths and issues in the pharmaceutical sector.....	15
Strengths.....	15
Issues.....	16
Key Issues.....	18
Key issues for priority attention during 2013-2018.....	20
Overall expected outcomes.....	20
Introduction to Annex 1 (PSSP 2015-2018).....	21

Annex 1. Pharmaceutical Sector Strategic Plan of Action 2013 – 2018 for implementation of Medicines Policy 2010

Annex 2. Strengths and Issues associated with the Implementation Plan

Annex 3. DDF Organogram

Annex 4. Cross-cutting strategic areas of the HSP 2008-2015

DRAFT

Acknowledgements

The second strategic plan of the pharmaceutical sector is a significant achievement for Cambodia. 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 Department of Drugs and Food, Ministry of Health, 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 Cambodian pharmaceutical services.

Phnom Penh 2012

Abbreviations

ACT	Artemisinin Combination Therapy
ACTD	ASEAN Common Technical Dossier
ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
AIDS	Acquired Immune Deficiency Syndrome
ASEAN	Association of South East Asian Nations
BCC	Behaviour Change Communications
BHEF	Bureau of Health Economics and Financing (MoH/DPHI)
CBIA	Community Based Interactive Approach
CMDG	Cambodian Millennium Development Goals
CMS	Central Medical Store
CTMO	Cambodian Traditional Medicines Organisation
DDF	Department of Drugs and Food
DPHI	Department of Planning & Health Information (MoH)
DTC	Drugs and Therapeutics Committee
DTCA	Direct to Consumer Advertising
EDB	Essential Drugs Bureau
EML	Essential Medicines List
FEFO	'First Expired First Out'
FP	Faculty of Pharmacy (University of Health Sciences)
GDP	Good Distribution Practices
GF	Global Fund
GMP	Good Manufacturing Practice
GPP	Good Pharmaceutical Practice
HIV	Human Immunodeficiency Virus
HosDID	Hospital Drug Inventory Database, at hospital store level
HR	Human Resources
HRD	Human Resources Development
HSP2	The Second Health Strategic Plan
HSS	Health Systems Strengthening
IEC	Information, Education, Communication
IMCI	Integrated Management of Childhood Illness
INCB	International Narcotics Control Board
IPR	Intellectual Property Rights
ISO/IEC 17025	International Organization for Standardisation/International Electrochemical Commission

M&E	Monitoring and Evaluation
MEF	Ministry of Economy & Finance
MLMIS	Medicines Logistics Management Information System
MoH	Ministry of Health
MRA	Medicines Regulatory Authority
MTP	Monitoring, Training, Planning
NatDID	National Drug Inventory Database (located at the CMS)
NEC	National Exam Committee
nEML Committee	National Essential Medicines List Committee
NGO	Non Government Organisation
NHQC	National Health Products Quality Control Centre
NIPH	National Institute of Public Health
NSDP	National Strategic Development Plan
OD	Operational District
ODDID store level	Operational District Inventory Database, at the Operational District
PAC	Pharmacists Association of Cambodia
PEAC	Prequalification, Evaluation and Awarding Committee
PPU	Public Procurement Unit (of the MEF)
ProDID	Provincial Drug Inventory Database, at the provincial level
PSSP	Pharmaceutical Sector Strategic Plan (PSSP)
PU	Procurement Unit (of the MoH)
PV	Pharmacovigilance
RACHA	Reproductive and Child Health Alliance
RUM	Rational Use of Medicines
SSF	Single Stream of Funding
SOP	Standard Operating Procedures
SR	Sub Recipient
STG	Standard Treatment Guidelines
STI	Sexually Transmitted Infections
SWiM	Sector Wide Management
TB	Tuberculosis
TM	Traditional Medicine
TNA	Technical Needs Assessment
TOR	Terms of Reference
TRIPS	Trade Related Aspects of Intellectual Property Rights
UMC	Uppsala Monitoring Centre
WHO	World Health Organisation

Foreword DRAFT

The first national Pharmaceutical Sector Strategic Plan provided direction to the development of the pharmaceutical sector (public and private) and to donors interested in supporting the sector development in Cambodia for period 2005-2010. This second Strategic Plan is intended to compliment the National Health Sector Strategic Plan 2010-2015 (HSP2) and further provide direction to the development of the sector and to donors interested in supporting this sector for the period 2013-2018. The Planning process, for the preparation of this strategy, was led by the Department of Drugs and Food (DDF) with participation from Central Medical Store (CMS), National programs, Faculty of Pharmacy, the National Health Products Quality Control Centre (NHQC) and other sector institutions. 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 Cambodia, especially the poor and those living in remote rural areas, whose first source of modern medical advice and treatment is usually the drug seller. Evidence suggests that the people of this country are spending a large proportion of their household income on health care without gaining significant change in their health status. Most of this spending is on medicines purchased from pharmacies or other category of medicines outlets

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

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, 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.

Mission Statement of the Ministry of Health, Kingdom of Cambodia

The Ministry of Health's mission, as expressed in the National Health Sector Strategic Plan, is 'a commitment to ensure sector wide, equitable and quality health care for all the people of Cambodia through targeting resources, especially to the poor and to areas in greatest need.' The Ministry of Health's mission, values, working principles and its national health policy set the broad context for the Pharmaceutical Sector Strategic Plan.

Values of the Ministry of Health

- Right to health
- Equity
- Pro-poor

Working Principles of the Ministry of Health

- Social protection for vulnerable groups
- Listening to what people want
- Affordability and sustainability
- Focus on rural areas and the poor
- Capacity building including human resource development
- Sector wide management
- High quality evidence based interventions
- Good governance and accountability

Policy Statement 2013 - 2018

The policy statement is based on the national health policy which can be found in the 'Health Strategic Plan 2008-2015' (HSP2).

1. Reinforce pharmaceutical legislation, professional ethics and code of conduct, and strengthen regulatory mechanisms, including for the production and distribution of pharmaceuticals, drug quality control, cosmetics, food safety and hygiene, to protect providers and consumers' rights and their health.
2. Strengthen and invest in health information systems and health research for evidence-based policy-making, planning, monitoring performance and evaluation.
3. Strengthen sector-wide governance focusing on increased national ownership and accountability to improved health outcomes, harmonization and alignment, greater coordination and effective partnerships among all stakeholders.
4. Increase investment in physical infrastructures and medical care equipment and advanced technology, as well as in improvement of non-medical support services including management, maintenance, blood safety, and supply systems for drugs and commodities.
5. Improve quality in service delivery and management through establishment of and compliance with the national protocols, clinical practice guidelines and quality standards, in particular establishment of accreditation systems.
6. Increase competency and skills of health workforce to deal with increased demand for accountability and high quality care, including through strengthening allied technical skills and advanced technology through increased quality practice of training, career development, right incentives, and good working environment.
7. Make services more responsive and closer to the public through implementation of a decentralized service delivery function and a management function guided by the national policy.
8. Encourage community engagement in health service delivery activities, management of health facilities and continuous quality improvement.
9. Promote effective public and private partnerships in service provision based on policy, regulation, legislations and technical standards.
10. Systematically strengthen institutions at all levels of the health system to implement policy.

DRAFT

Executive Summary

This second Pharmaceutical Sector Strategic Plan (PSSP-2) for the period 2013 – 2018 is an implementation strategy for the revised Medicines Policy (2010).

The second Health Strategic Plan was developed by the Ministry of Health for the period 2008-2015 (HSP) and the Medicines Policy (2010) is one of the tools that contribute towards achieving goals of the HSP2.

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 Medicines Policy (2010) and include short- medium- and long-term strategies and plans to be implemented in the next 5 years. It builds on the first Pharmaceutical Sector Strategic Plan (2005 – 2010) and has two parts. Like its predecessor, the first part sets the context for the plan: the mission, values, and working principles. It identifies the current strengths and weaknesses in the pharmaceutical sector and key issues to be addressed, the goals and strategies for priority attention during 2013-2018 and the expected outcomes of development activities to be implemented in the sector within that time frame. The second section provides an implementation plan.

The **building blocks** of the HSP2 Strategic Plan cover three main program areas: Reproductive, Maternal, Newborn and Child Health; Communicable Diseases; Non Communicable Diseases and other health problems. HSP2 uses five cross-cutting health strategies: health service delivery, health care financing, human resource for health, health information system, and health system governance.

This PSSP-2, 2013 – 2018 is arranged according to the logical flow of the pharmaceutical supply system but addresses the key five cross-cutting strategic areas of the HSP 2008-2015, which are described in Annex 1.

Pharmaceutical sector situation analysis

The situation analysis summarizes the key structures, roles and functions of the pharmaceutical sector, the context, and identifies strengths and issues to be addressed.

The Department of Drugs and Food (DDF) organogram is Annex 3.

The DDF is the regulatory authority under the Directorate General for Health. It is authorized to ensure the safety and quality of drugs, medical devices, general medical items, cosmetics and food. The goal of the DDF is a strengthened pharmaceutical sector that will become an integral part of health sector development. Part of this goal will be improved health of Cambodian people by alleviating poverty and developing the socio-economic climate. The DDF is also responsible for educating the pharmaceutical industry on how to improve their quality assurance obligations during drug manufacturing among other responsibilities listed below.

Each Provincial Health Department has a Bureau of Drugs and Food. Operational Districts, Referral Hospitals, and Health Centers have pharmacists or staff responsible for the distribution, storage, dispensing and quality of drugs.

The DDF has five Bureaus, each with responsibility for specific Sections or Units:

- **Drug Regulation Bureau responsible for:** Administration, Regulation, Inspection and Advertising;
- **Registration Bureau responsible for:** Manufacturer Registration, Pharmaceutical Product Registration, including Traditional Medicines and Health Supplements; supporting product registration and Medical Devices and Reagent Registration and Notification of Cosmetics;
- **Pharmaceutical Trade Bureau responsible for:** Import/Export of Drugs and Cosmetics, Raw Materials, Chemical Substances; Import/Export and Control of Narcotics, Psychotropic Drugs; and Opening/Closing Drug Companies, Cosmetics Companies and Centre of Cosmetics; Monitoring Training on Narcotics, Psychotropics, and Cosmetics in Provinces;
- **Food Safety responsible for:** Food Regulation, Food Inspection and Consumer Protection
- **Essential Drugs Bureau responsible for:** Supervision Unit, Planning Coordination, Supply Unit, Information, Rational Drug Use Unit and Pharmacovigilance Unit.

Examples of other key institutions in the pharmaceutical sector are:

- **The National Health Products Quality Control Centre (NHQC)** - Responsible for drug analysis and technical advice on suspect pharmaceuticals.
- **The Central Medical Store (CMS)** - Responsible for receiving, storing and distributing drug supplies to public sector.
- **The Procurement Unit** - A unit within the Ministry of Health responsible for pharmaceutical procurement for the public sector.
- **University of Health Sciences - Faculty of Pharmacy** - Responsible for the education of pharmacists.

The health services also include:

- National programs including disease based programs like malaria, HIV, TB programs
- NGO programs
- Private sector: A large number of pharmaceutical retail outlets and some private pharmaceutical companies.

Context

Years of internal strife had a major impact on the pharmaceutical sector in Cambodia. During the Khmer Rouge years, the country lost most of its pharmacists and pharmacies. Prior to this, pharmaceutical laws and regulations are reported to have been well enforced, when only over-the-counter drugs could be bought without a prescription.

Since the period of civil unrest, a more open market has been introduced. Most drugs can now be bought over-the-counter and most people choose to buy drugs directly from pharmacies or drug stores rather than going to a doctor.

Cambodia is well on course to meet most of its health related Millennium Development Goals (CMDG) and National Strategic Development Plan (NSDP) indicators. The only exceptions are malaria and nutrition.

Health indicators still show a high disease burden from infectious diseases such as malaria, TB, HIV and AIDS. Infant and child mortality and morbidity from acute respiratory infections, diarrhoeal disease, dengue fever and malaria is still too high but work in these programs is producing positive results. Resistance to traditional anti-malarial drugs has occurred. There has also been an increase in the number of antiretroviral drugs coming onto the market to treat HIV positive patients as a result of the Global Fund support. Resistance to these drugs may happen if effective controls are not well established.

Poor quality pharmaceuticals increase the burden of poverty in Cambodia. The amount spent on health is very high with little improvement in health conditions.

In 2010, a substantial share of resources (71%) was allocated to the central level. Out of these resources, 9.11% were allocated to programs, while 90.99% were distributed across expenditure line-items (MoH-DPHI 2010). Non-programmed budget lines included medicines (72%), equipment procurement (20%), salaries (6%) and maintenance (1.2%). In future, these resources could be reallocated to service delivery programs. Regarding the resources distributed to provinces in 2011, 50% went to salaries, 20% went to equipment, 7% went to medicines and 14% went to maintenance (MoH-DPHI-BHEF 2011).

Strengths and issues in the pharmaceutical sector¹

Strengths

The national medicines regulatory authority includes sections (commonly referred to as Bureaus) 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, together with a Bureau for Food Safety.

To ensure and maintain standards for public safety in the pharmaceutical sector, many building blocks have been established.

A drug evaluation system is in place for pre-marketing evaluation, marketing authorization and post-marketing surveillance. The system includes a fast-track registration process as well as a computerized Registration System (which is yet to be fully utilized). Nearly 10,000 medicinal products are currently registered, in line with strict quality control procedures based on ASEAN Common Technical Dossier (ACTD) for the registration of pharmaceutical products. Only products from registered manufacturers are considered for registration.

