PNACD-713

98695

COMMENTS ON ERITREA'S NATIONAL DRUG POLICY

Budiono Santoso, MD, PhD, DSFK

October 6-20, 1997

BASICS Activity Code 017-ER-01-035
USAID Contract No HRN-Q-19-93-00032-00

A

TABLE OF CONTENTS

B

ACRONYMS

ADR	Adverse Drug Reaction
BASICS	Basic Support for Institutionalizing Child Survival Project
DPS	Department of Pharmaceutical Services
INRUD	International Network for the Rational Use of Drugs
MOH	Ministry of Health
NDP	National Drug Policy
OTC	Over the Counter
SOP	Standard Operations Procedures/Practices
USAID	United States Agency for International Development
WHO	World Health Organization

INTRODUCTION

In the process of the national drug policy (NDP) development, the Ministry of Health (MOH) of Eritrea appointed a committee to draft a policy document in 1995 The committee composed of health professionals from within the MOH and representatives of health associations in Eritrea

For the purpose of NDP development, an assessment of the situation in pharmaceutical sector has also been undertaken by the committee The draft policy was developed, taking into account the existing situation of pharmaceutical sector in Eritrea, which derived from the assessment

A draft policy document has been completed by the committee and subsequently has been reviewed in consultations with various parties from within the MOH and other relevant bodies However, prior to formal endorsement of the NDP by higher authorities within the government, review and consensus from wider audiences representing government bodies, health care providers, consumers, professional associations, and other relevant stakeholders are to be pursued in order to get support from all interested parties A national workshop on the national drug policy would be an appropriate forum for such review and consensus building

Input from external consultant was considered necessary for the final review and for the NDP workshop, in order to reflect relevant experiences from other countries in the final draft of the policy The consultant, therefore, has been involved in the review process before and during the workshop, and in the preparation of the final draft The final document then will be submitted to the government for the further approval process and promulgation

PURPOSE OF ASSIGNMENT

The overall objective of the assignment was to assist the MOH (Department of Pharmaceutical Services, DPS) in reviewing and finalizing the draft NDP and to prepare a consultant report for BASICS, in order to follow up the task

The scope of work to be performed included the following tasks

1 Work with designated counterparts in the MOH, i e , DPS, in the review and discussion of the draft NDP

2 Hold meetings with the MOH, DPS committee, and the former drafting committee to comment on and recommend policy provisions as they relate to Eritrea, and provide input from the report of a WHO expert advisory panel on drug policies and management

3 Recommend relevant legal/technical matters concerning the NDP

4 Submit to the MOH recommendations and options concerning the NDP

5 Play a role in defending, verifying, and directing the national NDP workshop

6 Modify and edit the draft according to the amendments and suggestions to form a final NDP document for submission to the higher authorities concerned

ACTIVITIES UNDERTAKEN

Review of NDP Draft Document

During the consultancy period, the consultant had several meetings within the DPS with Mr Johannes Embaye (director general), Mr Bernardos KW (head of Drug Management Division), Mr Asgedom-Mosazghi (head of Drug Control Division), Dr Besrat Hagos (head of National Drug Quality Control Laboratory), Mr Embaye Andom (head of Drug Information Services), Mr Zeccarias (head of Drug Inspection), and Mr Iyasu Bahta (head of Licensing) Reviews and discussions on the NDP draft were undertaken mainly with these parties to prepare a revised draft document to be used for the national workshop

A number of modifications were agreed upon during this review, for instance, the addition of a ***Preamble*** and the rearrangement of the sequence of the ***Specific Objectives,*** in order to reflect the priorities on health-related objectives of the policy Some amendments on the policy elements were also agreed upon to make them coherent with the objectives

In the review process, efforts were made to refer to the relevant publications from the World Health Organization, or from experiences in other countries But any provisions, amendments, or additions in the draft policy were based on the existing situation of the pharmaceutical sector in Eritrea

National Drug Policy Workshop

The consultant was involved in the workshop on the Eritrean NDP, which took place on October 13-14, 1997, at the Selam Hotel Inputs and suggestions regarding the designing of the workshop were proposed and discussed with counterparts Terms of reference for the workshop and guidelines for group discussions were prepared and agreed upon, these were distributed during the workshop to provide direction in the review and discussions The workshop was attended by more than 100 participants, representing health care providers, professional associations, the MOH, health care facilities, the private sector, nongovernmental organizations (NGOs), and so forth

