KINGDOM OF CAMBODIA

NATION RELIGION KING



Ministry of Health

Medicines Policy of The Kingdom of Cambodia

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MEDICINES POLICY FOR THE KINGDOM OF CAMBODIA

I. INTRODUCTION

The first National Medicines Policy for the Kingdom of Cambodia was prepared in 1995.

The Pharmaceutical Sector Strategic Plan 2005-2010 provided comprehensive direction for strengthening the pharmaceutical sector and guidelines for Good Pharmacy Practice were endorsed by the Ministry of Health in 2006.

Fifteen years after the development of the first Policy many things have changed. A new Health Strategic Plan has been developed by the Ministry of Health for the period 2008-2015. It is important that the National Medicines Policy should always align with the National Health Strategic Plan.

A policy, no matter how carefully formulated, has no value if it is not implemented. Therefore, a detailed strategic plan will be developed to link with the revised policy and include short- medium- and long-term strategies and plans for specific activities in the next several years.

Issues of equitable access to good quality, safe and efficacious medicines and their rational use remain the focus of the policy. The revised Medicines Policy is intended to ensure a reliable supply of quality medicines for all citizens of Cambodia and support the Health Strategic Plan 2008-2015.

The general purpose of a national medicines policy is to ensure:

- **Access:** equitable availability and affordability of essential medicines
- **Quality:** the quality, safety and efficacy of all medicines
- **Rational use:** the promotion of therapeutically sound and cost-effective use of medicines by health professionals and consumers.

The Medicines Policy is a commitment and guide for action. It should support the Health Strategic Plan (HSP2) 2008-2015 and revisions thereof.

Implementation of this Policy would be the best way to ensure a reliable supply of quality medicines for all citizens of Cambodia.

The medicines regulatory authority in the Ministry of Health is the government agency responsible for pharmaceutical control in Cambodia and is the body entrusted to coordinate and supervise the implementation of the Medicines Policy. Within the medicines regulatory authority there are units responsible for registration and regulation, all aspects of medicines management and pharmaceutical trade; and these units will assist in the implementation of the policy.

The extent to which objectives of this policy are being met will be monitored and evaluated by the medicines regulatory authority.

This policy should be revised and always align with the revision of the Health Strategic Plan when that falls due.

Vision

To help maintain and improve the health of all the people of the Kingdom of Cambodia, with a focus on remote areas and the poorer segment of the population, through access to and rational use of affordable, quality, safe and effective medicines.

Mission

The Mission of the Medicine Policy is to ensure that quality, safe and effective medicines are always available and affordable to the people of the Kingdom of Cambodia throughout the nation's health care system by:

- Strengthening, and implementing regulations and guidelines for pharmaceutical products including manufacture, sale, import, export and distribution.
- Establishing and implementing standards for the practice of training and education.

Key objectives

Key objectives of this Policy are to provide direction for:

- The development and maintenance of appropriate medicines legislation and regulations to ensure the full implementation of the Medicines Policy
- The establishment and maintenance of improved quality control and registration procedures
- Ensuring a significant allocation in the health budget and development of relevant financing policy to maintain the budget for the purchase of essential medicines and maintenance of the whole essential medicines system
- Development and maintenance of an appropriate work force
- The rational and evidence-based selection of essential medicines
- The improvement of medicine procurement procedures
- Strengthened medicine management procedures and practices
- Strengthened medicine distribution and logistics
- Strengthened promotion of the quality use of medicines across all sectors of the health services
- The maintenance of information and continuing education programs to improve medicine use.
- Enhanced management capacity and practice at all levels

Approaches

In developing and implementing the Medicines Policy, the main approaches would be:

- to maximize partnership between the major players: the Government including other sectors, eg economy and finance, foreign affairs, commerce, the customs, ministry of health , academics, community leaders, private sector and development partners
- to increase coordination within the health sector: public, private, international agencies and development partners
- to maximize collaboration with vertical programs to ensure integration with the national systems

- to promote inter-sectoral cooperation with other sectors such as Legal, Transport, Education, Personnel and Training Departments
- to enhance technical cooperation with other countries and international agencies such as WHO and other development partners.

II. LEGAL FRAMEWORK

The aim of this section is to provide a legal framework to allow the execution of the Medicines Policy by implementing appropriate legislation and regulations.