Revised Drug Law (2007), sub-decrees, ministerial orders and notices (Prakas), are in place, to implement the drug legislation.

The MoH has developed an essential drug list. Six editions have been prepared since 1995 and the 7th Edition will be published 2013. Monitoring, training and planning programs on rational drug use are being implemented in close collaboration with the Department of Hospital Services. The program requires strengthening.

Distribution of medicines is centralized in the CMS. The CMS has a computerized inventory control system which captures all aspects of inventory management, including relevant reports from all levels of the supply and distribution system. The computerized system is referred to as National Drug Inventory Database, at the CMS or central level (NatDID), Provincial Drug Inventory Database, at the provincial level (ProDID), Operational District Inventory Database, at the Operation District (OD) store level (ODDID), and Hospital Drug Inventory Database, at hospital store level (HosDID). The Department of Drugs and Food, in addition to conducting regular supervision visits, uses the computerized system to monitor drug supplies and use at all levels.

An improvement in the pharmaceutical supply system to public health facilities has been reported in previous years. For example, donor funded projects have supported the development and/or revision of several drug management standard operating procedures and guidelines; and staff have been trained on their use to improve the supply, distribution and management of essential medicines. Also, donors have supported the establishment and initial operations of a Pharmacovigilance (PV) Unit since 2008. Scale up of PV Units to national, referral, provincial and district hospitals, is on-going.

By the end of the year 2011, nearly 2000 staff (baseline 1 in 2006) at the central and facilities level have been trained on the quantification of medicines; and accordingly nearly 70% (baseline 49% - 2008) of health facilities have sufficient capacity to undertake accurate quantification of medicines needed in their facilities. Capacity for sampling and testing at the CMS is currently at 47% (targeted at acceptable standard of 20%) of all the batches received. Ninety two percent of the batches tested passed quality control testing. The testing is done from a WHO prequalified laboratory. Stock out of medicines, as measured by a basket of 15 tracer items, at health facility level was estimated at less than 5% by end of 2011 (Annual Report GF HSS SSF SR-DDF 2011).

An Inter-Ministerial Committee on Combating Counterfeit and Substandard medicines has existed since 2005. The Committee guides the fight against counterfeit and substandard medicines and illegal health services.

¹ See Annex 2 for a more detailed tabulation of Strengths and Issues associated with the Implementation Plan

Overall the prevalence of counterfeit and substandard medicines significantly declined to around 3% (in 2009) from 13% according to WHO (in 2002). The MoH claims lower figures of 0.18% in 2011. The overall decline is mainly attributed to several actions being implemented in the sector to combat counterfeit and substandard medicines. Some of these activities include Operations Jupiter and Storm 1 & 2 - projects which have resulted in a strong collaboration between the national drug regulatory authority (drug inspectors) and law enforcement agencies (the police, customs and the judicial). Other interventions include the on-going post-marketing surveillance – sampling and testing programs together with programs for raising awareness of health care professionals and the general public on the dangers of fake medicines through IEC campaigns. These campaigns include TV and radio spots, calendars, T-shirts, and posters; and workshops, targeting manufacturers, wholesalers, retailers, and health care professionals, to discuss issues of counterfeit and substandard medicines.

As of June 2012, the Pharmacovigilance Unit has followed over 2,000 patients prescribed Artemisinin based Combination Therapy (ACT) to document long-term side effects and Adverse Drug Reactions (ADR) of the approved first line ACTs in Cambodia; and over 1,700 drug outlets have been inspected to enforce various government bans and to ensure adherence to the pharmaceutical laws. Sampling and testing of ACTs in the private sector showed that there were no fake ACTs in the market (PV Unit Annual Report March 2012).

A technical Forecasting and Quantification Committee that operated in previous years can be revived and strengthened. A system of collecting pharmaceutical usage data is in place. Some national programs, like malaria, TB and HIV and AIDS programs, are involved in making sure there are good practice guidelines and an adequate supply of quality drugs so treatments are readily available. 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.

Cambodia has several local manufacturing companies with potential good capacity and the National Health Products Quality Control Centre has had a complete review including laboratory buildings, equipment and human resource capacity. Expanded, upgraded facilities as needed to ISO/IEC 17025, together with maintenance plans with donor assistance, should be operating by 2014.

Issues

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

Some articles of the drug law (Royal Kram), Sub-decree, ministerial orders or notices (Prakas), and guidelines, need to be strengthened or publicized more widely. 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. There are insufficient appropriately trained pharmaceutical workers in the public and private sectors to follow national policy and procedures and achieve desired quality of work.

According to the Mid Term Review of the HSP2, low salaries have led to dual practice, where Public sector health workers engage in private practice. Government will have limited leverage power if salaries are not dramatically increased.

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

Production techniques of local manufacturers are not up to an acceptable ASEAN Good Manufacturing Practice (GMP). Existing Cambodian GMP guidelines for the production of pharmaceutical products need to be strengthened. Government standards for establishing quality premises, systems and products, or to prosecute the drug manufacturers are limited.

The adoption of an official Cambodian Code of Good Manufacturing Practice would mean all manufacturers will know what standards all of their products have to reach in order to receive registration from the MoH. Trained DDF auditors would then conduct audit checks of all local pharmaceutical manufacturers to make sure their manufacturing licenses comply with acceptable GMP and product licensing standards. Drug

Inspectors were trained on GMP in 2009 and they are undertaking inspection of manufacturing sites regularly. Also a GMP training for local drug manufacturers was conducted in the same year. Cambodian GMP standards are available but not fully implemented.

There is a Cambodian Traditional Medicines Policy which aims at the integration of the use of traditional medicines into the Primary Health Care system. Under this policy, commercially produced traditional medicines need to be registered. They need to satisfy the same GMP and other quality requirements as modern medicines. About 50 commercially produced traditional medicines from other countries are registered. However, to date none of the known Cambodia traditional medicines are registered. A better understanding between the NHQC and the Traditional Medicines manufacturers should be developed.

Drug shortages in the public health system still happen. Quantification is one of the most difficult aspects of the supply chain and ongoing assistance and support will be needed to help estimate the quantities of drugs needed for appropriate use according to clinical guidelines and be able to order those drugs in a timely manner. Communication between drug distribution centers in the public sector, and service delivery points, requires strengthening to reduce stock-outs, unexpected delivery and potential storage problems. Monitoring and supervision in provincial health departments and operational districts need to be strengthened so that national standards can be met.

The Procurement Unit in the Ministry of Health could be assisted with the implementation of their own Procurement Guidelines.

The CMS inventory control system needs review. Efficient communication between stake-holders, but above all with procurement and service delivery counterparts, is needed partly because of extra demands from donor funded programs but also because there is insufficient understanding of relevance of accurate stock records. Improved inventory control would result in less wastage of products and funds. Disposal of pharmaceutical waste needs special facilities that are not available in Cambodia.

Medicines storage conditions at all levels need improvement. Performance indicators and adherence to SOPs would enhance operations at the CMS.

There is poor drug prescription in Cambodia. Current prescribing practices include poly-pharmacy and inappropriate use of intravenous infusions, injections and antibiotics. Irrational drug use results in ineffective treatments, an increase in the risk of drug resistance and the cost of health care. Limited family incomes are wasted. Development and dissemination of clinical guidelines, together with education about their use will improve prescribing in Cambodia. The importance of the use of generic products needs better understanding.

Most drugs in Cambodia are purchased over the counter. In the private sector, ways need to be explored on how to improve the use of high volume potent drugs, especially antibiotics. Physicians and drug sellers in the private sector need to be educated to use clinical guidelines. Classification of potentially toxic pharmaceutical substances exists but there needs to be more awareness of restrictions on their distribution and use; and the regulations regarding their availability need to be enforced.

Drugs are 'prescribed' by a number of different health workers: doctors, nurses, midwives and pharmacists. Some of these health professionals do not yet have the knowledge of clinical guidelines or rational drug use. Training, and monitoring or supervision of practice needs to be introduced and maintained. Many drugstore owners are motivated by profit and satisfying their customer at the expense of good practice.

Some doctors (in private clinics) dispense and sell medicines from their own supplies. This practice is not legal and the laws regarding separation of roles of prescribing and dispensing need to be enforced.

There is poor patient compliance with prescription instructions and there are many traditional beliefs and practices that influence consumers' behaviour. Cambodia has a relatively high illiteracy rate. Many people cannot read or understand the labels on 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.

Many people believe injections are more effective than tablets. People often use drugs prescribed for somebody else, and are more concerned about the color of a tablet than its therapeutic value. Some family

members in rural and remote areas have poor access to health services, so self-prescribing is common. Pharmacies and drug sellers may be their only source of modern health treatments. International experiences in introducing strategies to improve drug use need to be assessed in a Cambodian context.

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.

Counterfeit drugs: Although the problem with counterfeit drugs in the country has decreased significantly, vigilance is still important. Regulations and surveillance procedures for counterfeit drugs are in place with responsibilities of all relevant government agencies identified to maximize intra and inter-ministerial coordination. The MoH, with the support of the judicial ministries, can prosecute people involved in drug counterfeiting, but the MoH lacks adequate support from law enforcement agencies. Penalties to counterfeiters are significantly low.

Overall there are few monitoring and evaluation mechanisms in place.

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

Key Issues

The first Pharmaceutical Sector Strategic Plan identified seven key issues for priority attention during 2005-2010 and these issues remain important today. We still need to:

- strengthen drug policies, laws and regulations
- strengthen planning, management and discipline within the pharmaceutical sector
- overcome the inconsistent quality of drugs and unacceptable prevalence of counterfeit drugs
- overcome the shortages of pharmaceuticals in the public sector
- reduce irrational use of pharmaceuticals
- increase financial resources and technical assistance in order to focus on priority weaknesses in the pharmaceutical sector
- increase awareness for improved education and training of the pharmaceutical workforce.

The current Strategy will address these key issues to further ensure:

- An effective legal and regulatory framework in the pharmaceutical sector to encourage sustainable private and public partnerships and practice in pharmaceutical service delivery
- A more efficient and effective health system with quality management and service provision in the pharmaceutical sector guided by strong laws and regulations to strengthen planning, management and discipline within the pharmaceutical sector
- A strong regulatory and registration system to overcome any inconsistent quality of drugs and prevent entry of counterfeit drugs
- A strong procurement and supply system to ensure reliable supply of pharmaceuticals in the public sector which are safe, effective and of good quality
- Quality prescribing, dispensing and rational use of medicines
- Adequate sustainable skilled human resources with improved education and training to enhance the pharmaceutical sector
- Increased access to essential medicines and medical devices especially for the poor

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 drug laws and regulations which reflect selection, registration, quality management and control requirements for all drugs 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 Medicines Policy. 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 drugs and medical devices registration system operating promptly and efficiently to ensure quality of products and protect the health of the public in collaboration with the National Health Products Quality Control Centre
- Strengthened procurement, storage, management and distribution of essential supplies nationwide
- Improved prescribing and dispensing of appropriate drugs
- Strengthened management, surveillance, monitoring and follow-up to maintain medicines safety

The second part of the plan sets out a detailed implementation plan. It provides strategic actions, priority ranking for resource allocation and a timeframe of implementation for each strategic activity. This plan will guide sector institutions so they may develop appropriate activities within their annual action plans and in the 5-year rolling plans.

Key issues for priority attention during 2013-2018

There is need for strengthened drug 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 them with appropriate salaries and incentives
- improve availability of pharmaceuticals in the public and the private sector
- eradicate substandard and counterfeit medicines and accordingly improve the safety, quality and effectiveness of medicines available for use in the country
- strengthen programs aimed at improving the rational use of medicines
- lobby for increased financial resources and technical assistance to focus on priority weaknesses in the pharmaceutical sector
- provide quality management and services in all areas in order to increase affordable access to essential medicines, especially in the poor 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 Cambodia, 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, especially for the poor
- 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 (Annex 1).

Introduction to Annex 1.

This second Pharmaceutical Sector Strategic Plan identifies key issues for development, strategies to strengthen access to quality essential medicines in the public and private sectors, and improvement in the use of those medicines in line with the Medicines Policy 2010.

It compliments the Health-Strategic Plan 2008-2015 (HSP) by offering recommendations to all those in the pharmaceutical sector. It will help focus, coordinate and monitor all government and donor funds toward achieving the best possible outcomes for the period 2013-2018.

The supporting 5-year rolling plans will provide further detail of what can be achieved during each year. These plans will recommend related activities to improve human and financial resources and technical support. The plans provide the timing requirements, means of verification of activities undertaken, monitoring and evaluation criteria and reporting mechanisms.

The Department of Drugs and Food management team will prioritise activities and monitor and evaluate the strategic plan and annual operational plans, including a midterm review in 2015. This team is an integral part of the Ministry of Health's monitoring and evaluation framework.

**Annex 1. PHARMACEUTICAL SECTOR STRATEGIC PLAN OF
ACTION 2013 – 2018**

for implementation of Medicines Policy 2010

DRAFT

PHARMACEUTICAL SECTOR STRATEGIC PLAN OF ACTION 2013 – 2018 for implementation of Medicines Policy 2010

1. 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 weaknesses and threats in the sector through the articulation of feasible and doable 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 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.

