ERITREAN
NATIONAL MEDICINES POLICY

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MINISTRY OF HEALTH
GOVERNMENT OF ERITREA
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ERITREAN NATIONAL MEDICINES POLICY

PREAMBLE

The Government of Eritrea is committed to the goal of health for all through primary health care as the key approach, and has formulated health strategies to achieve this goal. The infrastructures of health care services in the prevention, control and treatment of diseases, have been established throughout the country and will be strengthened from time to time.

The Government considers health development as an integral part of national development aimed at achieving a prosperous country and for every citizen to live healthy and contribute to the welfare of the society.

Medicines constitute an integral part in the prevention and treatment of diseases. The provision of medicines is by all means an important element for health care services. Medicines can promote trust and participation in health services. Any development in the pharmaceutical sector has, therefore, a social impact. Expenditures on medicines also constitute a considerable portion of health budget, that optimal utilization of resources is imperative. Safe, effective and economical use of medicines is of utmost importance in attaining the outcomes of health services.

In accordance with the objectives of health policy, a National Medicines Policy has been promulgated for implementation in Eritrea. The National Medicines Policy will serve as framework to coordinate activities in the pharmaceutical sector in Eritrea, which cover the selection, production, importation, supply, storage, distribution and use of medicines. The National Medicines Policy relates to the health system in the country, which is based on
primary health care; it includes the concept of essential medicines, with emphasis on preventive health care. Commitment and active participation of various relevant stakeholders will be of utmost importance in achieving the objectives of the policy.

**Definition of a medicine**

Medicine shall mean any substances or mixture of substances used in the diagnosis, treatment, mitigation, or prevention of a disease, disorder, abnormal physical state, or the physical symptoms thereof, in man or animal; restoring, correcting, or modifying organic functions in man or animal; or disinfection in premises.
POLICY OBJECTIVES

General
To ensure the availability and accessibility of safe, effective and good quality essential medicines to the whole population and to promote rational medicines use.

Specific

• Ensure adequate regulatory mechanisms leading to effective regulations of manufacture, importation, exportation, marketing and use of essential medicines by strengthening the system of medicine registration, licensing of pharmaceutical premises and pharmacy practitioners, inspection and control.

• Ensure the availability of safe, effective and good quality medicines at the lowest possible cost.

• Promote the rational use of medicines by prescribers, dispensers, patients and community through provision of necessary measures including training, education and information.

• Increase the efficiency of medicine procurement and distribution.

• Reduce losses and wastage.

• Improve the knowledge, and management skills of pharmaceutical personnel.

• Encourage private investors to participate in the manufacture, importation and distribution of medicines.

• Promote and support the local production of essential medicines.

• Incorporate the principles of National Medicines Policy in the medical, paramedical and pharmaceutical education.

• Promote research in priority areas related to medicines.

• Optimize the use of available resources through co-operation with international and regional agencies.
• Document and identify the widely used traditional practices and traditional medicines in order to establish their safety and efficacy.

POLICY AREAS

1. Executive Body
1.1 The Department of Regulatory Services will be the body entrusted to co-ordinate and supervise the implementation of the National Medicines Policy. In order to be able to carry out its functions effectively, it will have the necessary structure, facilities and resources.

1.2 As this body requires the support of advisory council and clearly defined legal proceedings for enforcing the regulations, an advisory council and other necessary committees will be appointed by the Ministry of Health.

2. Legislation and Regulations
Proclamation no. 36/1993 will be revised to reflect the requirements of the National Medicines Policy and will include all the elements of a medicine law relevant to the country. The revised act will be supported by a number of regulations, specifying standards, requirements, fines, fees etc.

The law will have provisions that support, promote and when necessary enforce rational prescribing and dispensing. Instruments to promote this include National List of Medicines, the Standard Treatment Guidelines (STG) and others.

2.1 Inspection
The legislation and regulations will be supported by an adequate and effective inspection under the direction of the Department of
Regulatory Services. Inspection guidelines will be developed. Most inspection functions (e.g. inspection of government depots, hospital stores, private pharmacies,) will be gradually devolved to zonal authorities, with a few specialized inspection functions (e.g. inspection of manufacturing facilities and wholesale premises) retained at the national level. In order to strengthen inspection, adequate number of inspectors with the required knowledge and skills will be assigned.