1. Legislation and Regulation

1.1 Legislation

- Medicines-related legislation will continue to guide the management and control of the pharmaceutical sector. Existing legislation and amendments there-of will be strengthened to support the implementation of the policy.
- Strong penalties will be included in legislation for breaches of the law including dealings in substandard and counterfeit products.
- Pharmaceutical legislation must be compatible with all other legislation affecting implementation of the Medicines Policy, either under the responsibility of the Ministry of Health or under other Government Ministries and Departments.

1.2 Intellectual Property Rights related to Pharmaceuticals

- Trade Related Intellectual Property Rights (TRIPS) compliant, health sensitive legislation will be developed to enable access to affordable medicines for the treatment of HIV-related infection, and other expensive patented medicines that are needed to address the health problems in Cambodia.
- The Government shall take advantage of all the flexibilities and safeguards within the TRIPS Agreement for the promotion of public health and ensuring access to pharmaceuticals. The Ministry of Health shall collaborate with the Ministries of Commerce, Foreign Affairs, Justice and other relevant agencies in the area of Intellectual Property Rights in developing a legal framework that enhances access to essential medicines including grant of compulsory licensing and parallel importation, local production and public use. Public health and access to pharmaceuticals must remain in the forefront while undertaking and signing any bilateral or international treaties or agreements.
- International treaties and conventions related to trade will be studied to safeguard the national interest concerning public health and ensure access to pharmaceuticals. In particular, any potential Free Trade Agreements will be examined in detail to ensure that flexibilities available under the TRIPS agreement are not affected.

2. The role of the national medicines regulatory authority

- Relevant units of the national medicines regulatory authority will continue to be responsible for registration of medicines, issuing of licences for pharmacy premises, and for the regulation of any business pertaining to the practise of pharmacy, as proscribed by the Legislation. The national medicines regulatory authority will be strengthened structurally and organisationally and empowered to implement its mandate effectively and efficiently.
- Licences or permits issued by the Ministry of Health will indicate the conditions for which they are issued.

- A Board of Pharmacists will be strengthened to implement functions as specified by the Ministry of Heath, including the registration of pharmacists and control of their conduct as well as addressing issues of conflict of interest.
- Schedules (classes) of medicinal products will be determined in order to control the sale and supply of medicinal products which may be prescribed or distributed over-the-counter and at different levels in the public, private and non-government sectors. The national medicines regulatory authority will compile, publish and update as required, a list of the schedules and the medicines included in each schedule.

3. Regulatory Affairs, Quality Assurance and Licensing

All companies (local and international) and their products must comply with proscribed national and international standards before they can be registered in Cambodia. The Registration Office will be consulted by all manufacturers intending to export medicines and medical supplies to Cambodia.

1. Those manufacturers who meet the requirements for registration by the Office will be eligible to submit products for registration as long as the products comply with national or international quality requirements as confirmed by the national laboratory.
2. The responsible Office of the national medicines regulatory authority will issue Import Licences to individuals who are authorized to import medicines and medical supplies to Cambodia.
3. The customs authority will only permit entry of products with valid Import Licences.
4. Medicine inspectors will liaise closely with customs officials in the monitoring of medicines imported into the country.

3.1. National Laboratory for Medicines Quality Control

- The National Laboratory for Medicines Quality Control is responsible for the Quality Control of health products.
- The National Laboratory for Medicine Quality Control will be strengthened to attain international acceptable standards of operations.
- The laboratory buildings, equipment and capacity will be upgraded and human resource capacity for the laboratory will be expanded, maintained and upgraded.

III. HUMAN RESOURCES

The policy aims to ensure that an appropriate number of adequately trained personnel are available to meet the needs of the Medicines Policy.

- In close coordination with the relevant departments, a strategic plan for the expansion and maintenance of the human resources needed to implement the Medicines Policy will be developed. This plan will enable human resources needs to be identified so that strategies can be developed for the selection and training of future staff required to implement the Policy.
- The Ministry of Health will strive to improve the career prospects of all pharmaceutical personnel and will encourage and support opportunities for upgrading and refresher courses for existing personnel, in order to secure their positions and develop a good human resources base.