The workshop was inaugurated by Minister of Health Dr Salih Meki, who emphasized in the importance of the NDP as part of the national health policy, and to ensure the accessability, quality, and affordability of essential drugs for the population in Eritrea The minister participated in the discussions on major issues of the NDP during the two-day workshop

After a plenary presentation, participants were divided into six groups and then the groups were independently assigned to review and discuss certain sections of the draft NDP, as follows

Groups I and II	*Preamble, Policy Objectives, and Policy Areas*
Groups III and IV	*Selection and Supply of Drugs*
Groups IV and IV	*Rational Dug Use, Traditional Medicines, Veterinary Medicines, Human Resource Development, Research and Development, Technical Cooperation with Other Countries and International Agencies, and Monitoring and Evaluation*

Each group reviewed and discussed the draft policy, led by a selected chairman and facilitated by an assigned facilitator Review and discussion were referring to the existing situation in Eritrea NDP documents from other country (e g , Tanzania) and relevant documents from WHO were also made available for reference Each group proposed comments and suggestions based on their review

Comments and suggestions, including modifications, additions, and deletions to the draft policy from each group were presented and discussed in a plenary session during the second day of the workshop Some suggestions were accepted by the plenary forum and were incorporated in the revision to produce a final draft document

After the workshop, the consultant and the DPS prepared and edited the final draft of the national drug policy, based on the consensus made during the workshop (The final draft NDP document is enclosed as the appendix)

Visits to Health Facilities

Visits and observations of health facilities were made by the consultant to have more insight and understanding about the real situation related to pharmaceuticals and health in Eritrea Visits were made to the following institutions

- Pharmecor, a parastatal agency responsible for drug procurement and distribution in the public and private sectors in Eritrea
- Central Medical Store, responsible for handling and distributing donated drugs
- Edaga-Hamus Mini Hospital, a 30-bed mini hospital located in Asmara
- National Drug Quality Control Laboratory
- National Hospital

Pharmecor is a parastatal agency that operates like a private company It deals in the procurement and distribution of drugs, medical supplies, and laboratory chemicals for public, private, and army institutions The procurement of drugs is entirely based on the National List of Essential Drugs The quantification is based on previous consumption, since no morbidity-based estimates are available In general, the storage management is fairly satisfactory, although it employs a manual system The storage space, however, is very limited and should be expanded in some way within the next two to three years

Central Medical Store handles drugs and supplies deriving from donations It employes a computer system for its drug management In general, the storage management is satisfactory No problematic donations are enountered, as often the case in many other developing countries

Edaga-Hamus Mini Hospital is well-managed, clean, and neat The drug management and drug storage practices are satisfactory There are no shortages of pharmaceuticals in the pharmacy This hospital employs four physicians, one head nurse, four nurses, two midwifes, one dental technician, one technician, one pharmacy technician, and seven health assistants Director Dr Efram is well aware of the importance of the effective, safe, and economical use of services, as well as an efficient supply of pharmaceuticals, and will keep maintain the standard quality of drug use and care services

The National Drug Quality Control Laboratory is a newly established laboratory facility, equipment is still being installed Quality control sampling and testing have not been routinely done, but, according to Dr Besrat, they have already made a plan for sampling, which may begin in 1998 or as soon as the instruments and chemical reagents are ready One of the staff is undergoing training in South Africa The facility has a link with similar laboratories in neighbouring countries (Kenya, South Africa), as well as in United Kingdom, where they can refer testing if necessary and some samples have been sent to these laboratories by the National Quality Control Laboratory The laboratory facilities will be sufficient to serve for the quality control of drugs in Eritrea Microbiological and biological testings are not performed by this laboratory at the present stage

The National Hospital is a referal centre for the whole of Eritrea It consists of 550 beds and employs 38 doctors The services cover pediatrics, internal medicine, gynecology, surgery, and general medicine The discussions with Director Dr Habte-ab were about the problems of drug utilization and the possibility of forming a Hospital Therapeutic Committee in the facility The importance of rational use of drugs was well appreciated by the director Although there currently is no Hospital Therapeutic Committee in the facility, a regular meeting among the physcians has been undertaken to discuss and to review problems related the medical services, including the use of drugs There are no objections or obstacles in forming a Hospital Therapeutic Committee, as required by the future policy to deal with problems of drug utilization in the hospital

The observations in these facilities were later given to the DPS as feedback

REVIEWS, COMMENTS, AND NDP IMPLEMENTATION ISSUES

This section reports relevant comments made during the review and during discussions on the NDP draft policy, especially regarding implementation issues