2.2 National Medicines Quality Control Laboratory
The national medicines quality control laboratory established within the Department of Regulatory Services will be adequately equipped and staffed for assessing the quality of medicines in the national medicines distribution system. Collaborative relationship with other quality control laboratories will be established.

2.3 Registration of Medicines and Medical Supplies.
Formal medicines registration system will be strengthened so that only medicines which are registered in Eritrea or in countries that have collaborative agreements with Eritrea may be imported, produced, stored, exported and sold.

The Department of Regulatory Services will ensure periodic and regular publication and wide dissemination of the list of registered medicines.

Registration procedures based on quality, efficacy, safety, and needs will be adopted through the introduction of:
• a five year re-licensing system for medicines
• computerization of the evaluation system
• an evaluation report exchange system with reputable regulatory bodies in other countries
• prioritization of registration based on need
• fast track procedures for essential medicines, and
• norms and standards for registration of medical devices.

A National Medicines Advisory Council supported by committees appointed by the Ministry of Health composed of persons with the
widest possible representation will be set up to advice the medicines regulatory authority on matters relating to registration of medicinal products and cancellation or suspending of such registration, based on evaluation of quality, safety and efficacy.

2.4. Registration and Licensing of Pharmacy Practitioners
Registration, classification, and licensing of pharmacy practitioners will be carried out by the appropriate body.

Pharmacy practitioners will be licensed if they are to practice in community pharmacy. Priority and encouragement will be given to pharmacists and pharmacy technicians who would want to own and run their retail outlets. However, ownership of private retail outlets by non-pharmacy professionals will be permitted.

2.5. Registration and Licensing of Premises
All medicines manufacturing, import, wholesale and retail enterprises as well as quality control laboratories, trading agencies and scientific offices will be established only if they are licensed. The enterprises should be operated under the technical responsibility of a licensed professional only.

2.6. Narcotic Drugs and Psychotropic Substances
A national committee consisting of members from different organizations will be set up to carry out a coordinated control on narcotic drugs, psychotropic substances and precursor chemicals on the basis of international conventions.

2.7 Clinical Trials
Clinical trials on medicines will be carried out in compliance with Good Clinical Practice Guidelines of the Ministry of Health and the WHO "Model of items to be included in a clinical trial protocol."

2.8 Advertising and Marketing of Medicines.
Promotion or advertising of medicines to the general public will not be permitted. They will be restricted to medical, pharmaceutical, dental, and veterinary professionals only. In order to ensure that promotion of medicines to health professionals comply with the National Medicines Policy and regulations, all promotion-making claims should be reliable, accurate, informative, balanced, up-to-date, capable of substantiation, and in good taste. They will not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable medicine use or to give rise to undue risks.

Promotion or advertising of medicines to health professionals will be carried out by qualified persons who are registered and licensed by the Ministry of Health.

Promotion in the form of financial or material benefits will not be offered to or sought by health care practitioners to influence them in the prescribing of medicines. Scientific and educational activities shall not be deliberately used for promotional purposes.

Ethical criteria and guidelines for the promotion and advertising of medicines will be established, widely disseminated and strictly enforced. The Ethical Criteria for Medicinal Drug Promotion adopted by the World Health Assembly (WHA) and the Pharmaceutical Manufacturers Association (PMA) Codes of Marketing Practice will be considered in the development of the national criteria.
3. **Selection**

3.1 **Eritrean National List of Medicines**

The objective of the Eritrean National List of Medicines is to have a list of essential medicines rationally chosen to satisfy the health care needs of the population.

- The Eritrean National List of Medicines will be used as an instrument for:
  - production, procurement, prescribing and dispensing of medicines
  - standard treatment guidelines and training in rational prescribing
  - medicines information to health care providers, including a national formulary, and
  - medicines donation.

The list will be reviewed at least every three years. A National Medicines Committee composed of experts in all spheres of medical and pharmaceutical practices, including clinical pharmacists and pharmacologists, medical specialists, professional nurses from community practice, health professionals involved in primary health care, a member of pharmaceutical information centre etc., will be responsible for reviewing the Eritrean National List of Medicines.

