THE FEDERAL GOVERNMENT OF SOMALI REPUBLIC
MINISTRY OF HEALTH AND HUMAN SERVICES

THE SOMALI NATIONAL MEDICINES POLICY

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ACKNOWLEDGEMENT

Putting this document into place - The Somali National Medicines Policy - is a result of combination of efforts of all health stakeholders in all the three zones of the country.

We do particularly appreciate the roles and inputs of health practitioners in the private sector in the exercise.

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We do express our gratitude to WHO(Somalia) under the leadership of WHO Representative DR Ghulam R. Popal and his technical team especially the Essential Medicines Policies and Health Technology Unit (EMP) who ensured that the exercise is brought to a successful completion.

We do express our very much thanks and appreciation for the interest and technical back-up support provided by the Essential Medicines Policies and Health Technology Unit (EMP) at WHO(Hq) and the WHO Regional Office (EMRO).

We believe that this policy will be a guide for the stake holders in all matters related to procurement, Management, Distribution and the Regulation of medicines to ensure the availability of adequate essential medicines and that good quality medicines are brought in to the country.

FOREWORD

The collapse of the central government in Somalia in 1991, resulted the collapse of the health system, including the pharmaceutical sector, across many parts of the country. This, together with the combination of insecurity, drought, famine and other natural disasters caused huge population displacement resulting in the population having some of the worst health indices in the world.

Prior to 1991, the Somali Agency for Import of Pharmaceuticals and Allied Products (ASPIMA), a government entity, was responsible for the importation and distribution of all the pharmaceutical and medical-related products to public health facilities in the country. However this entity gradually stopped functioning in the early period of the civil war.

Since 1991, the public supply system of the pharmaceutical sector in Somalia has been funded mainly by the UN Agencies and international NGOs. However this accounts for about 30% of drugs/ supplies needs of the country. The remaining 70% is catered for by a large number of private importers of drugs and an increasing number of private pharmacies and outlets not only selling medicines but also providing treatment that are operating without any regulatory framework. Due to the very limited human and financial resources, the activities of these private drugs importers and private pharmacies are not being overseen by national health authorities.

Our mission statement in the Health Sector Strategic Plan (January 2013 – December 2016), is to *"ensure equitable affordable and effective essential health services to all people in Somalia"*. In order to achieve this, we make use of six strategies based on WHO's six building blocks of an effective health system as a foundation for our plan. In the fifth strategy of the plan, the issue of availability of adequate of good quality essential medicines at all levels of health facilities as well as the quality and safety of the medicines and other products that are imported and sold in the private sector is taken as a very top priority. Towards that end, we are putting in place necessary administrative requirements that must be adhered to in order to promote effective regulation and control of medical products and the establishment of National Medicines Regulatory Authority in the country.

The development of this *Somali National Medicines Policy*, is one major step in that direction; and it is expected to meet the present day challenges in the pharmaceutical sector including issues, among other things, having to do with procurement; management & distribution; financing; regulation & quality control; rational use of medicines; herbal medicines; and technical cooperation with other countries

This document is a product of painstaking joint efforts and consensus of opinion of all health stakeholders including health professional associations from all the zones of the country led by the Ministry of Health.

We do extend our especial thanks to WHO Representative and his team in WHO (Somalia) for providing all the necessary technical support so as to ensure the success of the exercise.

I do hereby commend to you all the use of this policy document – *The Somali National Medicines Policy* - to the Glory of the Almighty Allah.

H.E. Mr. Ali Mohamed Mohamud
Minster for the Ministry of Health and Human Services
Federal Government of Somali Republic
7th October, 2014

LIST OF ABBREVIATIONS

CM	Controlled Medicine
EM	Essential Medicines
EML	Essential Medicines List
IGAD	Inter Governmental Authority on Development
INN	International Non-proprietary Name
MOH	Ministry of Health
NMP	National Medicines Policy
NGO	Non Governmental Organization
NPRA	National Pharmacy and Regulatory Authority
PTC	Pharmacy and Therapeutics Committee
POM	Pharmacy Only Medicines
PRB	Pharmacy Regulatory Board
RMF	Revolving Medicine Fund
STG	Standard Treatment Guidelines
UNICEF	United Nations Children Fund
WHO	World Health Organization

INTRODUCTION:

Over the last two decades the health system in the country has collapsed across many parts of the country and the combination of insecurity, drought and famine have caused huge population displacement and resulted in the population having some of the worst health indices in the world. The new political developments and improving security across the country now provides an opportunity for rebuilding the Somali health system. The new Health Sector Strategic Plans (2013-2016) sets out ambitious agenda for rebuilding the health sector across the country.

The health care delivery system in the country is mainly characterized by the following two systems:

1. **Private health services**: Privately owned health services are spread all over the country, especially in urban and semi urban regions, and they account for approximately 70% of the country's health care needs. Most of the providers of services in the private health sector are inadequately trained hence, the prevailing lack of professional ethics and standards of practise in the country. In addition, the outlets which provide essential medicines do not meet the minimum standards of storage, leading to poor quality of the medicines supplied.