Preamble

The preamble was added to the draft policy during the review process prior to the workshop In it, the commitment of the State of Eritrea's goal for health for all is clearly stated, as is the importance of the national drug policy as an integral part of health policy in achieving the goal In the context of national development, thus, the NDP is in the frame of health development policy

Policy Objectives

The general objective of NDP is *to ensure the availability and accessability of safe, effective, and good quality essential drugs to the whole population and to promote their rational use* There are a number of specific objectives of the policy which were discussed and reviewed The consensus was that the sequence of these specific objectives should reflect the priority of the *health-related objectives*

Executive Body

The DPS is the government body entrusted to coordinate and supervise the implementation of the NDP In order to carry out this function, relevant advisory council or committees are to be established and/or appointed by MOH It is well accepted that for the implementation of the NDP, collaborative relationships between the Department of Pharmaceutical Services and other bodies from within and outside MOH are of great importance and need to be maintained in the future

Inspection

Some inspection functions under the DPS will gradually be devolved to the zonal level, reflecting the policy to decentralize the implementation of one of the policy functions However, a few specialized functions need to be retained at the central level, for instance, the inspection of manufacturing facilities and wholesale premises

Decentralization should be selective Indiscriminate decentralization of all functions only creates chaos in the pharmaceutical sector, as has often happened in some developing countries This issue has been properly dealt in Eritrean NDP

National Drug Quality Control Laboratory

A provision for the National Drug Quality Control Laboratory is included in the policy, an important policy element to ensure the quality of drugs in the country Guidelines for implementation should be made available Planning, as well as implementation of this function, should be evaluated and monitored from time to time In some countries, drug quality control functions are often neglected or not implemented due to a lack of resources, or weaknesses in planning and monitoring From discussions with the head of the National Drug Quality Control Laboratory, plans for sampling and drug quality testing have already been made

Registration of Drugs and Medical Supplies

The policy requires that a registration system for drugs and medical supplies will be established and implemented in Eritrea Evaluation of drugs and medical supplies will be done on the basis of quality, efficacy, safety, and need

At present, there are only essential drugs in Eritrea, with a limited number of brand products Therefore, it is more feasible to start the registration process with drugs For this purpose, a mechanism and guidelines need to be developed and made available to concerned parties A computer system for drug registration developed by WHO can be adopted and utilized A Drug Evaluation Committee consisting of relevant experts, i e , pharmacological, pharmaceutical, and clinical, needs to be formed by the MOH, under the coordination of DPS

Clinical Trials

Performing clinical trials of drugs in Eritrea will require special permission from MOH In addition, clinical trials should conform with WHO guidelines on good clinical practice In the long run, the MOH will have a special committee to review applications and protocols of clinical trials to be conducted in Eritrea This provision is aimed to avoid the misuse and misconduct of clinical trials by unauthorized and incompetent parties, as is often the case in many developing countries

Advertising and Marketing of Drugs

The promotion of drugs to the general public will not be permitted since there is no scheduling on OTC products Promotion of drugs to health professionals should conform with the national and ethical criteria and guidelines, which are to be established These guidelines will take into account the WHO ethical criteria for medicinal drug promotion Experiences from different countries show, that although there are such national criteria and guidelines, the control and monitoring of promotional activities are not always consistently implemented

Educating the health professionals to make them more competent and critical in justifying promotional informations is also an important strategy to minimize the unwanted impact of pharmaceutical promotions on drug use

Selection of Drugs

The National List of Essential Drugs will be the basis for drug selection in the country, from drug production, procurement, use, and information Drug donations should conform with the national list Adherence to the list in health facilities will be enforced and monitored from time to time The list of essential drugs, therefore, should be introduced to health professionals and made available to them in their professional practice This list should also be reflected in their inservice training

There was a proposal to revise the national list every two years, however, it was not accepted during the workshop since it is not practical or feasible

Import and Local Manufactures

Private enterprises will be permitted to import drugs, but only those on the national list The government will also encourage the private sector to participate in the manufacture of drugs, especiallly the essential drugs A price preference will be given to local manufacturers The provision may be regarded as a commitment from the government to gradually give a greater role to the private sector in pharmaceuticals