IV. FINANCIAL RESOURCES

The policy aims to ensure that sufficient funding is made available to provide adequate quantities of quality essential medicines at the lowest possible cost; and suitable provision within the total health budget, for the implementation of the medicines policy strategies.

Requirements for financial resources will be based on the careful estimation of the total quantities of medicines (and medical supplies) needed in the country using reliable data from all sources and the demands of the strategic plan for implementation of the Medicines Policy.

V. SELECTION

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

1. Treatment guidelines and Essential Medicines List

1.1 National Therapeutic Committee

A competent therapeutic committee composed of relevant experts will be strengthened to deal with the preparation of Standard Treatment Guidelines for all common conditions prevailing in the country. Expert sub-committees may be coopted to deal with specific disease areas.

1.2. Standard Treatment Guidelines and the selection of medicines

- The Selection of medicines to be used for treatment will be based on evidence of safety, efficacy and bio-availability, cost-effectiveness and therapeutic advantage.
- To ease reference, existing Standard Treatment Guidelines will be reviewed and integrated into a compendium by a competent committee composed of relevant experts. The integrated STGs will cover all common conditions prevailing in Cambodia. The process of developing treatment guidelines will identify medicines that must be included on the national list of essential medicines.
- The treatment guidelines and list will be updated regularly to maintain appropriate treatment of prevalent diseases.
- Selection of medicines will continue to be based on generic or International Non-proprietary Name (INN). Only medicines included in the national list of essential medicines will be used in public health facilities, other than some exceptional cases at central level when medically justified. The Committee will determine the levels at which different medicines will be available: Central level, Provincial level, District level, Commune level.

2. Use of medicines in expatriate medical teams and vertical programs

- Any expatriate medical teams or individuals wishing to implement programs in collaboration with the Government of Cambodia, in which the use of medicines is a significant component, will need to consult the national medicines regulatory authority to obtain an agreement concerning the use of such medicines.

- The national medicines regulatory authority will be consulted before the introduction of disease based or vertically integrated programs (for example IMCI, STI, HIV programs, diabetic public health initiatives) in which the selection and use of medicines is a significant component.

VI. PROCUREMENT

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

1. General principles on the purchase of medicines and medical supplies for the public sector

In the public sector the procurement of medicines will 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.

Medicines will be purchased with the aim of procuring effective, good quality medicines at the lowest possible cost.

- Procedures and guidelines for efficient harmonized procurement will be reviewed and strengthened.
- Only medicines registered or approved by the Ministry of Health under special circumstances will be procured.
- Medicines will continue to be procured by generic name (International Non-proprietary Name - INN
- Medicines will continue to be procured according to the National Essential Medicines List

1.1 Local production

- Preference in procurement will be given to locally produced medicines within defined limits.
- Efficient local production of good quality, safe and effective essential medicines, relevant to national needs of the citizens of Cambodia, will be encouraged.
- Manufacturers will be encouraged and supported to comply with all statutory requirements including National and WHO Good Manufacturing Practices (GMP) for the manufacture of pharmaceutical products.
- Manufacturers will be encouraged to produce and export pharmaceutical products complying with international standards, and to develop the capacity to assess standards and comply with the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce (CPP).

1.2 Donations

Medicines donations guidelines will be developed and donation of medicines in public, private and NGO sectors will comply with the national guidelines approved by the Ministry of Health.

2. Procurement by Cambodian private sector

- Private importers of medicines will continue to be licensed to import by the Ministry of Health.

- Only medicines registered in Cambodia will continue to be procured for sale in the private sector.
- Only medicines complying with national and international quality standards will be imported by the private sector for sale in the country.

VII. STORAGE FACILITIES AND SYSTEMS

The aims of the policy are to ensure:

- *maintenance of quality and security of medicines in storage throughout the public, private and non-government sectors from the time of receipt into stock until the time of issue to the patient. Continued availability of sufficient quantities of the required essential medicines at all levels of the health system will be maintained through accurate and systematic recording, monitoring and reporting of use and stock levels of all items; and*
- *waste minimization through efficient good storage conditions, accurate record keeping and stock control. Where disposal has to be done, it will be done in a safe and environmentally sound manner.*