2. Legal Framework

Refers to existence of impeccable Laws, Sub-Decrees and Ministerial Declarations (Prakas) to guide regulate and control players, operations and activities in the pharmaceutical sector

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification
						1	2	3	4	5	
2. Legal Framework 2.1 Legislation and Regulation	1	Examine, identify and act on areas and causes of inadequate enforcement of the existing legislation	A comprehensive list of areas of the existing legislation where enforcement of the law is inadequate	Compliance with Laws, Sub-Decrees and Ministerial Declarations (Prakas) & guidelines by majority of players in the sector	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inspections and prosecutions reports. Reduction in the number of incidences of violation of the drug Laws, Sub-Decrees & Ministerial Declarations/Prakas & guidelines
	2	Without exceptions enforce the existing law, its regulations and guidelines to the fullest extent possible by increasing inspection visits across the sector and prosecution for misconducts by	Increased adherence to the law in the sector Increased inspection visits and prosecution as appropriate	More pharmaceutical sector players complying with laws	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Increased inspection visits and reports and prosecution as appropriate
2.1.1 Legislation	3	Initiate the process to review the existing drug law and its Sub-Decrees and Ministerial Declarations (Prakas) to identify inadequate areas and seek to amend them accordingly	Inadequate areas of the pharmaceutical legislation identified	Updated pharmaceutical legislation	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Revised & updated pharmaceutical legislation
<i>Legislation relating to the practice of pharmacy</i>	4	Publicise to health professionals and the general public, the laws and licensing conditions that prohibit the sale or dispensing of prescription only medicines by pharmacists without valid medical doctors prescription in the private sector. Outline and disseminate steps and actions to be taken towards achieving this policy by setting deadline date.	Workshops and publicity campaigns to explain law regarding responsibilities of pharmacists dispensing prescription only medicines and a step by step process to achieve compliance	Understanding about unlawful dispensing of prescription only medicines by pharmacists and its cessation by a set deadline	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inspection shows ceased dispensing of prescription only medicines by pharmacists by the set deadline

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification
						1	2	3	4	5	
<i>Legislation relating to the practice of pharmacy (cont)</i>	5	Enforce the law to prevent the sale and dispensing of prescription only medicines without valid prescription by pharmacists, by increasing unannounced inspection visits to detect and report sale of such products.	Unannounced visits by Inspectors with relevant SOPs and checklist for monitoring pharmacies	Pharmacists are not selling or dispensing prescription only medicines without valid prescriptions	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports of inspection visits
	6	Prevent the sale and illegal dispensing of medicines by medical doctors and other prescribers through unannounced inspection visits to private health facilities	Unannounced visits by medical inspectors and drug inspectors with relevant SOPs and checklist for monitoring private health facilities	Medical doctors and other prescribers are not selling or dispensing medicines	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports of inspection visits
	7	Publicize to health professionals and the general public, the laws and licensing conditions that prohibit the sale or dispensing of medicines by medical doctors or other prescribers in the private sector. Outline and disseminate steps and actions to be taken towards achieving this policy by setting deadline date.	Workshops and publicity campaigns to explain the law regarding the illegality of doctors dispensing of medicines and a step by step process to achieve result	Understanding about unlawful doctors dispensing of medicines and that it will cease by a set deadline	DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inspection shows ceased dispensing of medicines by doctors by the set deadline
	8	Prepare a program and conduct workshops to raise public and private sector players' awareness of the pharmaceutical legislation	Workshops conducted to raise awareness	Improved awareness of legislation and positive behavior changes in the sector	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Workshop reports
	9	Prepare relevant IEC/BCC materials to raise awareness of the pharmaceutical legislation	IEC and BCC material to raise awareness and behavior changes	Better understanding and compliance with laws.	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> IEC and BCC materials
2.1.2 Intellectual Property Rights related to Pharmaceuticals	10	Encourage the National Intellectual Property Committee to continue examining 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	DDF Trade and Registration Bureaus National IPR Committee	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports on examination of treaties etc
	11	Maintain current collaboration between Ministry of Health, the Ministries of Commerce, Foreign Affairs and International Cooperation, Justice and other relevant agencies to develop a legal framework to allow compulsory licensing, parallel importation, Government Use and any other TRIPS flexibilities.	A strong collaboration resulting in sound legal framework to allow compulsory licensing and all other TRIPS flexibilities	Advantages of TRIPS flexibilities available	DDF Trade and Registration Bureaus National IPR Committee	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> TRIPS compliant health friendly legislation in place

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification
						1	2	3	4	5	
2.2 Medicines Regulatory Authority 2.2.1 Medicines Registration	12	Increase trained staff with skills to expedite medicines dossier evaluation (for evidence based medicines registration based on ACTD standards) and improve equipment and facilities	More staff available and with appropriate equipment, & 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	DDF Drug Registration Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Sufficient staff trained; and faster dossier evaluation
	13	Develop procedure for registration of medical devices, Traditional Medicines and health supplements, based on ASEAN harmonized standards. (See also 13. Technical cooperation with other countries and international agencies #129)	Procedure for registration of medical devices, Traditional Medicines and health supplements, based on ASEAN harmonized standards.	Registration of medical devices, Traditional Medicines and health supplements, based on ASEAN harmonized standards.	DDF Drug Registration Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Registration system in place and operating
	14	Develop clear guidelines and a form for an appeal procedure, in case an applicant wishes to appeal against denial of registration of their product	Appeal procedure developed	A clear procedure to deal with appeals is known by most applicants	DDF Drug Registration Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Approved procedure for appeals in place
	15	Optimize the use of the computerized registration system to ensure that most updated registered products are reflected in the system	Up-to-date computerized drug registration system with all registered products in the system	Assurance that computer reflects up-to-date registration information	DDF Drug Registration Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports of all registered products generated from the computerized registration software
	16	Make the list of registered products public	List of registered products and publicly available	List of registered products easily available on request from MoH or the DDF website	DDF Drug Registration Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> List of registered products available on request from MoH or on the DDF website
	17	In collaboration with other relevant Ministries, 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	DDF Drug Registration Bureau	x	x	x	x	x	<input type="checkbox"/> (1) A list of hazardous substances & products; & (2) Procedures for their registration and guidelines for handling

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification
						1	2	3	4	5	
2.2.1 Medicines Registration (cont)	18	Ensure, by enforcing without exceptions, the relevant provision of the legislation requiring that all companies, organisations & NGOs involved in importing medicines for use in Cambodia have appropriate licenses for the medicines they import. Companies exporting must also have relevant licenses.	A list of credible and law-abiding import and export companies and NGOs operating in the country.	Only credible and law-abiding import and export companies and NGOs operating in the country.	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> A list of licensed, credible and law-abiding import & export companies & NGOs operating in the country
	19	Increase the number of monitoring visits to licensed individuals and premises to ensure compliance with license conditions and to remove licenses if necessary	Increase visits by drug inspectors equipped with relevant SOPs and checklists	Monitoring capacity and licenses removed if appropriate	DDF Regulation Bureau	X	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report on drug inspectors visit & action taken when necessary
	20	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 Cambodian Law	SOP and Checklist in place to conform with INCB protocols and National laws	Import/management in line with INCB & National Law	Trade Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> SOP and Checklist in place and being used
2.2.3 Pharmacy Council of Cambodia	21	Proceed with the development of the Pharmacy Council and TORs. Develop and document criteria for membership and structure. Individuals with appropriate legal, financial and administrative expertise should be included along with respected professional pharmacists, elected or appointed.	TORs and criteria for membership	Fully fledged PC and operating	PC/DDF/UHS-FP/NEC	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Fully fledged PC and operating
	22	Expand the role of the Pharmacy Council to carry out the (a) registration of pharmacists; (b) standards for continuing education as a condition for continued registration; and (c) control of pharmacists' conduct (consider the need for technical assistance)	Agreement on the registration and continued education of pharmacists and control of their conduct by the PC	PC registers pharmacists, manages standards for CE and controls pharmacists' conduct	PC/DDF/UHS-FP/NEC	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> PC manages the registration, CE and control of pharmacists
	23	Encourage Pharmacist Association of Cambodia (PAC) and other relevant organizations to prepare suitable CE activities that comply with PC accreditation standards for CE eg annual point system (consider the need for technical assistance)	Providers of suitable CE activities	Maintenance of pharmacist registration, continuing education and competency standards by the PC	PC/DDF/UHS-FP/NEC	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Accredited CE activities available and used to re-register pharmacists

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator / Verification
						1	2	3	4	5	
2.2.4 Schedules of medicinal products and restrictions on distribution and use	24	Review the list of medicines available in Cambodia and their allocation to Schedules – General sale, OTC, Pharmacist only, Prescription only, other special category control (eg narcotic) and ensure they are allocated appropriately for current best practice	Reviewed approved list/schedules of – General sale medicines, OTCs, Pharmacist only, Prescription only medicines, and other special category controlled medicines (eg narcotics)	Clear categories for better management of pharmaceutical substances and conditions for their sale and distribution	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Approved schedules of medicines by their level of restriction for sale and distribution
	25	Publicize the schedules widely (through eg workshops, radio/TV, leaflets, etc.) to health professionals (and to the public so they will be aware there are restrictions on sale and use of medicinal products.)	Approved Schedules Published and disseminated	General awareness on the schedules of medicines by their level of restriction for sale and distribution	Trade Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Approved Schedules published and disseminated
	26	Issue licenses based on qualification of the seller or the distributor and the permitted category of schedules.	Licenses issued based on qualification of the seller or the distributor and the permitted category of schedules	Seller and/or distributors only operating according to their qualification and permitted categories	DDF Regulation Bureau/ Trade Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Internal audit reports
	27	Ensure, through inspections, that all individuals/premises that have licenses operate within their mandate to sell drugs based on license conditions stipulated in their licenses	Inspection and inspectors reports	Seller and/or distributors only operating according to their qualification and permitted categories	DDF Regulation Bureau/ Trade Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inspection reports
	28	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	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Penalties for contraventions in place and operational
<i>Narcotic control</i>	29	Regularly disseminate the requirements on the import and management of narcotics and psychotropic substances in line with the INCB in the public and private sectors	Protocols for all stages of management of narcotics and psychotropic substances in the public and private sector	Appropriate management of narcotics and psychotropic substances in the public and private sectors	Trade Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inspection reports on imports and management of narcotics

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicators or verification
						1	2	3	4	5	
2.3 regulatory Affairs, Quality Assurance and Licensing	30	Identify needs for increased staffing, resources and other support. Formulate actions needed to respond to the needs of DDF and initiate procedures to achieve the necessary results.	Documented recommendations for DDF staffing levels and categories; and other resources needed	Appropriate staff allocated to satisfy the needs of the department and undertake the necessary tasks and resources assured	DDF Director Office	x	x				<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Adequate staff and resources for the tasks being undertaken
	31	Develop code of ethics for all DDF staff including procedure for declaring conflict of interests, relationships between staff, manufacturers or distributors; and applicants for various licenses issued by the MoH/DDF	Code of Ethics	Conflict avoided from pressure from distributors, license applicants etc.	DDF Director Office	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Code of Ethics developed, understood and used
<i>Cambodian Manufacturers meet registration requirements</i>	32	Seek international technical support to assist local manufacturers to adhere to Cambodian Good Manufacturing Practice	Technical Assistance identified and provided	Manufacturers operate in accordance with GMP standards	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inspection reports of manufacturers
<i>Customs Authority responsibility</i>	33	Continue to support Customs authority to undertake their role in checking consignments' compliance with import licensing requirements, including providing regular training to update on recent changes, if needed.	Customs Officials regularly supported by Drug Inspectors	Confidence in the role of Customs Authorities	DDF Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports of support provided to Customs Officials
2.3.1 National Health Product Quality Control Laboratory (NHQC)	34	Implement the existing roadmap to attain ISO/IEC 17025 certification or WHO prequalification	ISO/IEC 17025 certification or WHO prequalification obtained	Improved capacity for health products testing based on acceptable International standards	NHQC/DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> ISO/IEC 17025 certification or WHO prequalification
	35	Continue to improve HR capacity through on the job and overseas training, as well as invited consultants as needed	Training plan	Improved HR capacity for the health product analysis	NHQC/DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Training plan and records of implementation
	36	Seek the relevant approvals for the use of testing fees to supplement staff salaries to motivate staff	Part of testing fees approved for use to supplement staff salary	Well supported staff	NHQC/DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Records of fees paid to staff to supplement their salaries
		Develop collaboration with regional and other quality control laboratories. <i>(See also 13. Technical Cooperation with other countries and international agencies, # 142)</i>	List of appropriate collaborating regional QC laboratories	Improved QC testing capacity and Assistance can be sought for tests beyond NHQC capacity or for validating local tests	NHQC	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Through WHO/WPRO collaboration and links developed