Drug Financing

A kind of cost sharing or co-payment scheme will be implemented for pharmaceuticals at various levels of health care At the primary health care level, drugs will be supplied at a nominal price and an exemption system will be established for those patients who can not afford to pay It should be noted, that any cost-sharing or co-payment schemes should not replace the commitment of the government to provide essential drugs, especially in primary health care facilities Such financing schemes should complement the government's commitment for financing

In a separate discussion with Minister of Health Dr Salih Meki, information about the cost of care (including pharmaceuticals) will be made available for providers and patients In order to explore the impact of providing this cost information, it is appropriate to have a pilot project in one area or hospital, whereby information on the cost of care (consisting of different elements, including drugs) is given to providers and patients Then, the impact of such cost information on cost efficiency, quality of care, including the rational use of drugs, and willingness to pay from the patients, can be evaluated If this is agreed upon, a project proposal needs to be developed and support for funding should be explored

In order to estimate the need of drugs in the country, proper quantification needs to be made, based on morbidity or service utilization An annual budget for the procurement of drugs in the public sector then can be properly allocated A workshop on drug quantification might be considered for this purpose During such a workshop, comparisons could also be made between morbidity or service utilization-based estimates and consumption-based estimates to identify inefficiencies in the supply or use of drugs

Pricing

Transparency in pricing structures will be implemented by the government for all levels of sales Selling price information will labeled on drugs at retail outlets This provision is aimed at ensuring that drugs are available to the public at their legal price

Distribution

The distribution of drugs and medical supplies should ensure efficient replenishment of stock at the various levels of care A harmonized inventory stock management will be developed at the zonal level and linked with the Central Medical Store through a computer system For this purpose, a pilot project in one zone should be implemented prior to nationwide implementation

Storage of Drugs

Standard operating procedures (SOP) and guidelines for drug storage will be developed and implemented in the public sector Prior to its implementation, such SOP should be introduced and be used for the training of staff The adherence of staff to the SOP should regularly be monitored and supervised

Disposal of Expired and/or Unwanted Drugs

In many countries, mechanisms for the disposal of expired and unwanted drugs often does not exist Problems will occur if expired drugs or unwanted drugs are encountered Such problems are anticipated in the policy and a provision has been included, however, regulations and guidelines need to be developed involving the concerned parties

Rational Drug Use

Provisions related to rational drug use in the policy cover a number of relevant issues, which include the use of generic drugs, scheduling of drugs, appropriate prescribing, information to prescribers and dispensers, information for patients and general public, adverse drug reaction (ADR) monitoring, therapeutic committees, and good dispensing practices

Some considerations need to be taken into account, especially relating to implementation

- Information about the policy on generic drugs and generic prescribing needs to be developed and distributed to health professionals to improve their understanding and acceptance It was apparent during the discussion at the workshop that there was insufficient understanding among prescribers regarding this policy, i e , its concept, goals, benefits, implementation, etc

- Drug information services to providers should also include relevant and existing problems of drug use that commonly occur in health facilities This information is aimed at making providers more aware and more critical about the problems of irrational uses of drugs

- Various possible channels to disseminate public education on rational drug use should be identified and utilized, for instance, through grass-root community organizations Innovative approaches for public education in the rational use of drugs need to be identified, developed, and field tested prior to implementation

- A comprehensive package on promoting rational drug use for health care providers needs to be devised This package will include training, educational supervision, monitoring, feedback, and evaluation Basic information materials, including the National List of Essential Drugs, standard treatment guidelines, and formulary, should be utilized in the strategy A workshop involving health managers and providers to devise a comprehensive strategy for promoting rational use of drugs in Eritrea should be considered Experiences from many countries have shown that training only, especially in a conventional format, is not sufficient to bring about an impact on drug use

- Functions of therapeutic committees need not be confined to hospitals only The committees could be extended to also cover the lower level health facilities in its surrounding area, especially in the zones Thus, Innovative measures to promote rational prescribing should be developed and implemented Such measures would consist, again, of training, educational supervision, monitoring, feedback, and evaluation of drug use practices

Veterinary Medicines

A provision is made in the policy that regulations and guidelines regarding veterinary medicines will be developed by the concerned ministry Any regulations and guidelines should be in accordance with the national drug policy The provision is important in avoiding any potential conflict between government bodies in dealing with veterinary medicines, especially in order to prevent adverse effects to human health

Traditional Medicines

Documentation of the practice of traditional medicines will be undertaken by MOH in collaboration with relevant bodies or organizations, especially in identifying beneficial and harmful effects Marketed traditional medicines will be registered and controlled