Adherence to the list in procuring or prescribing medicines is a legal requirement. However, in exceptional cases the MOH may consider application for permission to obtain non-listed products on condition that the request has the support of the Department of Health Care Services.

3.1.1. **An Essential List of Medical Supplies and Equipment**

An essential list of medical supplies and equipment for each level of medical institutions will be formulated and be made available.
4. Supply

4.1 Procurement

The aim of effective procurement is to ensure an adequate supply of effective and safe medicines of good quality to the whole population at the best possible price.

There will be a system by which the most reliable suppliers in terms of quality, efficacy, delivery and price of medicines and medical supplies could be selected. Tenders will be called for by generic name only. Preference will be given to products labeled by generic name; in all other cases the generic name must be printed immediately above or under the trade name, in a letter type at least as large as that of the trade name.

Adequate financial resources will be made available for the procurement of medicines and medical supplies for the public sector.

Medicines procurement and distribution will be limited to the medicines registered in Eritrea and on the Eritrean National List of Medicines.

Public and private enterprises will be permitted to import and distribute medicines and medical supplies in accordance with the regulations and guidelines laid down by the government. In order to keep prices low and undertake adequate quality assessment, medicines should as much as possible, be purchased in bulk.

The annual budget for procurement of medicines in the public sector will be based on proper quantification of estimates based on the population served, morbidity and related to consumption data.

4.2. Local Manufacture of Medicines.
The government will create favorable conditions for the establishment and development of local pharmaceutical industry so as to promote self-reliance in the production of essential medicines. Private investors will be encouraged to participate in the manufacture of medicines on their own.

The government will provide the necessary support and encouragement to manufacturers directly or indirectly involved in the production of raw and packaging materials for medicines. Production and marketing of essential medicines by their generic names will also be encouraged.

The national pharmaceutical manufacturing industry will receive a price preference as recommended by the State Tender Board regulations and conditions. The export of locally manufactured medicines will be encouraged.

The local manufacturing of pharmaceuticals will comply with the WHO guidelines for GMP and inspections will be carried out regularly by the inspectorate of the Department of Regulatory Services in order to ensure compliance with GMP.

4.3 Quality Assurance

The quality of medicines in the public and private sectors will be assured through adequate procedures for medicine registration, licensing, prequalification of suppliers, supplier monitoring, inspection and medicines quality control.

The following measures, additional to those already described, will apply:

- Guidelines for donated medicines, to follow WHO guidelines for medicines donations. Donated medicines will
  - match the health needs of the country and hence appear on the Essential Medicines List
  - be compatible with overall government policy
  - be of appropriate quality, efficacy and safety
4.4 Financing
The objective is to develop a system of joint responsibility between the government and the patient for the financing of medicines. However, in line with the National Health Policy, the government will ensure that essential medicines are available to all people in need. To this end, medicines will be provided at a nominal price at the point of service at the primary care level.

The annual budget for procurement of medicines in the public sector will be based on proper quantification of estimates based on the population served, morbidity and related to consumption data.

All medicines at the primary care level will be provided at a nominal price. At the secondary and tertiary levels a fixed affordable co-payment for medicines supplied by the State will be levied. A system of exemption will be established for patients
without the resources to meet such payment to ensure they are not deprived of treatment.

4.5 Pricing
The government will ensure that essential medicines are available at prices that are affordable to the majority of the population and that fair pricing practices are observed by the manufacturers, wholesalers and retailers. The Ministry of Health will act in collaboration with concerned organizations to ensure that medicines are available to the public at their legal prices.

There will be total transparency in the pricing structure applied to pharmaceutical manufacturers, wholesalers, retail outlets, and service providers. Selling prices will be labeled in all medicines at retail outlets.

4.6 Distribution
The objective of distribution is to ensure the prompt, efficient, timely and equitable distribution of essential medicines and medical supplies to all people in Eritrea.

The distribution of medicines and medical supplies to outlets will ensure the speedy and efficient replenishment of their stock. Standard lists based on levels of use will be established.

The distribution of cold-chain items such as vaccines will be the responsibility of public sector depots, according to EPI guidelines.

The distribution of medicines and medical supplies from the National Medical Stores to the Zonal warehouses will take place at regular intervals. The zones will make their own distribution arrangements to ensure that medicines and medical supplies are distributed in the most cost-effective manner.