3. Human Resources											
Human Resources refers to maintenance of an appropriate number of adequately trained and supported personnel to meet the needs of all components of the sector											
Policy Domain/Area	#	Activity	Outputs	Outcomes	Responsible	Year					Indicators/ Verification
						1	2	3	4	5	
3. Human Resources <i>1. Expansion and maintenance of human resources</i>	38	Conduct a Training Needs Assessment (TNA) related to strengthening staff capacity in the sector to identify key functions (in all areas pharmacy) and pharmacists training needs (in both in the private and public) (See activities # 42/43 for TNA for other pharmacy staff, the two should be separated)	Results of TNA	Knowledge to inform what is needed to improve staff capacity	MoH-HRD/ Personnel Department	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> TNA Report
	39	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-HRD/ Personnel Department	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Status reports on the implementation of training plan and programs
	40	Strengthen competency based curriculum at all institutions of higher learning through the adaptation of GPP & the Cambodia Pharmacist Competency Standards. Include the concept of Essential Medicines and the role of Standard Treatment Guidelines.	Reviewed Curriculum conforming with GPP & the Cambodia Pharmacist Competency Standards	Appropriately trained Pharmacists available in the sector to perform a range of pharmacy related roles	MoH-HRD/ Personnel Department /Institutes of Higher Learning/ NEC	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Copy of the Reviewed Curriculum
	41	Conduct National Exit Examinations for all graduating pharmacists in accordance to the Cambodia Pharmacist Competency Standards to ensure that candidates are competent for registration as pharmacists	National Exit Examination for pharmacists	Improved quality of pharmaceutical services by competent and registered pharmacists	NEC, FC	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report on Examinations conducted/year and the number of registered pharmacists
	42	Conduct a TNA for other pharmacy staff such as staff in provinces, districts and remote locations (in future no training should be carried out without TNA) (See also 10.3 Dispensing # 106)	Needs identified	A Knowledge to inform what is needed to improve staff capacity	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> TNA Report
	43	Develop and implement training plans and programs based on TNA to impart the necessary skills/competencies for the required tasks (roles and responsibilities) for other pharmacy staff (See also 10.3 Dispensing) # 106)	Training Plans and programs	Adequate trained and skilled staff in place to carry out their duties	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Status reports on the implementation of training plan and programs

Policy Domain/Area	#	Activity	Outputs	Outcomes	Responsible	Year					Indicators/ Verification
						1	2	3	4	5	
1. Expansion and maintenance of human resources (cont)	44	Prepare and implement an SOP that requires staff who have undertaken training eg 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	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports of meeting held to share knowledge gained from training opportunities
	45	Research new ways to strengthen support, supervision, monitoring and evaluation capacity at all levels to ensure efficient and effective management of drugs and medical devices (see also 14. Monitoring & Evaluation # 148)	Ideas submitted to strengthen support and M&E	Quality of work will be enhanced and work satisfaction improved	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> HR Capacity evaluation tools developed
2. Improved career prospects	46	Explore and identify ways to reward staff based on their performance	Ways to reward staff based on their performance identified	A motivated workforce	MoH/HRD Personnel Dept, DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reward system in place and operational
	47	Seek consensus and accordingly recommend salary structures for pharmacy staff (along with other staff as necessary) which conform with Government Salary Reforms Framework – to motivate staff to remain in service and eliminate the need for dual-practice (a second job)	Appropriate Salary Structure approved	Motivated staff remaining in the public sector without the need for second jobs	MoH/HRD Personnel Dept, DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Satisfactory salary structure developed, approved and implemented

4. Financial Resources

Refers to availability of adequate funds to implement strategic action of the policy, including the purchase of the needed medicines and supplies to address health needs of the people adequately.

Policy Domain	#	Activities	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
4. Financial Resources	48	Prepare a detailed itemize budget to cover all aspects of the DDF and pharmaceutical sector functions including HR support and in particular the supply chain management (selection, quantification, procurement, storage, distribution, medicines and other medical supplies use monitoring and supervision)	Budget estimate and justification	A well funded supply and management system	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Approved budget and financial allocation that meets identified needs
	49	Advocate for increased financial resources from government, donors and other health partners to provide adequate quantities of quality essential medicines for the public sector procured cost-efficiently and managed efficiently	Justified submission	Funds will be available if needed	MoH	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Submission for funds

5. Selection											
Refers to the choice of medicines for treatment of the most common conditions in Cambodia, 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					Indicators/ Verification
						1	2	3	4	5	
5. Selection 5.1 Treatment Guidelines and Essential Medicines Lists 5.1.1 National Therapeutic Committee (NTC)	50	Establish a National Therapeutic Committee (NTC) composed of experts in all the medical, pharmaceutical and administrative fields necessary to enable informed decisions to be taken about the use of medicines. The NTC will serve as an Advisory Committee to the MoH on all matters related to the use of medicines such as development of Standard Treatment Guidelines that generate an Essential Medicines List; as well as providing a formal mechanism for interaction with Hospital Drug & Therapeutic Committees. Procedures and criteria for recommending the inclusion or deletion of a product in the STGs and National Essential Medicines List must be included. <i>(Addenda or errata may be used to close the gap between new editions of STGs and nEML).</i> ToR for the Committee must include procedure for declaring and managing any potential or real conflicts of interest for members of the Committee. <i>(Ref: Drug & Therapeutic Committee – A practical guide – WHO/EDM/PAR/2004.1)</i>	NTC established with clear TORs	Improved coordination and oversight of best use of medicines	DHS, DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> EML committee with clear TORs in place
	51	Disseminate immediately and nationwide addendums and/or errata to STGs and/or nEML as they become available.	Addendums and/or errata to STGs and/or nEML	Contents of the nEML harmonized with STGs and any changes circulated promptly	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> A report on the extent of harmonization of the nEML with STG and circulation of information

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicators/ Verification
						1	2	3	4	5	
<i>National Essential Medicines Committee</i>	52	Strengthen the nEML Committee (possibly as a sub-committee to NTC) by developing and implementing clear ToRs (which include procedure for declaring and managing any potential or real conflicts of interest for members of the Committee). The ToRs should specify relationship with the NTC and responsibilities for developing and updating the nEML based on appropriate treatment protocols according to the level of facility type. <i>(Review and strengthen available draft ToR for the nEML)</i>	TORs for EML committee	A well functioning nEML Committee	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> EML committee with clear TORs in place
5.1.2 Standard Treatment Guidelines and the selection of medicines	53	Ensure, through regular communication, close collaboration between the NTC, the nEML Committee and national disease programs to guarantee the harmonization of treatments with national STGs and with products listed in the nEML	Regular communication between Chair of the nEML, Chair NTC and national program	Harmonization between national disease programs and nEML and STG achieved promptly	DDF/EDB, nEML Committee	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Copies of communication between the nEML and other relevant officials
5.2 Use of medicines in expatriate medical teams and vertical programs	54	Develop and publicize a process to ensure that any expatriate team or vertical program wishing to implement a program in which the use of medicines is a significant component must consult the NTC and nEML Committee and must comply with available STGs	Procedure and guidelines on use of medicines by expatriate teams or vertical programs prepared and disseminated as appropriate	Expatriate teams operate in compliance with nSTG and nEML	DDF/EDB, NTC, nEML Committee	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Guidelines prepared and disseminated

6. Procurement and quantification

Involves determination of the products and quantities to procure and the reconciliation the needed medicines with available funds. Procurement also includes choosing appropriate procurement method through acceptable bidding process the appointment of a reliable supplier, setting delivery conditions and signing of contracts, and monitoring order delivery and supplier performance

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicators/ verification
						1	2	3	4	5	
6. Procurement & quantification	55	Organize regular meetings with between the Procurement Unit (PU) and the DDF to obtain technical input in the procurement of medicines	Meetings organized	Improved collaboration between the DDF and PU	PU/DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Meeting Reports
	56	Harmonize donor funded procurements with national procurement, under the mandate of the Prequalification, Evaluation and Awarding Committee (PEAC), through consultation with donors	PEAC oversees the procurement of health products from all sources of funding	Harmonized procurement processes and procedures from all sources of funding	MoH/PU, MEF/PPU	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Existence of single and centralized Tender Board for the procurement of Health Products
	57	Develop separate guidelines and procedures for the procurement of medicines	Separate guidelines and procedures for the procurement of medicines	Increase efficiencies in public sector procurement	MoH/PU, MEF/PPU	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Monitoring and evaluation of procurement
6.1a. Forecasting & Quantification of needs <i>Refers to the determination of quantities to be procured or ordered and the reconciliation of the needs & quantities with available funds</i>	58	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 used appropriately	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	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Survey report indicating > 90% of public health facilities have staff capacity and proficiency to undertake accurate quantification of pharmaceutical needs
	59	Consistently provide oversight to ensure records of appropriate use leading to consumption data and stock out days are captured to generate accurate forecasts/quantification of medicines. For best results, use data from lower levels (user facilities) rather than from the central levels.	Accurate consumption data and stock out days used to adjust average monthly consumption rates	Accurate quantification based on consumption method according to appropriate use	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Supervision plans and tools available to ensure appropriate use & record keeping especially at lower level facilities
	60	Discuss with RACHA ways to strengthen the computerized Medicines Logistics Management Information System (MLMIS) to assist the generation of accurate data to be used separately for the quantification of essential medicines	Existing computerized drug inventory database providing at all levels, a module for the quantification of medicines	Computerized quantification of medicines	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Quantification report generated directly from the computerized system

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicators/ Verification
						1	2	3	4	5	
6.1a. Forecasting & Quantification of needs (cont)	61	Formally re-establish and strengthen the Forecasting and Quantification Committee	Functioning Forecasting & Quantification Committee	Harmonized and shared responsibility for the quality of forecasting & quantification of health products needs	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Functioning Forecasting & Quantification Committee
	62	Establish an internal costing tool for estimating the cost of medicines to be procured. Consider using average price listed in the most recent <i>International Drug Price Indicator Guide</i> (http://erc.msh.org/dmpguide/pdf/DrugPriceGuide_2010_en.pdf) to estimate the price of a quantified product until more accurate data is available.	Internal costing tool established	Medicines of assured quality procured at the lowest possible price	DDF/EDB /PU	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Costing tool in place
6.1 b. Cost effective procurement 6.1 c. Choosing procurement methods, locating and appointing suppliers, contracting, monitoring of order delivery and supplier performance	63	Revise and expand operational guidelines (or SOP) for the PEAC to include membership criteria, functions, powers and authorities of the PEAC; code of conduct of its members and policy on conflict of interest; types of meetings and meeting procedures, including decision making criteria; bids opening and adjudication procedures; a clear point policy for awarding contracts; etc.	Expanded operational guidelines (or SOP) for the PEAC	Improved efficiency of the PEAC	MoH/PU, MEF/PPU	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Expanded operational guidelines (or SOP) for the PEAC in place and being used
	64	Develop and implement a process for the prequalification of suppliers	A list of prequalified suppliers, with option for review every 3 years	Shortened tendering process. Contracts awarded to prequalified and performing and reliable suppliers	MoH/PU, MEF/PPU	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Tender contracts are obtained from a list of prequalified suppliers
	65	Establish a mechanism for an information system to improve planning, monitoring of suppliers' performance (with option for blacklist non-performing suppliers in the future tenders) and a system for evaluating efficiency in procurement and supply chain management	Information systems about suppliers' and their performance	Efficient procurement and supply management system. Only reliable suppliers are awarded contracts	MoH/PU, MEF/PPU	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Information system for M&E of supplier performance
	66	Encourage cross-country and Regional comparative price information-sharing. Regional Price Information Exchange at www.piemed.com information provides information on medicines prices among countries in the Region and on price trends. (See Also 13. Technical cooperation with other countries and international agencies #141)	Regional Price Information Exchanged	Regional Price Information available	MoH PU Donor PU	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Regional Price Information Exchanged

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicators/ Verification
						1	2	3	4	5	
6.1.1 Local production & GMP	67	Organize regular meetings with regulatory authorities and local manufacturers to explain the mechanisms for production of good quality, safe and effective essential medicines, relevant to national needs of the citizens of Cambodia so they can comply with all statutory requirements including Good Manufacturing Practices (GMP) for the manufacture of pharmaceutical products.	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 Cambodian health sector	DDF/ Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Meetings with local manufacturers to explain details of GMP and provide encouragement to achieve GMP standards.
6.1.2 Donations	68	Develop and disseminate to all relevant stakeholders (including the customs and foreign missions) <i>National Medicines Donation Guidelines</i> for donation of medicines in the public, private and NGO sectors so that any pharmaceutical donations comply with the national guidelines approved by the Ministry of Health.	Cambodian Donation Guidelines	Pharmaceutical donations comply to national standards and guidelines	DDF/EDB, CMS	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Approved Donation Guidelines developed
Receiving and Inspection of procured goods	69	Review and implement the SOPs for Inspection & Receiving, expand its use appropriately at peripheral health facilities and also establish a system for regular meetings of the Inspection & Receiving Committee	Mechanism for ensuring regular meetings of the Committee discussed and agreed upon. Revised SOP for Inspection & Receiving at all levels	Regular and coordinated feedback to all parties involved on received commodities at the CMS and Accurate checking & quality assured of products accepted for storage and distribution to users at all levels	DDF/EDB, CMS	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Minutes of meeting of the Inspection & Receiving Committee <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Record on implementation of the revised SOPs for Inspection & Receiving
6.2 Procurement by the private sector	70	Ensure, through regular inspection visits, that all private importers are licensed and only procuring products registered in Cambodia. Develop penalties for non-compliance. <i>(see also Medicines Registration # 18, 19, 20)</i>	Schedules of regular inspection of private importers. Penalties for importing unregistered products clearly outlined and disseminated	Only quality products registered for use in Cambodia imported by the private sector. Contraventions punished.	DDF/ Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inspection reports