For such purpose, therefore, a mechanism for registration and a criteria for evaluation should be developed This will not be an easy task at the present stage, so it is more realistic to avoid the importation and distribution of traditional products at present, since the mechanism of registration is yet to be developed

Human Resource Development

A provision on human resource development is included in the policy stating that an adequate number of health professionals will be trained because of their role in implementing the national drug policy

From the perspective of NDP implementation, it should be noted that the curricula of training and inservice training of health professionals should also reflect relevant components of NDP, e g , concept or primary health care, concept and application of essential drugs, and the rational use of drugs This is especially important in the training curricula of medical, paramedical, and pharmacy professionals

Research and Development

Provision on research and development indicates that the priority for research will be given to operational research that supports the implementation of the NDP The priority areas include, for instance, the impact of the NDP on health care delivery, drug utilization studies, the economic aspect of NDP, sociocultural aspects of drug use, quality assurance of pharmaceuticals in health care, etc

This work will require collaboration and the active participation of relevant parties from within and outside MOH, i e , academic institutions, health professionals, and researchers The MOH should, therefore, encourage, support, and initiate such collaboration

Technical Cooperation with Other Countries and International Agencies

The objective of such cooperation is to ensure that all relevant forms of technical cooperation are explored and promoted to maximise the effective use of available resources Priority areas of technical cooperation are also laid down in the policy

For the implementation of NDP, different technical guidelines and regulations will be developed to cover a number of relevant issues For this purpose, available guidelines from WHO and other

international agencies or experiences from other countries should be taken into account as important reference and input

Monitoring and Evaluation

A mechanism for the monitoring and evaluation of the implementation of the NDP will be established Monitoring for its implementation will be undertaken from time to time, and a full evaluation and review will be undertaken every three years WHO NDP indicators will be adopted for this purpose

It is recommended that a baseline data showing the pharmaceutical situation prior to the NDP implementation be done Future evaluations can always be compared to baseline, what achievement has been made, and which area(s) requires further strengthening WHO indicators for monitoring drug policies are available and have been used in many countries, and they could also be used in Eritrea

RECOMMENDATIONS

For the implementation of the NDP, the following recommendations are proposed

1 Different technical guidelines and regulations will be established to cover various elements of the NDP in order to facilitate implementation For this purpose, existing guidelines from the World Health Organization and other international agencies should be taken into account as references, or be adopted and utilized, considering the pharmaceutical situation in Eritrea Experiences from other countries should also be taken into account as input

2 Prior to the implementation of the NDP, an indicator-based survey related to drug policy needs to be performed in Eritrea Data deriving from this survey will serve as a baseline for future evaluations WHO indicators for monitoring drug policies could be utilized with some modification, as required

3 In order accurately estimate the needs for pharmaceuticals in Eritrea, proper drug quantification should be made, based on morbidity records or service utilization in health facilities For this purpose, a national workshop on drug quantification will be required The objective would include training of health personnel with methods of drug quantifications the identification of inefficiencies related to drug consumptions in health facilities External input would be required and support for funding should be explored

4 A comprehensive strategy to promote the rational use of drugs should be developed, field tested, and implemented The strategy would consist of training or providing information, educational supervision, monitoring and feedback, and evaluation For such purposes, a

workshop on promoting the rational use of drugs could be planned, with the objective of formulating a strategy for promoting rational use of drugs A number of training materials and publications are available from WHO-DAP and INRUD (International Network for Rational Use of Drugs)

5 Some elements relevant to the NDP, including the concept of essential drugs, standard treatment guidelines, primary health care and so forth, should be reflected in the curricula for training and inservice training of medical, paramedical, and pharmacy professionals For this purpose, collaboration between the MOH and training institutions should be initiated

6 In the context of drug and health financing, a program needs to be developed and implemented in a pilot area or hospital The objective would be to examine the impact of providing cost information (including drug costs) to providers and patients on the cost-efficiency, quality of care, willingness to pay, and so forth

ACKNOWLEDGMENTS

The consultant wishes to express his sincere thanks to the designated counterparts Mr Yohannes Embaye (director general of Pharmaceutical Services), Mr Bernardos (head of Drug Management Division), and Mr Asgedom Mosazghi (head of Drug Control), and other staff of the DPS for their help and cooperation in accomplishing the assignment Special thanks are due to Dr Nosa Orobaton and staff from BASICS/Eritrea for their support and assistance