All medicines purchased or donated to government at all levels will be channeled through the National Medical Stores. Medicines supplies to public health facilities will be based on expressed
need. Returned non-expired stock and re-usable items will be redistributed as necessary.

Computerized inventory control systems will be established in all zonal warehouses. These systems will be linked to computerized inventory control systems in the Logistic Management Information System (LMIS) of the Department of Regulatory Services.

The private sector will participate in medicines distribution system in an equitable and efficient manner. Private importers and wholesalers are required to keep adequate stocks of their products at all times. For effective inventory control, computerization of private medicine distribution channels will be encouraged.

4.7 Storage and Safeguarding of Medicines

*In order to ensure the maintenance of quality and security of medicines and medical supplies in storage from the time of receipt into stock up to the time of issue to the patient, the following steps will be taken:*

- Guidelines will be developed to enforce appropriate storage facilities.
- Standard operating procedures (SOPs) will be developed with practical guidelines to cover all administrative procedures to manage and control effectively the storage and distribution of medicines and medical supplies, including methods to define minimum and maximum stock levels, guidelines on systematic stock rotation and handling of expired and obsolete stock. These SOPs will be used for training and supervision of staff and will be updated regularly.
- Effective and standardized security systems will be developed and implemented in all public sector depots.
- Appropriate inventory control and stock management systems will be established in all medicines stores and health facilities.
Central and zonal warehouses will be assisted in drafting long-term plans for the rationalization and upgrading of depots, including plans for the reconstruction or replacement of existing facilities.

4.8 Disposal of Expired and Unwanted Medicines

In order to ensure that all unwanted and expired medicines, medical supplies and associated waste are disposed of promptly, efficiently and safely:

The Ministry of Health, in co-operation with other concerned bodies will ensure that appropriate methods are applied for the removal and disposal of expired and returned stock, medical supplies and medical waste.

The government will ensure through legislation that the removal and/or disposal of medicines and medical supplies and medical waste takes place in such a manner that is neither harmful nor dangerous to the community or environment. It will ensure that appropriate physical disposal facilities for safe disposal are instituted.

Authorized inspectors will carry out regular inspections to ensure that the disposal of unwanted items takes place according to prescribed guidelines, which will carry a penalty for infraction.

5. Rational Medicines Use

The objective is to promote the rational prescribing and dispensing of medicines by medical, paramedical and pharmaceutical personnel and to support the informed and appropriate use by the community.

This will be achieved through appropriate measures including training, provision of scientifically validated medicine information for professionals and the community, establishment of hospital therapeutic committees, good dispensing practice and an
enhanced role for the pharmacy professionals, and control of commercial marketing practices.

5.1 Use of Generic Medicines
The use of generic name or the International Non-proprietary Name (INN), is a recommended step to reduce medicines cost and expenditure. It also contributes to a sound system of procurement, distribution and medicine information at every level of the health care system.

Prescriptions in both the private and public sectors will be written using the approved name (INN). Generic substitution will be allowed, through legislation, in the public and the private sectors. The Ministry of Health will prepare and disseminate regularly the list of equivalent generic names of branded products.

5.2 Appropriate Prescribing
The aim is to ensure that medicines are prescribed correctly by appropriately trained and duly authorized personnel according to the essential medicines concept.

All medicines will be prescribed by generic name in accordance with recommended Standard Treatment Guidelines and the Eritrean National List of Medicines.

Standard prescription forms will be instituted by the Ministry of Health for different levels of health care facilities.

The Ministry of Health will collect, evaluate and disseminate systematic data on medicines utilization to monitor and act on policy adherence. Appropriate indicators will be developed and field-tested for this purpose.

5.3 Scheduling of Medicines.
The Ministry of Health will prepare a classification schedule of medicines in which each class of product will be approved for use:
• to be dispensed upon prescription;
• to be handled by pharmacy, drug shop, and rural drug vendors;
• standard lists for the different levels of health institutions and for other purposes.

Furthermore, there will be a list of classifications for chemicals, poisons, radioactive materials and other products as necessary. The control and proper usage of these products will be conducted based on guidelines in collaboration with concerned stakeholders.