7. Storage facilities and systems											
<i>Refers to good storage infrastructure and adhering to good storage conditions and practices, including accurate inventory management, processing of orders for distribution and accurate records</i>											
Policy Domain	#	Activity	Outputs	Outcomes	Responsible	1	2	3	4	5	Indicator/ Verification
7. Storage facilities & systems <i>MLMIS</i>	71	Initiate discussion with the DPHI on the feasibility of integrating the HIS and the MLMIS (including the capture of private sector medicines use) to help reconcile medicines needs, and quantities to be supplied, with disease profiles	MLMIS integrated into (or appropriately linked with or accessible from) the central HIS	Easy of access of disease profiles, patient number, etc linked to medicines use	DDF/EDB, DPHI	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Central HIS linked to MLMIS in place
<i>Storage facilities staffing and conditions</i>	72	Seek funding (government or donor) to further improve the storage conditions at the CMS (all stores), including peripheral stores at operational districts 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)	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	DDF/EDB, CMS	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports on (improved) storage conditions for medicines and related products at all level of the supply system
	73	Recruit adequate staff at CMS (including drivers) and other levels to ensure that necessary duties can be carried out efficiently	Adequate staff for CMS and other level needs	Timely and efficient operations	DDF/CMS	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Improved Staff level at CMS and other levels
7.1 Record keeping and stock management at all levels	74	Update training modules, train staff and increase support / supervision to encourage good stock management including FEFO principles and accurate record keeping for staff at all levels based on RUM. Ensure stock management at peripheral facilities is in line with best practice and that accurate records of use are maintained. Conduct training as needed.	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	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Training modules prepared and staff trained. Supervision /support happening
	75	At all medicines storage stores, set up a mechanism for monthly physical stock checks and the reconciliation of records and actual/physical stock	Reports of physical stock checks and reconciliation by all facilities submitted to central level on regular basis according to agreed schedules	Physical stock checks and reconciliation of records undertaken and reported to central level by all facilities regularly based on agreed schedules	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports of regular physical stock checks and reconciliations by all facilities

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
7.2 Waste management 7.2.1 Waste Minimization	76	Encourage staff understanding about waste minimization through rational procurement and ordering from facilities, adherence to the available stock management guidelines, good prescribing practices based on the Standard Treatment Guidelines and EML, good stock management, prevention of unsolicited donations of pharmaceuticals.	Motivated staff who implement good stock management and waste minimization	Rational Use of Medicines, good record keeping and rational ordering, no unwarranted donations, minimized waste	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Survey/inspection reports
7.2.2 Waste disposal	77	Operationalize and disseminate the guidelines for the safe disposal of unusable and unserviceable pharmaceutical products and waste	Approved and disseminated Guidelines for the disposal of unusable and unserviceable pharmaceutical waste products	Timely and safe disposal of unwanted pharmaceutical waste	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Approved, disseminated and utilized Guidelines for the disposal of unusable and unserviceable pharmaceutical waste products
	78	Formalize the training of all relevant staff to implement the SOPs/guidelines for the proper storage of health products and the proper disposal of expired or damaged health products	Staff at all levels of the of the supply chain trained on the SOPs/guidelines for the proper storage of health products, including procedure for the proper disposal of expired or damaged health products	Improved storage of medicines and related products, and proper disposal of products unfit for human use	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports on training and implementation of the guidelines at facility level

8. Distribution											
Refers to timely delivery and ensuring the availability of affordable Right medicines in the Right quantity, in the Right condition (of quality), at the Right place											
Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ verification
						1	2	3	4	5	
8. Distribution 8.1 Distribution and sale of medicines	79	Strengthen structured and systematic inspection, through increased visits, to ensure that only registered medicines or those authorized by the Ministry of Health are distributed and/or offered for sale in Cambodia. <i>(See also Medicines Registration # 5, 6 It should be done together)</i>	Inspection mechanisms	Distribution of unsafe or inappropriate medicines will be avoided.	DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Authorized inspection undertaken routinely
	80	Seek funding and MoH approval to conduct a detailed feasibility study to articulate the specific operational, structural and organizational, staff and equipment changes needed to improve the overall performance of the CMS	A feasibility study articulating the specific operational, structural and organizational changes needed to improve the overall performance and efficiency of the CMS	Efficient CMS implementing GPP, GSP and GDP	CMS, DDF, DPHI	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Feasibility study stating the specific operational, structural and organizational changes needed to improve the overall performance and efficiency of the CMS
	81	Develop and enforce guidelines for ensuring compliance with Good Distribution Practices (GDP)	Good Distribution Practice guidelines approved	Good Distribution Practices	DDF/EDB, CMS	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Guidelines developed and enforced
	82	Establish performance indicators for the CMS to be monitored regularly eg % service level provided = number of items ordered vs issued; lead time to received scheduled CMS orders, etc	Indicators to monitoring the performance cycle of the CMS agreed upon	The performance of the CMS monitored regularly and timely remedial measures taken as needed	DDF/EDB, CMS	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports of performance of the CMS as measured by agreed indicators
8.1.1 Distribution of medicines in the public sector	83	Develop standardized order forms for different levels of health services that include only medicines and supplies for the particular level. A few extra lines can be available for special items. Train staff involved with processing orders at CMS to better understand the essential medicines concepts and medical supplies needs at different levels.	Standard order forms for each level of facility	Adherence to use of the right medicines in facilities and facilitated processing of orders for distribution by CMS	DDF/EDB, CMS, User facilities	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Standard order forms and routine audit of order processing at CMS

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ verification
						1	2	3	4	5	
8.1.1 Distribution of medicines in the public sector (cont)	84	Constantly communicate with health facilities, through telephone, to review and confirm the rational for their order quantities	Rational orders placed with the CMS	Orders are placed based on actual and confirmed needs	DDF/EDB, CMS, User facilities	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report on ordering habits of user facilities
	85	Work with the CMS to ensure that quantities ordered rationally by user facilities are respected and issued as requested	CMS respects order quantities made by health facilities	Improved availability at user facility	DDF/EDB, CMS, User facilities	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report on service level provided by the CMS (average % of ordered/issued)
8.1.2 Distribution of medicines in the private sector	86	Develop Guidelines for the importation and distribution of medicines in the private sector ensuring distribution only according to conditions stated in their licences or permits and covering pricing and best practice management. <i>(See also Medicines Regulatory Authority #5, 6, 7 . It should be done together)</i>	SOPs	Private sector compliance with license conditions related to the distribution of medicines	DDF/ Regulation and Trade Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Guidelines developed and circulated
	87	Authorize and conduct regular inspection of private sector premises and implement penalties for non-compliance with the law. <i>(See also Regulatory Affairs # 14,15)</i>	Regular Inspection	Law abiding private sector dealers	DDF/ Regulation and Trade Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inspection reports

9. Quality Assurance and Control of Medicines in circulation											
Refers to maintenance of quality of all aspects of the management of medicines throughout the public, private and NGO sectors and to ensure that medicines reaching the patients are safe											
Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicators/ Verification
						1	2	3	4	5	
9. Quality Assurance and Control of Medicines in circulation	88	Develop detailed SOP or Guidelines for the Inter-Ministerial Committee on Combating Counterfeit and Substandard Pharmaceuticals to ensure that results of post-marketing surveillance and sample testing are disseminated in a timely manner	Detailed SOP or Guidelines to guide the day to day operation of the Inter-Ministerial Committees on combating Counterfeit and Substandard Pharmaceuticals	Efficiency operations of the Committee and the timely release of reports on substandard and counterfeit medicines discovered in the market	DDF/Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports on implementation the SOP or Guidelines for Committees in place
	89	Identify funding needs/gaps and thereafter conduct a fund raising campaign to lobby for additional fund to support the National Health Product Quality Control Laboratory (NHQC) to implement its Roadmap towards the attainment of WHO prequalification or ISO 17025 certification	WHO prequalification or ISO 17025 certification identified Fund raising campaigns	NHQC is WHO prequalified and/or ISO 17025 certified	NHQC/DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> A WHO prequalified and/or ISO 17025 certified NHQC
	90	Strengthen mechanisms 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	Training modules and tools	Improved capacity to monitor the quality of medicines in the public and private sectors	DDF/Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Training and M&E reports and additional tools supporting effort to combat substandard and counterfeit medicines
	91	Prepare and implement a harmonized private sector drug outlets and pharmaceutical manufacturers inspection, sample collection and testing program to ensure adherence to pharmaceutical regulations and to combat counterfeit and substandard medicines in the public and private sectors <i>(see also Activities # 18,19...they should be done together)</i>	Harmonized (by all sources of funding) inspection schedules	Cambodia (private sector market) free of substandard and counterfeit medicines	DDF/Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inspection and QC testing reports
	92	Propose amendments to the current pharmaceutical law to provide for harsh penalties to medicines counterfeiters and their distributors	Law amended to provide harsh penalties to counterfeiters and their distributors	Effective deterrence to the contemplation of preparation and distribution of counterfeit medicines	DDF/Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Approved article of the Law on penalties to medicines counterfeiters and distributors

10. Rational Use of Medicines											
<i>Refers to patients receiving medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest cost to them and their community</i>											
Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
10. Rational Use of Medicines	93	Review curricula for training of health workers including pharmacy workers and nurses to identify where emphasis on RUM is needed	Reviewed and approved Curricula for health workers training that include RUM	RUM included in curricula	DDF/FP	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> RUM included in curricula
	94	Seek funding to maintain and to scale-up the Monitoring Planning Training (MTP) approach for improving the RUM at health facility level	Additional funding sources identified	The MTP approach for improving RUM implemented by all health facilities (public and private) in Cambodia	DDF/FP	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Survey report on the extent of use of the MTP approach to improve RUM
	95	Encourage the sharing of information and experiences among countries on successful interventions to promote rational use of medicines. <i>(See also 13. Technical Cooperation with other countries and International Agencies, # 141)</i>	Electronic or other information sharing network established	Improved decision making through timely sharing of information on RUM	DHS DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Network described above being used to share information
10.1 Education and training	96	Develop refresher courses on RUM and other suitable continuing education activities that will be maintained in collaboration with other relevant bodies	A range of refresher training courses	Rational use of medicines by health professionals	DDF/FP/PAC	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Appropriate refresher courses developed and implemented
	97	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 GPP, in particular good dispensing procedures	Medicines Counseling training modules	Improved patients understanding and compliance with prescribed medicines and their proper storage	DDF / FP	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Survey report on medicines understanding and use by patients
10.2 Prescribing	98	Define and publicize scope of staff prescribing responsibilities as determined by authorization to prescribe at different levels of health facilities.	Documentation of scope of staff prescribing responsibilities at different health service levels	Scope of prescribing responsibilities defined	DDF/EDB, Dept Hosp Services,	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Circulation to relevant parties of scope of prescribing responsibilities
	99	Conduct education and awareness activities for prescribers in all sectors, public, private, and NGOs, so they are familiar with the nEML and nSTGs and the list of medicines determined for the level of prescriber and according to the directions of the Ministry of Health.	Education and awareness activities	All health personnel aware of nSTGs and nEML and the drugs specified for use at their particular level of service	DDF/EDB, Dept Hosp Services	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report on education and awareness campaigns Audit of prescribing

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
10.2 Prescribing (cont)	100	Implement policies that encourage generic prescription and generic substitution, including financial incentives, in both the public and private sectors. Provide leaflets showing generic names and their common equivalent trade name products to prescribers (public and private)	IEC materials and campaigns	Generic prescribing accepted and used (both in the public and private sector)	DDF/EDB, Dept Hosp Services	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Survey reports on the extent of prescribing by INN in the sector
	101	Inform health professionals and the general public, through newsletters, the print and electronic media (TV, Radio, websites, etc), about cost-savings when using generics and provide information on medicines prices	IEC materials on cost-savings when using generic products A compilation of medicines prices	Cost-effective procurement and use of generic medicines in the private and public sectors	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Survey reports on the extent of use of INN in the sector
	102	Constantly monitor and assess prescribing practices in the country and collaborate with other sections of the national medicines regulatory authority to ensure appropriate, efficient, and cost-effective prescribing. (See also <i>Monitoring and Evaluation # 149</i>)	Tool for conducting survey on prescribing practices developed	Prescribing practices regularly monitored	DHS, DDF/EDB, Hosp/DTCs	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Survey reports on prescribing practices
	103	Seek funding (through proposal development and submission to relevant organizations) to fund pilot interventions that address appropriate and safe use of medicines, especially for maternal and child health, adherence to medicines for non-communicable diseases or other chronic illness	Proposal developed and submitted for funding to relevant organizations Pilot test programs established	Scaling up of evidenced based interventions on safe use of medicines for MCH and NCDs	DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Pilot test programs
	104	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 <i>14. Monitoring and Evaluation # 150</i>)	Economic studies	Positive economic impacts of interventions are influential in gaining further support		x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Studies undertaken
10.3 Dispensing	105	Develop or strengthen dispensing guidelines, as part of Good Pharmacy Practice (GPP) and make their use mandatory.	Dispensing Guidelines	Good dispensing practices both in the private and public sectors	DDF/EDB, DHS	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Survey report on GDP
	106	Include Good Dispensing Procedures and Practices in the training curricula for all other categories of staff who are involved with dispensing 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 <i>Human Resources #42, 43</i>)	Comprehensive dispensing modules routine part of training curricula for relevant health staff.	Good dispensing practices by all categories of health staff	DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reviewed and revised training curricula as needed
	107	Enforce through regular inspections of premises, where dispensing operations are performed, to ensure that the provisions of the law in relation to the dispensing practices are being satisfied in all respects (See also <i>#5, 6, 7 – they should be done together</i>)	Schedule of Inspection visits to ensure compliance to Good Dispensing Practices	Compliance with Good Dispensing Practices nationwide	DDF/ Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Inspection report highlighting dispensing practices

