Republic of Vanuatu

National Medicines Policy

2015 - 2020

NATIONAL MEDICINES POLICY REPUBLIC OF VANUATU

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MINISTRY OF HEALTH

REPUBLIC OF VANUATU

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INTRODUCTION

The First National Medicines Policy for Vanuatu 2015-2020 will contribute to the development, provision and use of medicines throughout Vanuatu. It is recognized that medicines constitute an integral and vital part of healthcare. Vanuatu is an island nation with inherent barriers to access to medicine such as geographical remoteness, transport, limited human resources, communication and unpredictable natural disasters.

The National Medicines Policy is a framework to work within available resources and to develop the potential that medicines have to alleviate suffering and to control common diseases. On consultation with our health partners at WHO, the Vanuatu Ministry of Health, Pharmacists and Medical Practitioners in the development of the first National Medicine Policy, it has been shown that when working together much can be achieved. Eight key objectives have been identified to be the backbone of this framework. Within each are components on which we can build develop, expand and measure to give access to safe, good quality and affordable medicines throughout Vanuatu.

DEFINITION

The National Medicines Policy is an integral part of the National Health Plan.

It is the primary statement of the Government of the Republic of Vanuatu's policies, expectations and aspirations concerning the sourcing, supply and use of medicines. In this context, medicines are taken to include herbal medicines, traditional and complementary medicines, biologicals, and vaccines.

MISSION

The National Medicines Policy is a commitment to a goal and a guide for action. It expresses and prioritizes the medium to long-term goals set by the Government of the Republic of Vanuatu for the pharmaceutical sector, and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and private sectors and involves all the main participants in the pharmaceutical sector.

GOAL

To develop within the available sources, the potential that medicines have to control common diseases and alleviate suffering through health promotion, preventive and curative health services.

OBJECTIVES

I. To ensure the accessibility, availability and affordability of essential medicines to all citizens of Republic of Vanuatu
II. To ensure efficient medicines supply management system and promote good pharmaceutical practices for the selection, purchasing, storage, distribution and use of medicines
III. To ensure the acceptable quality, efficacy and safety of medicines
IV. To promote rational and cost-effective use of medicines by health professionals and consumers.

In order to achieve the objectives of the National Medicines Policy, the following components have been identified and the policy statements mentioned under each component are below

1. RATIONAL SELECTION

The essential medicines are those which are necessary to satisfy the health needs of the majority of the population. They should therefore be available at all times in adequate quantities in the appropriate dosage forms. They are to be selected with due regard to public health relevance, evidence of efficacy and safety, and comparative cost effectiveness.

1.1. Selection of medicines is essential in ensuring access to essential medicines and promoting their rational use. Selection of medicines which will be used in the public health system in the Republic of Vanuatu shall be based on the essential medicines concept of the World Health Organization (WHO).

1.2. Selection of medicines shall be made on the advice of the National Drug and Therapeutics Committee (NDTC) which is composed of experts in the medical and pharmaceutical fields necessary to enable informed decisions to be taken.

1.3. The Director General of Health shall appoint the members of the NDTC and approve the Terms of Reference

1.4. Selection of medicines shall be based on a number of criteria including the pattern of disease prevalence; treatment facilities and guidelines; financial resources; therapeutic advantage; likelihood of patient adherence; ease & safety in administration and dispensing and training and experience of the available personnel. The medicines that are selected will usually be selected from those included in the current WHO list of Essential Medicines.

1.5. Where two or more medications are available for a given indication or two or more medicines are therapeutically equivalent, the choice between them should be made following careful evaluation of their relative efficacy, safety, quality, price and availability.

1.6. Each selected medicine must be available in a form in which adequate quality, including bioavailability, can be assured; its stability under the anticipated conditions of storage and use must be established. Whenever possible, a selected medicine will have been prequalified by the WHO.

1.7. An Essential Drug List (EDL) for Vanuatu containing all medicines selected shall be maintained by the NDTC. It shall be revised at least every two years and distributed to all health personnel involved in prescribing, dispensing and administration of medicines.

1.8. The EDL for Vanuatu shall be provided by electronic copy to all visiting medical teams prior to their arrival in Vanuatu.

1.9. Suggestions for amendments to the EDL for Vanuatu are to be made in writing on the defined request form to the NDTC through the Secretary of the Committee.
1.10. Selection of medicines shall be made by generic or International Non-proprietary Name (INN) only. The labelling of the medicines must be in English, French or Bislama to ensure easy identification during use.
1.11. The Essential Medicines concept shall be promoted in the private sector.