5.4 Medicines Information Services

The objective is to ensure the provision of practical and scientifically validated information on the correct handling and rational use of medicines to health personnel at all levels, including community pharmacists, as well as to patients and the general public.

Medicine information services will be provided to ensure the dissemination and utilization of practical, unbiased information on the correct handling and rational use of medicines to health workers at all levels, patients and the general public.

5.4.1 Information to Prescribers and Dispensers

To facilitate the collection, compilation and dissemination of scientifically validated information on medicines, the Ministry of Health will establish and maintain an appropriately equipped and staffed Pharmaceutical Information Service under the supervision of the Department of Regulatory Services which will be gradually developed and expanded to include Adverse Drug Reaction Monitoring and Poisons Information Service.

Regularly updated Standard Treatment Guidelines for treatment of common conditions with essential medicines will be produced by the MOH.
The MOH will also produce a national formulary based on the Eritrean National List of Medicines for distribution to all health care providers and dispensers. This publication which will be revised periodically will include guidelines to good dispensing and prescribing, together with information on medicine interactions.

Adherence to Standard Treatment Guidelines and Eritrean National List of Medicines will be monitored regularly.

Periodical medicine bulletins which contain latest information of new or established medicines, new developments in regulatory actions etc., will be produced and widely distributed.

5.4.2 Information for Patients and the General Public
The public will be provided with access to objective, validated and practical information on medicines and their proper use, written in lay language.

Information for the public on subjects including disease prevention, limited self-diagnosis, appropriate and inappropriate self-medication and suitable alternative non-medicinal treatment, and communication with health care providers, will be promoted through all available communication media. This will include community organizations and traditional medical practices.

A partnership among government, industry, health workers, professional association, the public/consumer and academic institutions will support this campaign.

The Ministry of Health will collaborate with other bodies responsible for school, adult literacy and other educational programs to integrate into the curriculum basic education that will lead to a better appreciation of the benefits and limitations of the role of medicines in health care.

5.4.3 Adverse Drug Reaction (ADR) Monitoring
The Ministry of Health will develop a program for surveillance of medicines marketed in the country. Information on Adverse Drug Reactions will be widely circulated to relevant parties.

5.5 Therapeutic Committees
In order to ensure rational, efficient and cost-effective supply and use of medicines in health facilities in the country, the Ministry of Health will promote the formation of and facilitate the effective functioning of Therapeutics Committees.

Therapeutic Committees will be established in all hospitals. Membership of such committees will comprise representatives of pharmaceutical, nursing, medical and administrative services of the institution.

- A Therapeutic Committee will, among other duties, be responsible for:
  - the selection of medicines for use in the institution, based on the Eritrean National Medicines List.
  - the accurate estimation, prompt procurement and optimal storage and supply of medicines and medical supplies.
  - the establishment of Standard Treatment Guideline for health facilities and monitoring adherence to it.
  - the compilation and preparation of a medicine formulary
  - rational medicines use in the institution
  - documentation, reviewing, monitoring, reporting and feedback of adverse drug reactions

5.6 Dispensing
The objective is to ensure that medicines are dispensed efficiently and correctly by appropriately trained and duly authorized personnel according to the essential medicines concept and recommended dispensing practices.

The Ministry of Health will establish Good Dispensing Practices Guidelines. It will institute and maintain a system for the
monitoring and evaluation of dispensing practices in order to ensure the provision of efficient and cost effective and safe dispensing services.

6. Veterinary Medicine
Regulations and guidelines concerning veterinary medicines will be developed by concerned Ministry in accordance with the National Medicines Policy.

Particular care will be taken to prevent adverse effects on human health due to residual concentration of medicines in food products of animal origin used for human consumption.

7. Traditional Medicine
Documentation of the practice of traditional medicine in Eritrea will be conducted by the Ministry of Health in collaboration with other appropriate organizations to find out the patterns of use, and also to identify the beneficial and harmful effects.

Marketed traditional medicines will be documented, registered and controlled.

Traditional healers will be encouraged to get organized in collaboration with the Ministry of Health, in order in the long term to compile and develop a “Code of Practice”. They will also be encouraged to co-operate with other workers in the formal health sector.

8. Human Resources Development
In order to support the successful implementation of the policy and to promote the concepts of essential medicines and rational medicine use and ensure their adoption
throughout the country, the necessary expertise and human resources should be developed.