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
10.4 Medicines Information	108	Ensure, through inspection and/or monitoring and supervision visits, that independent, reliable, scientifically-based information supporting rational prescribing and dispensing, including Cambodian Standard Treatment Guidelines, Essential Medicines Lists and other appropriate reference materials are available to health workers.	Relevant Information available to health facilities	RUM through the use of good sources of information and national guidelines	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report on sources of information available at health facilities
	109	Collect and collate information and data on medicines utilization and pharmacy practices to identify targets for education; or the review of pharmacy practice as necessary. Use as a guide for further education.	Data collection tools	Targets identified for strengthening practices	DHS, DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> System for collecting, collating and use of data in place
10.4.1 Community understanding about all medicines and self-medication	110	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 and other special categories as determined by studies of community needs.	Good examples of priority information	Priority areas eg antibiotic prescribing addressed and improved	DHS, DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Appropriate IEC materials produced and distributed
	111	Conduct appropriate community based training eg use of the 'Community Based Interactive Approach (CBIA)' 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	DHS, DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Appropriate IEC materials, CBIA programs implemented
10.4.2 Pharmacovigilance General	112	As pharmacovigilance is new in Cambodia all PV Unit staff should undertake self-studies on the scope of pharmacovigilance on ensuring the safety of medication and patients. All PV Unit staff should read the short Chapter 35 on PV - MSH Management Drug Supply book 3 rd Edition which can also be accessed from: http://www.msh.org/resource-center/mds-3-digital-edition.cfm	Understanding by all PV staff what is PV and its scope	Ease of implementation of PV activities as the result of a better understanding of PV and its scope	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Number of PV staff reporting to have read the referred short chapter on PV
	113	Set up a Working Group or Committee with clear terms of reference to review and coordinate all efforts undertaken in the country to monitor drug use and drug resistance in the public and private sectors	A Working Group or Committee established and ToRs for the Group/Ctee developed	Coordinated monitoring of medicines use and drug resistance	DDF/EDB, DHS	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> A Working Group or Committee established and operating with clear ToRs
	114	PV unit focus attention on addressing issues related to medicines quality, Adverse Reaction Monitoring and discovering and resolving medication errors.	PV Unit activities focused on medicines quality, Adverse Reaction Monitoring and the discovery and resolving medication errors	PV activity constantly focused on medicines quality, ADRs, and medication errors	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> PV Unit Semi Annual reports highlighting activities conducted

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
10.4.2 Pharmacovigilance (cont)	115	Organize a retreat for the PV Advisory Committee to orient members on their expanded roles and responsibilities based on the Committee expanded terms of reference	Retreat to orient the PV Advisory Committee on their expanded roles and responsibilities held	PV Advisory Committee members aware of and exercise their roles and responsibilities	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report of the retreat
Product quality	116	Continue to 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 drug resistance, substandard and counterfeit medicines. (Refer also to 13. Technical cooperation with other countries and international agencies # 138)	Participation in program for ensuring the quality of medicines	Only quality assured, safe and effective medicines available in Cambodia market	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Market surveillance reports highlighting the prevalence of substandard and counterfeit medicines in the market
ADR reporting	117	Strengthen ADR 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	Tools for collecting information and trained focus staff	Routine collection of ADRs, medication errors, ineffective medicines reports	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> PV system strengthened and includes strengthened ADR reporting
	118	Continue to conduct advocacy meetings to advocate for ADR reporting by the health profession, drug companies, and the general public	Prompt, unhindered and blameless ADR reporting by health profession, drug companies and the general public	Blameless reporting of ADR and events by health profession, drug companies and communities	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report of advocacy meetings, tools and list of facilities and/or health profession and drug companies willing to report and/or reporting ADRs
	119	Implement follow-up schedules (after advocacy meeting) to ensure prompt reporting of ADRs by health professions, communities and drug companies in accordance with the recent MoH approved guidelines and tools for reporting ADRs	Schedules for follow-up to ensure ADRs are reported	Prompt reporting of ADRs by health professions, communities and drug companies	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report of follow-up and ADR reports
	120	Establish close contacts with national programs (PV focal points for HIV, TB, Malaria and others) to obtain related information on quality of medicines, ADRs, ADEs (due to a medication itself, inappropriate use of a medicine, including associated medication errors, if any)	Contacts established with national programs' focal points for PV	ADRs, medication errors and ineffective medication documented and appropriate actions taken to prevent their recurrence	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports submitted to PV Unit by national programs

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
10.4.2 Pharmacovigilance (cont)	121	Review and present information on collected ADR reports to the PV Advisory Committee for decisions and guidance for actions to be taken	List of ADR reports to be shared with PV Advisory Committee	Recommendations of the Advisory Committee to MoH on action to be taken to confirmed ADRs, ineffective medication batches, medication errors incidences	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Minutes of PV Advisory Committee – indicating clearly decisions of the Committee
	122	Enter reported and confirmed ADR into the global monitoring database maintained by Uppsala Monitoring Centre (UMC)	List of ADR reported to UMC	Global consolidation and analysis of ADR reactions specific to identified medicines	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> List of ADR reported to UMC
Medication errors	123	Investigate and document common causes of medication errors and accordingly develop mechanisms and procedures for their identification, monitoring and implementation of a blameless reporting of such errors	Clear understanding of causes of medication errors Procedure and/or mechanism for their identification developed Forms for reporting medication errors	Medication errors prevented and safety to patient improved	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Demonstrated understanding of medication errors and Procedure for the identification and monitoring medication errors in place

11. Traditional Medicines

Refers to the use of and the role traditional or complimentary medicine practices and products play in improving individual health

Policy Domain	#	Activities	Output	Outcome	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
11. Traditional Medicines (TM)	124	Collaborate with the Center for TM in its role to promote and disseminate policy, regulations, guidelines and TM knowledge to the relevant bodies, public, and especially health care providers to meet the goal of integration of traditional medicine into the Primary Health Care system as clearly stated in-TM policy and the requirement of ASEAN and WHO.	Collaboration	Policy concerning integration can be considered.	DDF Regulation Bureau/DDF Registration Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Collaboration on integration of TM with PHC
	125	In collaboration with the Traditional Medicines Unit (under Prakas 040 Dated 16 Nov 2007), aim for the registration of all commercially produced traditional medicines in Cambodia in accordance with all registration requirements.	Registration of commercially produced TMs	Commercially produced TMs of assured quality and safety available in the market	Registration Bureau/CTMO	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> An update list of registered TM locally produced commercially
	126	Ensure that commercially produced TMs that are imported into Cambodia satisfy the regulatory requirements and are registered before they become available to the public.	Procedure for the registration of imported TMs disseminated to potential importers	Commercially produced imported TMs of assured quality, and safety available in the market	DDF Drug Registration Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> An update list of registered imported TM

12. Advertising & Promotion

Refers to the advertising and promotion of medicines and compliance with a high professional standard and compliance with the requirements of the medicines legislation and regulations

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
12. Advertising & Promotion	127	Review and strengthen regulation on drug promotion to cover all aspects of medicines, cosmetics and medical devices promotion and advertisement to ensure that there is compliance with Ethical Criteria for advertising and promotion	Regulations on drug 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	DDF/Trade Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Revised and strengthened regulation on drug promotion, information and advertisement, in place and implemented; special guidelines for advertising medicines for children included
	128	Provide for special emphasis to cover advertising of medicines for children	Check list for assessing advertising for children's medicines	Inappropriate advertising of medicines for children eradicated	DDF/Trade Bureau	x	x	x	x	x	
	129	Develop and circulate guidelines that are in line with Medicines Policy 2010 for medicines promotion, to all relevant parties	Advertising guidelines prepared and circulated	Awareness of inappropriate advertising and follow-up	DDF/Trade Bureau	x	x	x	x	x	
	130	Develop SOPs for pre-approving and monitoring drug promotion and advertising	SOPs for pre-approving and monitoring of drug promotion and advertising	Improved procedure for approving and monitoring drug promotion and advertising	DDF/Trade Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> SOPs for pre-approving and monitoring of drug promotion and advertising, in place and implemented
	131	Develop 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)	Checklist circulated to relevant people with reporting instructions	Reports received and acted on	DDF/Trade Bureau	x	x	x	x	x	<input type="checkbox"/> Checklist developed and circulated to appropriate people with instructions for use

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
12. Advertising & Promotion (cont)	132	Develop a mechanism for providing 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	DDF/Trade Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Mechanisms for providing regularly independent, unbiased and accurate information on health products, in place
	133	Develop and implement programs for empowering the general public to minimize self-medication	Programs for educating and empowering the general public to minimize self-medication developed and implemented	Decline in self-medication by the general public	DDF/Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Programs for empowering the general public to minimize self-medication developed, in place & implemented
	134	Develop a regulatory mechanism to prevent direct to consumer advertising of prescription only medicines	Sub-Decree banning DTCA	DTCA can be prevented	DDF/Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Regulatory mechanism in place
	135	Prohibit pharmaceutical advertising in Government Publications	Government order prohibiting publications of commercial advertisements and logos on government publications	Government publications free of commercial advertisements	DDF/Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> No incidences of Government publication bearing commercial advertisements and logos
	136	Develop ethical guidelines for pharmaceutical company support of health professionals' education, travel and other activities to avoid conflict of interest.	Ethical guidelines based on similar documents from WHO and other countries	Conflict of interest and industry influence on health professionals avoided	DDF/Regulation Bureau	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Ethical guidelines developed

13. Technical cooperation with other countries and international agencies

Refers to the consideration of all relevant forms of technical cooperation with other countries and international agencies in order to maximize the efficient utilisation of the limited resources available in Cambodia for the implementation of components of Medicines Policy

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
13. Technical cooperation with other countries and international agencies	137	Promote information-sharing among countries through interregional meetings, conferences and projects, web-based communication, and printed technical materials.	Attendance to interregional or international meetings, conferences, web-based communication, etc	Gained insight to improve the pharmaceutical sector in Cambodia	All DDF Bureaus	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports of interactions
	138	Build on multi-country operations to combat substandard & counterfeit pharmaceuticals such as Operation Storm. Continue initiatives with all actors and share intelligence within Cambodia and regionally to prevent escalation in availability of counterfeit & substandard pharmaceuticals.	Maintained mechanism for sharing information and initiatives	Maintenance in control of counterfeit and substandard products facilitated	DDF ASEAN WHO Interpol	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Reports of collaborative activities to combat substandard and counterfeit medicines
	139	Collaborate with ASEAN to make use of initiatives developed by ASEAN, if any, that could be helpful for Cambodia in areas of NMP implementation such as quality control and any other areas that might be helpful.	Relationship with ASEAN to facilitate awareness of useful initiatives	Use or adaptation of prepared and tested initiatives	DDF	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report on communication with ASEAN on NMP implementation
	140	Collaborate with regional initiatives supported by WHO in surveillance for emerging diseases in order to develop rapid response capacity involving use of medicines if needed.	Maintained relationship with existing networks	Knowledge shared resulting in rapid response involving medicines when needed.	DDF/NTC	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Established links with WHO and relevant bodies
	141	Encourage cross-country and Regional comparative information-sharing. (i) Explore the possibility of developing an electronic network within the Region for sharing knowledge, queries and announcements about pharmacy-related initiatives and activities. (The Drug Information Exchange for Pacific Island Countries (DIEFPIC) supported by WHO is a model) (ii)Regional Price Information Exchange at www.piemed.com information provides on medicines prices among countries in the Region and on price trends.(Refer also to 6. Procurement # 66)	Electronic or other network for discussing any pharmacy related matters including supplier performance and price trends - etc	Knowledge shared beneficially in the pharmaceutical sector.	MoH PU Donor PU	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report or records indicating that such information exchange/sharing of price information is happening and/or a Network developed for sharing information

Policy Domain	#	Activity	Output	Outcome	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
13. Technical cooperation with other countries and international agencies (cont)	142	Develop collaboration with regional and other quality control laboratories. <i>(See also NHQC # 37)</i>	List of appropriate collaborating regional QC laboratories	Improved QC testing capacity and Assistance for tests beyond NHQC capacity or for validating local tests	NHQC	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Through WHO/WPRO collaboration and links developed
<i>Product quality</i>	143	Continue to 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 drug resistance, substandard and counterfeit medicines. <i>(Refer also to 13. Technical cooperation with other countries and international agencies # 138 and Product Quality # 116)</i>	Participation in program for ensuring the quality of medicines	Only quality assured, safe and effective medicines available in Cambodia market	DDF PV Unit	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Market surveillance reports highlighting the prevalence of substandard and counterfeit medicines in the market

14. Monitoring and Evaluation

Refers to establishment of mechanisms for monitoring and evaluating performance under the policy. (M&E activities are also listed within the relevant domains)