APPENDIX

FINAL DRAFT OF ERITREAN NATIONAL DRUG POLICY

ERITREAN NATIONAL DRUG POLICY FINAL DRAFT

(October, 1997)

MINISTRY OF HEALTH
STATE OF ERITREA

CONTENTS

15

ERITREAN NATIONAL DRUG POLICY

PREAMBLE

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

The provision of drugs and vaccines is by all means an important element for health care services, and it should become an integral part of health policy In accordance with the objectives of health policy a National Drug Policy has been promulgated for implementation in Eritrea The National Drug Policy relates to the health system in the country which is based on primary health care it includes the concept of essential drugs with emphasis on preventive health care

The National Drug 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 Commitment and active participation of various relevant stakeholders will be of utmost importance in achieving the objectives of the policy

The role of drugs in health care

Drugs constitute an integral part in the prevention and treatment of diseases Drugs can promote trust and participation in health services Any development in the pharmaceutical sector has, therefore a social impact Expenditures on drugs also constitute a considerable portion of health budget that optimal utilisation of resources is imperative Safe effective and economical use of drugs is of utmost importance in attaining the outcomes of health services Thus particular attention is given to the policy

Definition of a drug

Drug shall mean ***any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of a disease or the symptoms thereof in man and animal***

POLICY OBJECTIVES

General

to ensure the availability and accessibility of safe, effective and good quality essential drugs to the whole population and to promote rational drug use

Specific

- Ensure adequate regulatory mechanisms leading to effective regulations of manufacture importation, exportation marketing and use of essential drugs by strengthening the system of drug registration, licensing of pharmaceutical premises and pharmacy practitioners inspection and control
- Ensure the availability of safe effective and good quality drugs at the lowest possible cost
- Promote the rational use of drugs by prescribers, dispensers patients and community through provision of necessary measures including training education and information
- Increase the efficiency of drug 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 drugs
- Promote and support the local production of essential drugs
- Incorporate the principles of National Drug Policy in the medical paramedical and pharmaceutical education
- Promote research in priority areas related to drugs
- Optimise the use of available resources through co-operation with international and regional agencies
- Document the widely practiced traditional medicine and traditional drugs for safety

POLICY AREAS

1 Executive Body

The Department of Pharmaceutical Services will be the body entrusted to co ordinate and supervise the implementation of the National Drug Policy In order to be able to carry out its functions effectively it will have the necessary structure facilities and resources

As this body requires the support of advisory council and clearly defined legal proceedings for enforcing the regulations there will be provisions in the law for the establishment of advisory council and other necessary committees appointed by the Ministry of Health

2 Legislation and Regulations

Proclamation no 36/1993 will be revised to reflect the requirements of the National Drug Policy and will include all the elements of a drug 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 Drugs 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 Pharmaceutical 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 specialised inspection functions (e g inspection of manufacturing facilities and wholesale premises) retained at the national level The number of inspectors will be increased and in-service training programmes will be strengthened

2 2 National Drug Quality Control Laboratory

A national drug quality control laboratory within the Department of Pharmaceutical Services will be established Collaborative relationship with other quality control laboratories will be established

2 3 Registration of Drugs and Medical Supplies

Formal drug registration system will be introduced so that only drugs which are registered in Eritrea or in countries that have collaborative agreements with Eritrea may be imported produced stored, exported and sold

Registration procedures based on quality efficacy safety and needs will be adopted through the introduction of

- a five year re-licensing system for drugs
- computerisation of the evaluation system
- an evaluation report exchange system with reputable regulatory bodies in other countries
- prioritisation of registration based on need
- fast track procedures for essential drugs and
- norms and standards for registration of medical devices

A National Drug Advis ory Council supported by committees appointed by the Ministry of Health composed of persons with the widest possible representation will be set up to advise the drug 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 the private drug retail sector Priority and encouragement will be given to pharmacists and pharmacy technicians who would want to own and run their retail pharmacies However ownership of private pharmacies by non-pharmacists will be permitted

2 5 Registration and Licensing of Premises

All drug manufacturing import wholesale and retail enterprises will be established only if they are licensed The enterprises should be operated under the technical responsibility of a licensed professional only

2 6 Narcotics and Psychotropic Drugs

A national committee consisting of members from different organisations will be set up to carry out a co-ordinated control on narcotics and psychotropic drugs on the basis of international conventions