Adequate number of all health professionals will be trained; and because of their special role in the implementation of the National Medicines Policy, the training of adequate number of pharmacy professionals intended for both the public and the private sectors will be taken as one of the priorities in training.

Formal pharmaceutical training should be based on the requirements and health needs of the country.

A systematic and comprehensive program of refresher courses and other suitable continuing education activities will be developed and implemented. Various incentives and conducive career structures for professionals will be instituted in accordance with the characteristics of the job and post.

The concept of the principles of essential medicines, rational medicines use and primary health care will be reflected in the training curricula of medical, paramedical and pharmaceutical personnel.

9. The Role of Pharmacy Professionals

Although all health care providers and the public are involved in the rational use of medicines, WHO has recommended a special role for pharmacy professionals, particularly in quality assurance, effective medicines management and safe and appropriate use of medicines. Pharmacy professionals will be in a strong position to promote the rational use of medicines through their extensive knowledge.

Pharmacy professionals, particularly those in the community, have a special role in educating the community about the correct
use of medicines. Professional associations will be encouraged to develop coordinated programs to facilitate and further this role.

Pharmacy professionals will be involved in multi-disciplinary approach to the rational utilization of medicines. Greater co-operation between pharmacy professionals and other health professions within the communities and hospitals should be encouraged to facilitate the rational use of medicines. They also have a critical role to play in primary health care and preventive health services.

Pharmacies will be required to have available scientific sources of reference. They will also require access to additional essential information from a central pharmaceutical information system.

The policy will also aim at expanding and standardizing the training of pharmacy technicians and other pharmaceutical support staff. Pharmacy technicians will be prepared for certain tasks in hospital pharmacies under the supervision of pharmacists, and managing medicines supply in primary care clinics under the indirect supervision of a zonal pharmacist.

10. Research and Development.

The objective is to promote research that will facilitate the implementation of the National Medicines Policy.

The Ministry of Health will support and encourage operational researches that can promote the successful implementation of the monitoring and evaluation of the National Medicines Policy. The findings of such researches will be used to make necessary adjustments in strategy and to ensure that policy objectives are achieved.

- Research will focus particularly on the following areas:
- the impact of the NMP and its core principles on health service systems and delivery
• problems related to prescribing and dispensing at different levels of the health system
• economics of medicine supply (procurement methods, stock management, distribution etc.)
• socio-cultural aspects of medicines use, including self-medication, acceptability and use of supply systems, and knowledge, attitudes and practices of users of medicines, and
• quality assurance of pharmaceuticals at all levels.

11. Technical Co-operation with Other Countries and International Agencies

The objective is to ensure that all relevant forms of technical co-operation are explored and promoted to maximize the effective use of limited resources.

The aim will be achieved through effective technical co-operation with international agencies, such as the WHO, and the maintenance and strengthening of the co-operation.

Possibilities for further international and regional collaboration will be systematically identified.

Co-operation, particularly in the following areas, will be encouraged and supported:
• evaluation and registration of medicines
• regional procurement systems and the exchange of information on pharmaceutical supply source
• quality assurance and collaboration with regional and other medicines quality control laboratories
• production and formulation of medicines
• transfer of appropriate technology
• research and development
• studies on medicines utilization
• exchange of pharmaceutical information
• training and human resources development
• control of drug abuse, and
• emergency situations, such as epidemics and diseases.
The guidelines and recommendations of the WHO will be followed wherever possible.

12. Monitoring and Evaluation
Mechanisms for monitoring and evaluation of performance and impact of the National Medicines Policy will be established.

• Indicators for monitoring the NMP will be compiled and will form part of the national health information system. These indicators will conform to internationally agreed standards, e.g. that of WHO.
• Progress in NMP implementation will be monitored at regular intervals.
• A full evaluation of the NMP will take place every three years.

CONCLUSION
A National Medicines Policy has been developed for Eritrea. It covers the wide range of activities which contribute to the effective production, supply, storage, distribution and use of medicines. Its successful implementation depends on a commitment to its principles by all role players and stakeholders. This commitment must be manifested to include active participation in the process of initiation, implementation, review and modification to ensure that the people of Eritrea receive the medicines they need at a cost that they and the system as a whole can afford.