Policy Domain	#	Activity	Outputs	Outcomes	Responsible	Year					Indicator/ Verification
						1	2	3	4	5	
14. Monitoring & Evaluation	144	Semi-annually conduct an evaluation workshop to review and document the progress of the implementation of this Pharmaceutical Sector Strategic Plan (2013-2018) by evaluating progress made in achieving the suggested Indicators/Means of Verifications	Evaluation workshop held and decisions to speed up implementation rate, prioritize activities or modify some activities reached	Improved implementation of the sector strategy	DDF and relevant stakeholders	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Workshop reports
	145	Undertake periodical assessments 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.	Model for assessment and analyses of results developed for periodic use in all settings	Gaps identified for further interventions	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Assessment report on national pharmaceutical situation
	146	Disseminate feedback on the national pharmaceutical situation assessment and results to national policy-makers, health workers, consumer groups, and other stakeholders.	Dissemination Workshop on the results of the national pharmaceutical situation assessment reports	Informed policy changes, where needed, to improve the pharmaceutical situation in the country	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Dissemination Workshop report
	147	Share the pharmaceutical situation reports at national, regional and global levels.	Report shared globally as necessary	Awareness of the pharmaceutical situation in Cambodia by other countries	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Report on presentations at national, regional or global level
	148	Research new ways to strengthen support, supervision, monitoring and evaluation capacity at all levels to ensure efficient and effective management of drugs and medical devices. <i>(See also Human Resources # 45)</i>	Ideas submitted to strengthen support and M&E	Quality of work will be enhanced and work satisfaction improved	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> HR Capacity evaluation tools developed
	149	Constantly monitor and assess prescribing practices in the country and collaborate with other sections of the national medicines regulatory authority to ensure appropriate, efficient, and cost-effective prescribing. <i>(See also Prescribing # 102)</i>	Tool for conducting survey on prescribing practices developed	Prescribing practices regularly monitored	DHS, DDF/EDB, Hosp/DTCS	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Survey reports on prescribing practices
	150	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 <i>(See also 10. Rational Use of Medicine # 104)</i>	Economic studies	Positive economic impacts of interventions are influential in gaining further support	DDF/EDB	x	x	x	x	x	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Studies undertaken

Annex 2. Strengths and Issues associated with the Implementation Plan

Strengths	Issues
1. Introduction	
2. Legal Framework including regulatory affairs, quality assurance and licensing	
<p>The revised drug law (2007) and relevant regulations (Sub-degrees) and guidelines (Prakas) support enforcement of the law concerned with pharmaceuticals.</p> <p>The national medicines regulatory authority includes strong sections responsible for registration of medicines, issuing of licenses for pharmaceutical facilities, and for the regulation of any business pertaining to the pharmaceutical practices. The system includes a fast-track registration process as well as a computerized Registration System (which is yet to be fully utilized). Drug laws are in place.</p> <p>Drug Inspectors were trained on GMP in 2009 and they are undertaking inspection regularly. Also a GMP training for local drug manufacturers was conducted in the same year. (Cambodia GMP standards are available but not fully implemented).</p> <p>There is a strong National Health Product Quality Control Laboratory (NHQC) which has been reviewed and plans are already in place for it to attain international acceptable standards of operations.</p> <p>There is a dedicated unit/bureau for pharmaceutical trade licensing matters, import and export and narcotic control. Pharmaceutical trade licensing of companies and products accepted by the registration bureau and other matters of import and export and concerned with narcotic management are controlled by licenses.</p> <p>There is a strong and capable Pharmacy Council in place whose mandate for supporting pharmacists and monitoring their practice could be strengthened.</p>	<p>Some articles of the drug law and Sub-Decrees need to be strengthened or publicized more widely. 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.</p> <p>Overall enforcement of the law is weak.</p> <p>Legislation to enable access to affordable medicines by using TRIPS flexibilities is not yet in place.</p> <p>Although there is a good drug registration system in place the drug evaluation and registration system needs strengthening. In addition, there is a severe backlog of documents to be processed for product registration and inadequate use of the new computerized drug registration system. Registered products lists are not readily available to the public and there is insufficient control of harmful products.</p> <p>There is not yet a Code of Conduct for medicines registration staff; and an Appeal procedure, in case an applicant is denied registration of a product, is not in place</p> <p>Production techniques of many local manufacturers are not up to acceptable Good Manufacturing Practice (GMP) and need to be strengthened in order to receive registration from the MoH. Government standards for establishing quality premises, systems and products, or to prosecute the drug manufacturers are limited. The adoption of an official Cambodian Code of Good Manufacturing Practice would mean all manufacturers would know what standards all of their products have to reach.</p> <p>Currently there is no system for Registration of Pharmacists and the Pharmacy Council does not have a mandate at present to oversee regulatory matters concerned with pharmacists and their practices in line with the conditions of their licenses.</p> <p>There is insufficient adherence to the laws restricting the sale of different levels of pharmaceutical substances according to their safety; and prescription only medicines are sold freely over the counter. Schedules have not been updated recently and there is inadequate classification of potentially toxic pharmaceutical substances. There is lack of clear guidelines on the management of narcotics and psychotropic substances.</p>

Strengths	Issues
3. Human Resources	
<p>There is a strong and committed Faculty of Pharmacy at the University of Health Sciences and a large number of students keen to study pharmacy.</p> <p>The Human Resources Development Bureau is committed to the placement of sufficient pharmacy staff in all clinical settings according to the defined needs of those settings</p> <p>The Faculty of Pharmacy is developing a competency based framework in line with Good Pharmacy Practice (GPP) to guide the curriculum.</p> <p>The Pharmacy Council and the National Exam Committee are collaborating with the FP to ensure that the newly developed 'Exit Exam' satisfies the criteria to guarantee a competent pharmacy workforce.</p> <p>Success in the Exit Exam will lead to registration and licensing for practice as a pharmacist.</p> <p>In collaboration with the National Institute of Public Health, DDF and the FP are preparing a competency framework for pharmacy workers in remote and other special settings as well as a shorter competency based curriculum for training more senior level pharmacy workers (like auxiliaries or assistants).</p> <p>A pharmacy health workforce survey was conducted in 2012 and provided much information to guide the development of a strong and capable pharmacy workforce.</p>	<p>There are insufficient appropriately trained pharmaceutical workers in the range of areas in the public and private sectors to follow national policy and procedures and achieve desired quality of work.</p> <p>Training for all levels of pharmacy work has been insufficiently geared towards the competencies needed to undertake the range of work needed throughout the sector.</p> <p>In many areas there are insufficient numbers of staff to undertake the necessary tasks.</p> <p>To date there has been no registration process and there is no continuing education program in place.</p> <p>There are insufficient staff in DDF to carry out the necessary on-the-job training for staff doing pharmacy work in remote settings.</p> <p>Support, supervision, monitoring and evaluation of capacity at all levels are not yet available to ensure efficient and effective management of drugs and medical devices.</p> <p>Mechanisms are not in place for evaluating and rewarding staff performance and promoting rank of staff according to skill and responsibility. Government will have limited leveraged power if salaries are not dramatically increased.</p> <p>Low salaries have led to dual practice, where Public sector health workers engage in private practice during and after official working hours. Review of financing options for training, maintenance and support of all cadres of human resources necessary for implementation of the policy is needed.</p>
4. Financial resources	
<p>Cambodia spends relatively higher level of Government financial resources on health. More than three quarter of total health expenditure (eqv to US\$ 50-60 per capita or 5.7% of the GDP) is used to fund supplies and staff salaries.</p> <p>There are national programs that are supported by funds from external donor sources. Cambodia has developed a strategy for SWiM – a Sector wide Management Strategy - in the National <i>Strategic</i> Development Plan 2009 -2013. Use of this strategy will avoid fragmentation resulting from finances from a range of sources.</p>	<p>Efficiency of expenditures on health care could be enhanced by more efficient purchasing, particularly for pharmaceuticals, medical equipment, and supplies. Savings could exceed \$50 million a year, or one-third of government health spending, the equivalent of 0.4 percent of GDP.</p> <p>Systems are not in place to provide reliable data from all sources and the demands of the strategic plan as a basis for financial support for implementing all components of Medicines Policy.</p> <p>Mechanisms are needed to Include finance from other programs and vertical programs in the general income.</p> <p>Financial accounting, auditing and reporting practices in the public sector could be strengthened.</p>

Strengths	Issues
5. Selection	
<p>A strong Essential Medicines Committee exists and there is a Cambodian Essential Medicines List that is reviewed regularly. It includes medicines that are safe and cost-effective.</p> <p>Medicines are all identified by their INN (International Non-proprietary Name) also known as the generic name.</p> <p>All essential medicines available in Cambodia must comply with the quality control standards required for registration.</p> <p>There is strong understanding in the public sector concerning essential medicines and their place in the system.</p>	<p>The EML Committee has no clear ToRs that include the responsibility for developing and updating an EML based on appropriate treatments, for all levels of facilities in Cambodia.</p> <p>There is no process for the EML committee to be consulted for collaboration with vertical programs and donors to ensure harmonization of treatments with Cambodian EMLs and STGs. Expatriate medical teams or individuals implementing programs in collaboration with the Government of Cambodia, in which the use of medicines is a significant component, do not necessarily consult the national EML Committee.</p> <p>Ideally medicines for inclusion on the EML are identified according to their necessity for treatment of diseases. However, there are a limited number of clinical guidelines to identify the best choice of medicines for rational prescribing.</p> <p>There is no clear procedure with criteria for recommending the inclusion or deletion of a product in the STGs and Essential Medicines List.</p> <p>There is insufficient understanding in the private sector concerning essential medicines and standard treatment guidelines.</p>
6. Procurement	
<p>A Forecasting and Quantification Committee existed in previous years and nearly 2,000 public sector staff have been trained on forecasting and quantification of medicines. 70% of public health facilities are believed to have (staff) capacity and proficiency to undertake accurate forecasting and quantification of pharmaceutical needs for procurement.</p> <p>Procurement is according to INN in compliance with registration procedures and with the EML.</p> <p>Cambodia has several local manufacturing companies with potential good capacity and there is a policy to favour local procurement.</p> <p>There is a strong desire to implement Donation Guidelines and draft Donation Guidelines have been prepared.</p>	<p>In the public sector the procurement of medicines needs to be harmonised and integrated into the national system to attain economy of scale and to ensure reliable supply of medicines with minimum waste, to satisfy the needs of the citizens of Cambodia.</p> <p>Continuous hands-on support / supervision is not in place to ensure that all facilities have staff skilled in quantification of medicines.</p> <p>The Procurement Unit in the Ministry of Health could be assisted with the implementation of their Guidelines; and inclusion of specialist technical expertise in the Tender Committee (PEAC) would be valuable. Technical staff from the DDF are not part of the PEAC.</p> <p>The Tender process is not transparent and can be fragmented because donors and persons with technical expertise may not be included on the PEAC. Guidelines (or SOP) for the PEAC need strengthening.</p> <p>There is weak capacity to register local products so their procurement is limited.</p>

Strengths	Issues
7. Storage facilities and systems	
<p>The CMS has excellent capacity and storage conditions, has been assessed and is in the process of expanding to larger and upgraded facilities.</p> <p>The CMS will have 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.</p> <p>Inspection & Receiving SOPs for the CMS will be implemented.</p> <p>There will be capacity for continued availability of sufficient quantities of the required essential medicines at all levels of the health system to be maintained through accurate and systematic recording, monitoring and reporting of use and stock levels of all items.</p> <p>Efficient stock management and control can minimize wastage.</p>	<p>It is important the new CMS facilities are designed to good storage specifications such as air conditioning, security, drainage etc and that sufficient staff, including drivers are allocated.</p> <p>Communication between drug distribution centers in the public sector, and service delivery points, requires strengthening to reduce stock-outs, unexpected delivery, and potential storage problems. Monitoring and supervision in provincial health departments and operational districts needs strengthening so that national standards can be met.</p> <p>Efficient communication between procurement and service delivery counterparts is needed partly because of extra demands from the HIV program and other donor funded programs but also because there is insufficient understanding of relevance of accurate stock records. Improved inventory control would result in less wastage of products and funds.</p> <p>There are poor storage conditions in some places.</p> <p>Quantification is one of the most difficult aspects of the supply chain and ongoing assistance and support will be needed at all levels to help staff estimate the quantities of drugs needed for appropriate use in health services according to clinical guidelines and be able to order those drugs in a timely manner.</p> <p>MLMIS not integrated into the central HIS resulting in sub-optimal quantification of needs.</p> <p>Adherence to treatment guidelines and accurate record keeping at facility levels would facilitate quantification for orders and result in a reliable supply of stock and avoid wastage. Understanding of relevance of accurate stock records and stock management needs continuous strengthening.</p> <p>There are no clear guidelines and facilities for safe disposal of unavoidable waste.</p>