1. Stock management

- Storage and distribution of medicines and medical supplies to the public sector will continue to be managed centrally in an appropriate model that offers optimal efficiency structurally and organizationally.
- Pharmaceutical storage buildings and equipment, at central and lower levels, will be assessed and made adequate for the safe and secure storage of all pharmaceutical products under appropriate conditions of temperature and humidity, throughout their shelf-life.
- The Ministry of Health will endeavour to ensure the provision of sufficient appropriately trained staff.
- Medicines Management Guidelines will be updated and distributed at all level of the supply system to be used for training and guidance on all aspects of medicines management and storage.
- In accordance with these guidelines, stock will be arranged in a manner to ensure efficient management, including receipt procedures, stock rotation (FEFO), inventory control and record keeping, and distribution to facilities.
- Staff in health facilities will be provided regularly with training including accurate record keeping and stock control and maintenance by the unit of the Ministry of Health responsible for overseeing medicines management.

2. Waste management

2.1 Waste minimization

Waste will be minimized by:

- rational procurement
- adherence to good prescribing practices based on the Standard Treatment Guidelines and Essential Medicines List
- good stock management
- prevention of unsolicited donations of pharmaceuticals.

2.2 Disposal of expired and other unusable health products waste

- Appropriate guidelines for the safe disposal of expired health products and other unusable health products waste will be officially approved, disseminated and used.
- Where waste is unavoidable, it will be disposed of safely and in an environmentally sound manner in line with national guidelines for safe disposal of expired health products and other unusable health products waste.

VIII. DISTRIBUTION

The aim of the policy is to ensure the prompt, safe and efficient distribution of medicines to authorized end-users, so that the quality of the products is maintained throughout the supply chain and medicines are available when needed.

1. Distribution and sale of medicines

Only registered medicines or those authorized by the Ministry of Health will be distributed and/or offered for sale in Cambodia.

Adequate and appropriate transportation including temperature control, maintenance and communication facilities and the personnel necessary to maintain efficient operations of the public sector distribution system, particularly to less accessible areas of the country, will be ensured to facilitate the prompt, safe and efficient delivery to appropriate destinations.

1.1 Distribution of medicines in the public sector

- Medicines will be distributed in the public sector on the basis of orders supplied from the health facilities.
- Orders from health facilities will be prepared on the basis of accurate maintenance of records and documentation and medicines will be provided only according to level of health facilities.
- New facilities will be provided with kits of medicines initially and subsequent supplies will be provided on the basis of documentation as above.
- Medicines will be provided through the public sector at no charge to citizens of Cambodia.

1.2 Distribution and sales of medicines in the private sector

- Guidelines for the importation and distribution of medicines in the private sector will be developed.
- Medicines in the private sector will continue to be distributed only according to conditions stated in their licences or permits.
- A pricing policy will be developed and implemented.
- All medicines will not be distributed through unauthorized outlets.
- Storage and stock management will be in a manner that will maintain the quality of products.
- Comprehensive stock records will be kept in order to allow audits.
- Authorized medicines inspectors will undertake regular inspection of private sector premises and individuals found to contravene the law will be penalised accordingly.

IX. QUALITY ASSURANCE OF MEDICINES IN CIRCULATION

The aim of the policy is to ensure 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, effective and meet approved specifications and standards. The quality assurance system will include managerial, technical and legal aspects. Quality will be assured throughout the process of selection, procurement, distribution and use.

- The quality of medicines circulating in the public and private supply system will be monitored constantly.
- Post-marketing surveillance guidelines and procedures for the collection of samples for quality control testing will be reviewed and maintained to capture best practices.
- Procedures including strong penalties will be in place to deal appropriately with substandard and counterfeit medicines.

X. RATIONAL MEDICINES USE

The aim of this policy is to ensure that medicines are prescribed and dispensed by a well-trained health workforce and used rationally in order to maximize the therapeutic benefit to the patient and reduce loss, wastage and hazards arising from irrational practices, including larceny.

1. Education and Training

- Education and training of health workers including pharmacy workers and nurses will be ensured through relevant curricula.
- Refresher courses and other suitable continuing education activities will be maintained in collaboration with other relevant bodies.
- Specialised training will be provided for selected health workers for specific circumstances, for example in the management of malaria, tuberculosis, or of HIV infection, etc.
- Suitable training in counselling 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.