2. RATIONAL USE

Rational use requires that patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for an adequate period of time, and at the lowest possible cost to them and their community. Rational use promotes quality of care and cost-effective therapy.

2.1. The NDTC will coordinate and monitor rational use activities in hospitals and health facilities.
2.2. The Ministry of Health, through the NDTC, will maintain, update and distribute standard treatment guidelines to provide advice on treatment of the commonly presenting conditions encountered in the country. Where applicable, existing international or regional treatment guidelines will be used.
2.3. These guidelines shall be subjected to periodic revision and updating and new editions prepared and distributed to take account of changes in current therapeutic practices.
2.4. Regular supervision and monitoring of medicines use practices in health facilities including compliance with standard treatment guidelines and essential medicines lists should be implemented by the NDTC.
2.5. All medicines are labelled and dispensed using generic names. The labelling shall contain sufficient information to ensure appropriate use by the patient.
2.6. Patient record information systems including use of medicines should be in place.
2.7. The Ministry of Health and other relevant Government departments and consumers' organizations shall develop and implement a package of rational use interventions for health providers and consumers. Clinical pharmacy practices are encouraged by the MOH to ensure rational use of medicines.

3. AFFORDABILITY AND FINANCING

Medicines should be available at a cost that the health system and patient can afford.

3.1. The Government will maintain sufficient public funding for essential medicines, through improved financial management, especially for the public sector, based on properly quantified health care needs.
3.2. Medicines will continue to be provided free-of- charge at the point of delivery at public facilities in accordance with the existing Government policies.
3.3. Generic prescribing and dispensing shall be encouraged in both public and private sectors to promote affordability and rational use of medicines by health providers and consumers.
3.4. The Ministry of Health will pay special attention to cost containment and rationalization of the use of medicines. Financial analysis of medicines expenditure should be carried out at all health care facilities regularly to identify areas where cost containment measures are needed.
3.5. The Ministry of Health shall be responsible for projecting cost of medicines from time to time and shall develop appropriate models for budgeting.
3.6. The Government shall exempt essential medicines used within the public health system from all taxes.

4. INTELLECTUAL PROPERTY RIGHTS AND INTERNATIONAL TRADE AGREEMENTS

Trade agreements and intellectual property rights should not be an impediment to access to essential medicines and achievement of public health goals.

4.1. The Government shall take advantage of all the flexibilities and safeguards within the Trade-Related Intellectual Property Rights (TRIPS) Agreement for the promotion of public health and ensuring access to medicines.
4.2. The Ministry of Health shall collaborate with the Ministry of Trade and Industry and other relevant agencies in the area of intellectual property rights in developing legal framework that enhances access to essential medicines.

5. PROCUREMENT AND SUPPLY MANAGEMENT

A well-coordinated procurement and supply system ensures that public funds available for medicines purchases are used effectively to maximize access, obtain good value for money and to avoid wastage..

PROCUREMENT OFMEDICINES

Procurement of medicines should be based on Good Procurement Practices.

5.1. Government procurement of medicines shall be limited to the EDL.
5.2. Government procurement should be based on competitive procurement methods.
5.3. Procurement procedures are to be developed and implemented. They are to be transparent setting out formal procedures throughout the process and using explicit criteria for the awarding of contracts.
5.4. Procurement should assure quality according to international standards. Priority shall be given to the purchase of medicines pre-qualified by WHO. Other medicines should at the time of purchase have current certification under the *WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.*
5.5. Donations of medicines will follow approved procedures based on the WHO Guidelines for Drug Donations.

DISTRIBUTION AND STORAGE OF MEDICINES

Medicines should be stored under appropriate storage conditions to maintain the quality and efficacy and distributed to all health facilities in the country in a prompt, efficient, timely and equitable manner.

5.6. The Ministry of Health ensures the provision and regular maintenance of adequately sized, suitably constructed and equipped storage facilities in the public sector distribution system. Where necessary, new pharmacy stores are constructed or existing pharmacy

stores should be modernized and refurbished, in order to ensure that medicines are stored in a systematic, secure and safe way, so that losses due to deterioration and expiry are minimized.

5.7. Transportation of medicines to remote areas shall be treated as a high priority activity requiring all public and private shipping and delivery companies to respond appropriately.

5.8. National and provincial governments should allocate sufficient funding for medicines distribution and transportation to ensure equity in health services.