2 7 Clinical Trials

Special permission will be required for carrying out clinical trials of drugs in compliance with Good Clinical Practice Guidelines and the WHO ' Model of items to be included in a clinical trial protocol '

2 8 Advertising and Marketing of Drugs

Promotion or advertising of drugs 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 drugs to the medical professionals comply with the National Drug 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 drug use or to give rise to undue risks

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 drugs Scientific and educational activities shall not be deliberately used for promotional purposes

Ethical criteria and guidelines for the promotion and advertising of drugs 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 Drugs

The Eritrean National List of Drugs will be reviewed at least every three years A National Drugs 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 drug information centre etc will be responsible for reviewing the Eritrean National List of Drugs

The Eritrean National List of Drugs will be used as an instrument for

- production, procurement, prescribing and dispensing of drugs
- standard treatment guidelines and training in rational prescribing
- drug information to health care providers, including a national formulary and
- drug donation

Adherence to the list in procuring or prescribing drugs 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 Drug Supply

4 1 Procurement

The aim of effective procurement is to ensure an adequate supply of effective and safe drugs 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 price delivery and quality of drugs and medical supplies could be selected Tenders will be called for by generic name only Preference will be given to products labelled by generic name

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

Drug procurement and distribution will be limited to the drugs on the Eritrean National List of Drugs ,

4 2 Import of Drugs

Private enterprises will be permitted to import and distribute drugs and medical supplies in accordance with the regulations and guidelines laid down by the government

4 3 Quantification

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

4 4 Local Manufacture of Drugs

The government will create favourable conditions for the establishment and development of local pharmaceutical industry so as to promote self-reliance in the production of essential drugs Private investors will be encouraged to participate in the manufacture of drugs 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 drugs Production and marketing of essential drugs 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 local manufacturing of pharmaceuticals will comply with the WHO guidelines for GMP and inspections will be carried out regularly by the inspectorate of the DPS in order to ensure compliance with GMP

4 5 Quality Assurance

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

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

- Guidelines for donated drugs, to follow WHO guidelines for drug donations Donated drugs will
  - match the health needs of the country and hence appear on the Essential
  - Drugs List
  - be compatible with overall government policy
  - be of appropriate quality, efficacy and safety
  - be accompanied by appropriate legal and administrative documents
  - be reviewed through the fast track procedure
- Clinical trials of drugs will be carried out in compliance with Good Clinical Practice Guidelines and the WHO "Model List of Items to be included in a Clinical Trial Protocol
- Drug promotion and marketing will comply with national criteria, based on the WHO Ethical Criteria for Medicinal Drug Promotion
- There will be a mechanism to document regulate, and evaluate for safety and quality of traditional medicines
- Norms and standards will be set for medical devices and disposable items which appear on an essential equipment list These items will also be evaluated
- Mechanisms and guidelines will be developed to check quality of drugs which are already in the market

4 6 Drug Financing

The objective is to develop a system of joint responsibility between the government and the patient for the financing of drugs However, in line with the National Health Policy, the government will ensure that essential drugs are available to all people in need To this end, drugs will be provided at a nominal price at the point of service at the primary care level

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

All drugs at the primary care level will be provided at a nominal price At the secondary and tertiary levels a fixed affordable co-payment for drugs 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 7 Drug Pricing

The government will ensure that essential drugs are available at prices that are affordable to the majority of the population and that fair pricing practices are followed by the manufacturers wholesalers and retailers The Ministry of Health will act in collaboration with concerned organisations to ensure that drugs are available to the public at their legal prices

There will be total transparency in the pricing structure applied to pharmaceutical manufacturers wholesalers providers of services such as dispensers of drugs as well as private clinics and hospitals Selling prices will be labelled in all drugs at retail outlets

4 8 Distribution

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

The distribution of drugs 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 guidelines of the EPI review committee

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

Computerised inventory control systems will be established in all zonal pharmacies These systems will be linked to computerised inventory control systems in the Central Medical Stores

4 9 Storage and Safeguarding of Drugs

In order to ensure the maintenance of quality and security of drugs 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 drugs 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 standardised security systems will be developed and implemented in all public sector depots
- Appropriate inventory control and stock management systems will be established in all drug stores and health facilities
- Central and zonal warehouses will be assisted in drafting long-term plans for the rationalisation and upgrading of depots, including plans for the reconstruction or replacement of existing facilities

4 10 Disposal of Expired and Unwanted Drugs

In order to ensure that all unwanted and expired drugs, 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 Where possible returned non-expired stock and re-useable items will be redistributed