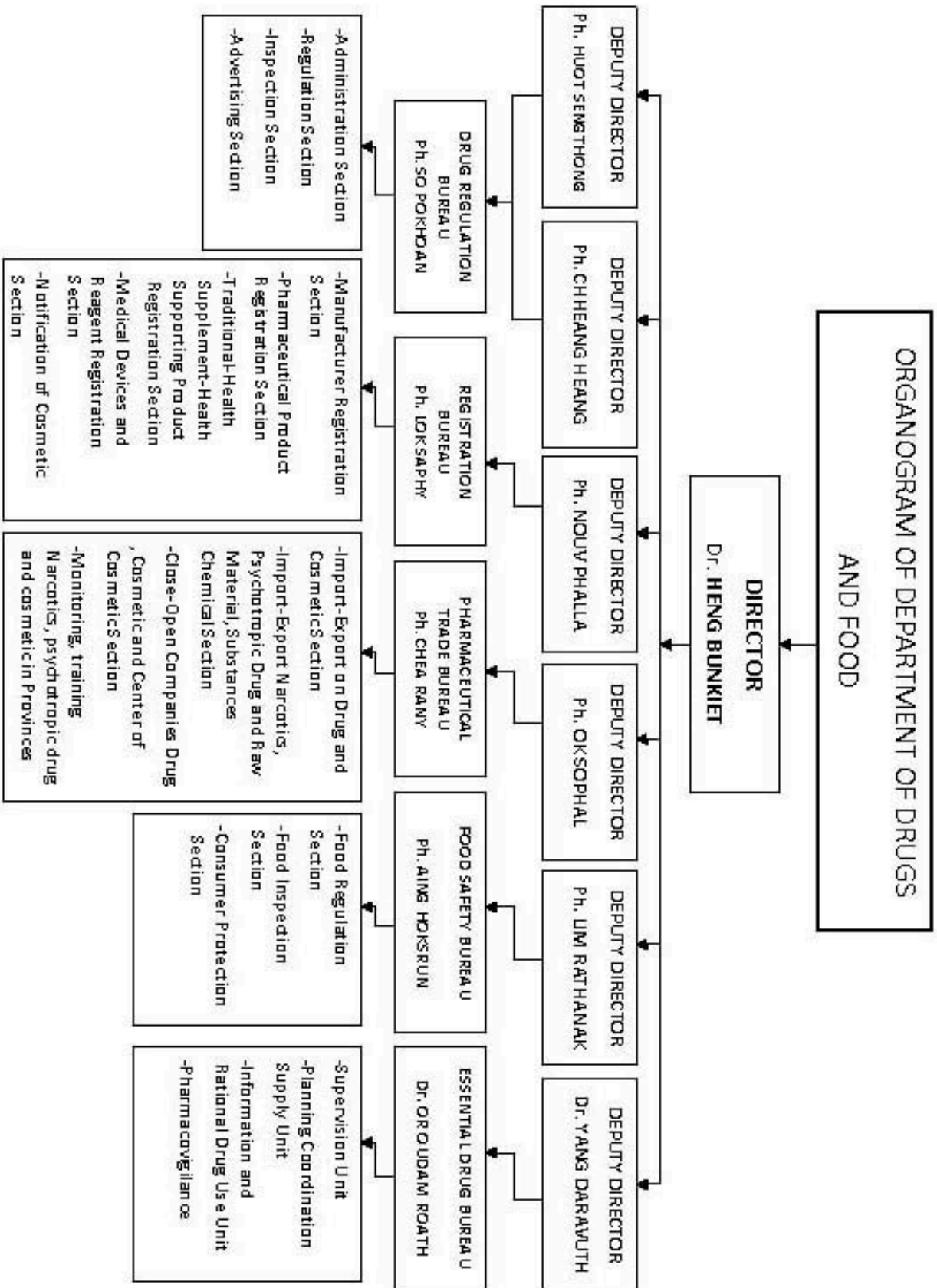
Strengths	Issues
8. Distribution	
<p>An improvement in the pharmaceutical supply system to public health facilities has been reported in the last 10 years. A Forecasting and Quantification Committee – operating in previous years - can be strengthened. A system of collecting pharmaceutical data is in place and a computerized supply management system has been introduced. The introduction of this system has improved the supply of drugs at provincial level.</p> <p>Some national programs, like malaria, TB and HIV, are involved in making sure there are good practice guidelines and an adequate supply of quality drugs so treatments are readily available. 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 drugs.</p> <p>Distribution of medicines is centralized in the CMS. The CMS has an inventory control system, while the Department of Drugs and Food monitors and supervises drug supplies and use at all levels.</p>	<p>Communication between drug distribution centers in the public sector, and service delivery points, requires strengthening to reduce stock-outs, unexpected or late delivery, and potential storage problems. Monitoring and supervision in provincial health departments and operational districts needs strengthening so that national standards can be met.</p> <p>At the central level SOPs are needed for receiving orders, responding to them and for dispatch.</p> <p>There are no SOPs for health facilities to make appropriate orders on the basis of maintenance of accurate records and according the level of health facility or for receiving orders.</p> <p>There is no system for regular monitoring, eg % service level provided such as the number of items ordered vs issued; lead time to received scheduled CMS orders, etc. Indicators for monitoring the performance of the CMS on its storage and distribution mandate would be helpful.</p> <p>There are no Guidelines for the importation and distribution of medicines in the private sector ensuring distribution only according to conditions stated in the licenses or permits and covering pricing and best practice management.</p>

Strengths	Issues
9. Quality Assurance of Medicines in Circulation	
<p>There is a strong Pharmacovigilance Unit and the National Health Products Quality Control Centre has the capacity to test products.</p> <p>To ensure and maintain standards for public safety in the pharmaceutical sector, many building blocks have been established. A drug evaluation system is in place for pre-marketing evaluation, marketing authorization and post-marketing surveillance.</p> <p>The Inter-Ministerial Committee on combating Counterfeit and Substandard medicines exists and Counterfeit medicines have been largely controlled.</p> <p>Regulations and surveillance procedures for counterfeit drugs are in place with responsibilities of all relevant government agencies identified to maximize inter- and intra-sectoral coordination. The MoH, with the support of the judicial ministries, can prosecute people involved in drug counterfeiting,</p> <p>Mechanisms for maintenance of quality of medicines in circulation has improved.</p>	<p>The quality of medicines circulating in the public and private supply system is not always ensured.</p> <p>There are insufficient measures in place for routine inspection of medicines in circulation.</p> <p>Operation of the Inter-Ministerial Committee on combating Counterfeit and Substandard medicines needs to continue be strengthened and staff need to continue to be trained for selecting and sending samples for testing.</p> <p>The MoH lacks support from law enforcement agencies; and penalties for counterfeiters are significantly low.</p>

Strengths	Issues
10. Rational Use of Medicines	
<p>The MoH has developed an essential drug list. Six editions have been prepared since 1995 and the 7th Edition will be published in 2013. Monitoring, training and planning programs on rational drug use are being implemented but require further strengthening.</p> <p>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.</p> <p>Clinical Guidelines are being prepared in more categories and these will enhance prescribing and use of medicines.</p>	<p>There is poor drug prescription in Cambodia. Current prescribing practices include poly-pharmacy and inappropriate use of intravenous infusions, injections and antibiotics. Irrational drug use results in ineffective treatments, an increase in the risk of drug resistance and the cost of health care. Limited family incomes are wasted. Development and dissemination of clinical guidelines, together with education about their use will improve prescribing in Cambodia. The importance of the use of generic products needs better understanding.</p> <p>Most drugs in Cambodia are purchased over the counter. In the private sector, ways need to be explored on how to improve the use of high volume potent drugs, especially antibiotics. Physicians and drug sellers in the private sector need to be educated to use clinical guidelines.</p> <p>Drugs are 'prescribed' by a number of different health workers: doctors, nurses, midwives and pharmacists. Most do not yet have the knowledge of clinical guidelines or rational drug use. Training, and monitoring or supervision of practice needs to be maintained. Many drugstore owners are motivated by profit and satisfying their customer at the expense of good practice.</p> <p>Some doctors dispense and sell medicines from their own supplies. This practice is not legal and the laws regarding separation of roles of prescribing and dispensing need to be enforced.</p> <p>There is poor patient compliance with prescription instructions and there are many traditional beliefs and practices that influence consumers' behaviour. More interventions to improve communication between providers and consumers, such as training and awareness campaigns, and to increase the knowledge about medicines in communities are needed.</p> <p>Many people believe injections are more effective than tablets. People often use drugs prescribed for somebody else, and are more concerned about the color of a tablet than its therapeutic value. People in rural and remote areas have poor access to health services, so self-prescribing is common. Pharmacies and drug sellers are their only source of modern health treatments.</p>
11. Traditional Medicines	
<p>The Cambodian Traditional Medicines Policy has been endorsed and aims at the integration of the use of traditional medicines into the Primary Health Care system. A community education program has begun.</p> <p>Cambodian Traditional medicines that are produced commercially must comply with the same quality standards as other medicines and must be registered for sale in Cambodia.</p>	<p>Unregistered products of unsure quality are available.</p> <p>Cooperation with Regulatory Authorities needs to be encouraged to enable recognition of Cambodian TMs and registration of products that comply with requirements.</p> <p>The quality and safety of commercially produced TMs that are imported into Cambodia from other countries cannot be assured. Foreign TMs must also satisfy the regulatory requirements and be registered before they become available to the public.</p>

Strengths	Issues
12. Advertising and Promotion	
<p>Regulation on drug promotion to cover all aspects of medicines, cosmetics and medical devices promotion and advertisement is in place but needs to be strengthened.</p>	<p>There is inadequate enforcement of control of advertisement and promotion of medicines, cosmetics and medical devices so unsafe or unsuitable products can be promoted.</p> <p>Procedures for approving and monitoring promotion and advertising of medicines, cosmetics and medical devices are not yet in place.</p> <p>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.</p> <p>There is possible influence on health professionals by promotional support.</p>
13. Technical cooperation with other countries and International Agencies	
<p>Regional initiatives exist in a range of areas that can be helpful, for example ASEAN initiatives associated with the upgrade of the NHQC.</p> <p>Collaboration has been undertaken with regional initiatives supported by WHO and other institutes in surveillance for emerging diseases in order to develop rapid response capacity if needed.</p> <p>The multi-country operation combating counterfeit pharmaceuticals resulted in Operation Storm implemented regionally to prevent availability of counterfeit and substandard pharmaceuticals and to prosecute people responsible.</p>	<p>More advantage could result from regional sharing and collaboration with regionally developed initiatives.</p> <p>Promotion of information-sharing among countries through interregional meetings, conferences and projects, web-based communication, and printed technical materials has only occurred to a limited extent and could be enhanced.</p>
14. Monitoring and Evaluation	
<p>The MTP approach has been used successfully: monitoring, planning and training to monitor activities and identify targets for interventions and planning particularly in relation to rational prescribing in health facilities and referral hospitals in collaboration with Drugs and Therapeutic committees. Injudicious use of antibiotics has been reduced markedly.</p> <p>The MTP approach is flexible and not costly and uses adult learning theories and can be applied in both public and private settings in a range of areas.</p> <p>The use of the MTP approach could be adapted for monitoring and evaluation of all components of MP10. Using this method, indicators could be identified for monitoring and the impact of interventions could also be measured.</p>	<p>Few M & E initiatives are in place at present.</p> <p>Situation analyses are rarely undertaken and assessment of the impact of interventions is not routinely undertaken.</p> <p>Indicators need to be developed.</p>

Annex 3. DDF Organogram



Annex 4.

HSP2 cross-cutting health strategies

The **building blocks** of the HSP2 Strategic Framework cover three main program areas: Reproductive, Maternal, Newborn and Child Health; Communicable Diseases; Non Communicable Diseases and other health problems together with five cross-cutting health strategies described here.

Health service delivery consists of both public health measures against disease organization of health promotion for reduction of risk behavior and health protection as well as a general strengthening of health service delivery through general and disease specific policies and plans and the infrastructure and networks that support those elements. Much emphasis is given to the subject of quality improvement. An increase in health demand and empowerment of patients are underlined as important ways forward for improved quality and accountability in health service delivery, which include availability and access to quality, safe and effective medicines.

Health care financing addresses both increases in investments in health and efforts to remove financial barriers to quality health care. Government allocation to the health sector is singled out thus underlining issues around the harmonization and alignment of financing between donors and government as well as efficient funding of operational levels. Strengthening of social health protection mechanisms, including equity funds, CBHI and SHI will contribute to reducing financial barriers to access to essential medicines as well as incidence of catastrophic health expenditures.

Human resources for health cover a comprehensive range of interventions:

- i) Assurance of sufficient staffing levels with adequate professional profiles and competencies for implementation of all components of the Medicines Policy;
- ii) Mechanisms for the revision of contents of staff training;
- iii) Increasing the intake of students into schools and universities;
- iv) Strengthening measures to safeguard the quality of training and trainers.

Human resource programming also includes safeguard to professional ethics. Special urgency is associated with implementation of salary reform for health services.

Health information system addresses the need for high quality, accurate, comprehensive and timely data to provide the basis for evidence-based policymaking, planning, and quantification of medicines to maintain reliable supply and performance monitoring and evaluation. It emphasizes improved coordination and collaboration through data sharing, management, analysis, dissemination and use and inclusion of private sector information, as well as tracking budgets and expenditures and expanded training to build HIS and Medicines Logistics Management Information System (MLMIS) capacity.

Health system governance. The governance perspective of the HSP2 focuses on decentralization and deconcentration. 'Harmonization and Alignment for Results' is stressed to achieve a common policy framework between government and development partners. It is proposed that the strategy will improve the comprehensive picture of the government and donor funding and strengthen harmonization (*coordinating external support to follow national procedures, institutions and systems where possible*) and alignment (*ensuring that priorities identified by Cambodia become the priorities of donors*) in line with the government policies for decentralization and deconcentration and HSP2 priorities. (HSP2, p 29).

DRAFT