INVENTORY MANAGEMENT

The purpose of excellence in inventory management is to ensure the constant availability without any stock-out of essential medicines. Standard operating procedures should be in place for all functions of procurement and supply management. Adequate staffing and training is supported by the MOH to ensure appropriate supply chain management throughout the country.

5.9. Appropriate inventory management systems (computerized or manual) shall be used and maintained throughout all health facilities to ensure accurate quantification and stock management.

5.10. Efficient management of stock should be maintained throughout health facilities to avoid waste and to ensure continuity of supplies.

5.11. All medicines which need to be disposed of should be disposed of in line with the approved procedures.

5.12. Where on the advice of the Principal Pharmacist pharmaceuticals are deemed as waste they must be disposed of safely and in an environmentally sound manner in line with the WHO Guidelines for Safe Disposal of Pharmaceuticals.

MEDICINES SUPPLY IN EMERGENCY SITUATIONS

Medicines donations should be of maximum benefits and they must be based on the needs of the country.

5.13. During an emergency, the Ministry of Health shall identify access and inform the donors about needs, approve donations and coordinate their receipt and distribution.

5.14. Guidelines for medicines donation should be distributed by the NDTC to main development partners.

6. MEDICINES REGULATION AND QUALITY ASSURANCE

All medicines available in the Republic of Vanuatu should be of good quality, safe and efficacious.

6.1. The Ministry of Health is responsible for overseeing all activities associated with the practice of pharmacy and the regulation of medicines, in addition to the implementation of the National Medicines Policy.

6.2. It is an aspiration of the Government of Vanuatu that medicines to be used in the Republic of Vanuatu (both public and private) should be registered for use.

6.3. It is an aspiration of the Government of Vanuatu that applicable legislation to regulate the manufacture, importation, exportation, marketing, distribution, prescribing and dispensing and use of medicines will be formulated and implemented.

6.4. Government shall allocate adequate funding to ensure the commencement of medicines regulatory functions including the assessment of the legality and quality of imported products, planning for the future licensing and inspection of products and premises.

6.5. A system for the reporting and monitoring of problems with medicines, including issues of quality, adverse reactions and medication errors should be developed and promoted. The Ministry of Health will institute a system for recall and withdrawal of medicinal products which have been demonstrated by testing or clinical assessment to be of unacceptable quality.

6.6. *WHO's Ethical criteria for medicinal drug promotion* shall be used and followed for all medicine promotional and advertising activities.

7. HUMAN RESOURCES DEVELOPMENT

Development and implementation of the national medicines policy require highly qualified and experienced professionals.

7.1. A comprehensive human resources development plan for the pharmaceutical sector shall be developed.

7.2. The Government shall ensure that adequate numbers of suitably trained pharmaceutical and stores management personnel are recruited to run and maintain public sector medicine facilities.

7.3. Appropriate in-service training programs shall be designed and implemented at different levels to enhance the skills and meet the emerging challenges and professional requirements. Health care providers and prescribers should be trained in the principles of rational medicines use and essential medicines supply management.

7.4. Funding will need to be addressed by the Government. Some training programs may need to be delivered by qualified persons from outside Vanuatu.

7.5. Career structure, bonding and remuneration will be reviewed to ensure that trained staff remains in the public sector, where they are most needed.

8. IMPLEMENTATION, MONITORING AND EVALUATION OF THE NATIONAL MEDICINES POLICY

In order to measure the effectiveness of the policy, appropriate implementation, monitoring and evaluation of systems shall be instituted by the MoHto identify possible problems and initiate corrective measures.

8.1. Implementation of this Policy should foster timely, judicious, appropriate and safe use of high quality, cost-effective medicines available to all population and thereby improve health and reduce suffering. The policy will be reviewed at five yearly intervals. Funding will need to be addressed by the Government. -

8.2. In order to implement the National Medicines Policy, appropriate legislation will be developed and existing legislation will be amended as appropriate.

8.3. A pharmaceutical strategic plan will be developed to ensure that all policy principles and statement herewith are implemented and sustained.

8.4. Suitable indicators will be selected for monitoring and evaluating the implementation of the National Medicines Policy. The monitoring and evaluation will be done every year. Initially, the key indicators will include:

- 8.4.1. Availability (%) of 30 key essential medicines in health facilities
- 8.4.2. Number of days for stock out of 30 key essential medicines (per year)
- 8.4.3. Number/value of expired medicines in health facilities
- 8.4.4. Percent of medicines prescribed from the EDL

8.5. The Ministry of Health will take part in cooperation with other ministries, departments, organizations and other countries to strengthen National Medicines Policy implementation.