The government will ensure through legislation that the removal and/or disposal of drugs 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

Authorised 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 Drug Use

The objective is to promote the rational prescribing and dispensing of drugs 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 drug 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 Drugs

The use of generic name or the International Non-proprietary Name (INN) is a recommended step to reduce drug cost and expenditure It also contributes to a sound system of procurement distribution and drug 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 Scheduling of Drugs

The Ministry of Health will prepare a list of those drugs approved for use

- to be dispensed upon prescription,
- to be handled by pharmacy drug shop and rural drug shops
- standard lists for the different levels of health institutions and for other purposes

5 3 Appropriate Prescribing

The aim is to ensure that drugs are prescribed correctly by appropriately trained and duly authorised personnel according to the essential drugs concept

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

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 drug utilisation to monitor and act on policy adherence Appropriate indicators will be developed and field-tested for this purpose

5 4 Drug Information Services

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

Drug information services will be provided to ensure the dissemination and utilisation of practical unbiased information on the correct handling and rational use of drugs 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 drugs, the Ministry of Health will establish and maintain an appropriately equipped and staffed Drug Information Service under the supervision of the Department of Pharmaceutical 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 drugs will be produced by the MOH

The MOH will also produce a national formulary based on the Eritrean National List of Drugs 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 drug interactions

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

Periodical drug bulletins which contain latest information of new or established drugs 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 drugs 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 organisations 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 programmes to integrate into the curriculum basic education that will lead to a better appreciation of the benefits and limitations of the role of drugs in health care

5 4 3 Adverse Drug Reaction (ADR) Monitoring

The Ministry of Health will develop a program for surveillance of drugs 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 drugs in health facilities in the country, the Ministry of Health will promote the formation of and facilitate the effective functioning of Therapeutics Committees

Their terms of reference will include responsibility for

- the establishment of Standard Treatment Guideline for health facilities and monitoring adherence to it
- the accurate estimation prompt procurement and optimal storage and supply of drugs and medical supplies
- the compilation and preparation of a drug formulary
- cost-effective drug use
- documentation, reviewing monitoring, reporting and feed back of adverse drug reactions
- proper staff establishments to carry out these functions

5 6 Dispensing

The objective is to ensure that drugs are dispensed efficiently and correctly by appropriately trained and duly authorised personnel according to the essential drugs concept and recommended dispensing practices

The Ministry of Health will establish Good Dispensing Practices 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 Drug Policy

Particular care will be taken to prevent adverse effects on human health due to residual concentration of drugs 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 organisations 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 organised 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 drugs and rational drug 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 Drug 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 programme 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 drugs rational drug use and primary health care will be reflected in the training curricula of medical paramedical and pharmaceutical personnel

8 1 The Role of Pharmacy Professionals

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

Pharmacy professionals, particularly those in the community have a special role in educating the community about the correct use of drugs Professional associations will be encouraged to develop co ordinated programmes to facilitate and further this role

Pharmacy professionals will be involved in multi disciplinary approach to the rational utilisation of drugs Greater co-operation between pharmacy professionals and other health professions within the communities and hospitals should be encouraged to facilitate the rational use of drugs 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 drug information system

The policy will also aim at expanding and standardising 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 drug supply in primary care clinics under the indirect supervision of a zonal pharmacist

9 Research and Development

The objective is to promote research that will facilitate the implementation of the National Drug 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 Drug 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 NDP 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 drug supply (procurement methods stock management distribution etc)
- socio-cultural aspects of drug use including self-medication acceptability and use of supply systems and knowledge attitudes and practices of users of drugs and
- quality assurance of pharmaceuticals at all levels

10 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 maximise 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 drugs
- regional procurement systems and the exchange of information on pharmaceutical supply source
- quality assurance and collaboration with regional and other drug quality control laboratories
- production and formulation of drugs
- transfer of appropriate technology
- research and development
- studies on drug utilisation
- exchange of drug information
- training and human resources development
- control of drug abuse, and
- emergency situations, such as epidemics and diseases

The guidelines and recommendations of WHO will be followed wherever possible

11 Monitoring and Evaluation

Mechanisms for monitoring and evaluation of performance and impact of the National Drug Policy will be established

- Indicators for monitoring the NDP 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 NDP implementation will be monitored at regular intervals
- A full evaluation of the NDP will take place every three years

CONCLUSION

A National Drug 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 drugs they need at a cost that they and the system as a whole can afford