2. Prescribing

- The scope of prescribing responsibilities will be determined by levels of authorization to prescribe.
- Prescribers in all sectors, public, private, and NGOs, will only prescribe within the list of medicines determined for the level of prescriber and according to the directions of the Ministry of Health.
- The unit in the Ministry of Health responsible for medicines management will strive to 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.

3. Dispensing

- Dispensing guidelines, as part of Good Pharmacy Practice (GPP) will be strengthened and their use made mandatory.
- Medicines will be dispensed efficiently and correctly throughout the public sector according to essential medicines concepts and in compliance with the Medicines Policy

and the provisions of the pharmacy legislation including directions for packaging and labelling. The same principles will be encouraged in the private and NGO sectors.

- In all sectors medicines will only be dispensed by authorized personnel.
- All level of pharmacies will sell medicines only with prescriptions, except over-the-counter medicines as specified by Ministry of Health.
- Authorized Inspectors will make regular inspections of premises where dispensing operations are performed to ensure that the provisions of the law in relation to the practices of dispensing are being satisfied in all respects.

4. Medicines Information

- Independent and reliable, scientifically-based information supporting rational prescribing and dispensing, including Standard Treatment Guidelines, Essential Medicines Lists and other appropriate reference materials will be made easily available to health workers.
- Useful information and data on medicines and medicines utilization and pharmacy practices will be collected to identify targets for education; or the review of pharmacy practice as necessary.

4.1 Community understanding about all medicines and self-medication

- The public will be provided with unbiased and practical information on use of medicines and treatment.
- Appropriate community based training to improve understanding about medicines and self-medication will be pursued.

4.2 Pharmacovigilance

- A pharmacovigilance system will be strengthened, and include medicines adverse reactions reporting procedures. The system will be improved to attain international standards.
- Health workers and community members will be encouraged to report adverse medicines effects to easily accessible designated pharmacovigilance offices.

XI. TRADITIONAL MEDICINES

The aim of the policy is to recognise the Cambodian Traditional Medicines Policy which aims at the integration of the use of traditional medicines into the Primary Health Care system.

A separate Traditional Medicine Policy will be implemented with the aim of integrating it into the core pharmaceutical services based on the principles of Primary Health Care.

1. ADVERTISING AND PROMOTION

The aim of the policy is to ensure that advertising and promotion of medicines are of a high professional standard and conform to the requirements of the medicines legislation and regulations.

- Guidelines for medicines promotion, including ethical criteria, will be developed and circulated for distribution to all relevant parties.
- Medicines promotional activities will be in line with the aim of the Medicines Policy.
- Direct to consumer advertising of prescription medicines will continue to be prohibited.
- Advertising aimed at or involving the inappropriate use of medicines for children will continue to be unlawful.

- Medicine advertising and promotional activities will be carefully monitored to ensure that they conform to the relevant ethical criteria.
- To avoid conflict of interest pharmaceutical advertising (companies' logos, support to activities, etc) will not be associated with any Ministry of Health programs.

XII. TECHNICAL COOPERATION WITH OTHER COUNTRIES AND INTERNATIONAL AGENCIES

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

1. International and regional cooperation

Where appropriate, relevant elements of the Medicines Policy, registration procedures and development of treatment guidelines, will aim to have a common approach with those of other countries in order to facilitate international and regional cooperation and to benefit from sharing common procedures and experiences. Opportunities for regional training in all aspects of pharmacy management and practice will be explored and encouraged.

2. Technical cooperation and information sharing

Technical cooperation and information sharing will be encouraged and supported in various areas including training and staff development in all aspects of medicines management, for example:

- upgrading and maintaining communication facilities
- transfer of appropriate technology
- strengthening Therapeutic Committees
- where appropriate, using common approaches to disease management through Standard Treatment Guidelines
- evaluation of medicines
- exchange of information on pharmaceutical suppliers
- quality assurance and collaboration with regional and other quality control laboratories.

XIII. MONITORING AND EVALUATION

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

- The Pharmaceutical Sector Strategic Plan 2005-2010 and 'Good Pharmacy Practice in Cambodia 2005-2010' will be reviewed and will form the basis for monitoring and evaluation of the implementation of the Medicines Policy.
- Indicators will be defined for measurement of progress towards achieving policy objectives at all levels.
- Operational research in all aspects of Medicines Policy is one of the tools for monitoring and evaluation.