2. **Public health services:** The majority of the population in either rural or urban residents lack access to adequate health services and the available health care services are often interrupted by perennial wars, particularly in the South Central zone. The poor in urban and semi urban areas cannot afford the private health services since they have no regular sources of income, hence most rely on public health services that are available mostly in urban and semi-urban areas of the country and funded by multilateral organisations such as the UN agencies and other bilateral international non-governmental organizations (INGO), who are concerned mainly with the provision of primary health care services.

Evolvement of Essential Medicines' Policies

In 1975, the World Health Assembly (WHA) requested WHO to assist its member states to develop essential medicines policies and implementation strategies.

Concept of Essential Medicines:

According to WHO:

I. Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness;

II. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.

The first essential medicines model was published in 1977 by WHO. In 1978, the Essential Medicines Programme was considered as a primary health care pillar by both WHO and UNICEF. In 1979, WHO introduced the Essential Medicines Action Programme. Following the above mentioned initiatives, World Health Organization (WHO) became involved and encouraged the issue of National Medicines Policy of which National Essential Medicines list is the priority area. Based on geographical, socio-economic and lifestyle differences, every state should have its own guideline to develop a National Medicines Policy, as a result of diversity of National Medicines Policies.

Methodology:

The development of a National Medicines Policy involves the following steps:

a) **Organising the policy process**: Identification and mapping of policy structure (frame) with regard to leadership, roles of stake holders, including the Ministry of Health and WHO, objectives, resources for policy development and prioritization of duties;

b) **Identification of the main problems**: Thorough analysis and study of medicines by a team of experts with previous experience, to examine the situation and systematically identify the main problems and provide recommendations for action.

c) **Identification of goals and objectives**: Identification of the goals and objectives based on defined main problems with the specific stakeholders through workshops and field visits.

d) **Drafting of the Policy:** A draft of the policy is written stating the main objective of the policy, as well as, the description of the specific objectives and strategies to be adopted;

e) **Circulation and Revision of the draft policy**: Circulate the draft policy widely, through consultative meetings involving all concerned parties, while taking cognisant of the fact that the ultimate responsibility falls with the Ministry of Health and the government.

f) **Obtaining formal endorsement for the policy:** This is subject to national policy legislation on health care and policy implementation by stake holders.

g) **Launching the Policy**: The launch of the policy should have a communication strategy that is cross-cutting; involving all concerned stake holders including; legislators, professionals, government departments, bilateral agencies and international organisations.

SCOPE

The National Medicines Policy (NMP) is a guide for action by the Ministry responsible for the development of the pharmaceutical sector. The document was developed and formulated by a partnership of stakeholders among them Government Ministries, Legislators, Importers, Distributors, Wholesalers, Retailers, Consumers, Health Care Providers, Professionals, Academia and Administrators.

The NMP provides a framework which seeks to co-ordinate the activities of all participants in the pharmaceutical sector including:

i. Government Ministries and departments;
ii. Donors;
iii. The public and private sectors;
iv. UN Agencies;
v. Non-Governmental Organizations;
vi. Professional Associations;
vii. Academia and
viii. Other interested parties.

The implementation of the NMP will depend on the human and financial resources of the Government and its development partners.

Priority should however be given to Policy components that are likely to solve key problems such as:

i. Appropriate Legislation and Regulation,
ii. Establishment of an Autonomous Medicines Supply Authority;
iii. Supply Chain Management of Essential Medicines;
iv. Promotion of Rational Use of Medicines;
v. Financing and Sustainability;
vi. Manpower Training and Development;
vii. Intersectoral and Technical Cooperation and
viii. Monitoring and Evaluation.
ix. Community awareness for negative consequences of irrational use of medicines

Experience in other countries has shown that success in terms of Public Health is linked to emphasis on the use of a list of Essential Medicines for both the public and private sectors. Hence, the National Medicines Policy should give priority to these sectors. The implementation process includes comprehensive strategies to achieve rational use of essential medicines by the public. The success of the National Medicines Policy will however, depend on the support from prescribers, dispensers, other health care providers and efficient management of the supply chain.

1. GOAL AND OBJECTIVES OF THE NATIONAL MEDICINES POLICY

1.1 The Goal of the National Medicines Policy

The goal of the National Medicines Policy (NMP) is to develop the pharmaceutical services using available resources to meet the requirements of the entire population in the prevention, diagnosis and treatment of diseases using efficacious, quality, safe and cost-effective essential medicines, and medical supplies; and the rational use of drugs by prescribers, dispensers and consumers.

1.2 Specific objectives of the National Medicines Policy

1.2.1 Health objectives

a) To ensure that the quality of medicines imported into the country meet internationally accepted quality standards;
b) To ensure the continuous availability, accessibility of safe and effective medicines to all segments of the population;
c) To promote rational use of medicines through sound diagnosis and prescribing, good dispensing practices and appropriate usage through provision of the necessary training, education and information;
d) To promote the concept of individual responsibility for health, preventive care and informed decision making.

1.2.2 Economic objectives

a) To facilitate establishment of a viable and effective demand driven commercial service for the selection, procurement, distribution and rational use of medicines and medical supplies;
b) To facilitate the supply of essential medicines through the supply chain of the government, private, and the non-governmental sector at affordable prices;
c) To facilitate the establishment a complementary partnership between Government departments and private providers in the pharmaceutical sector;
d) To advise on the optimum use of scarce resources through cooperation with international and regional agencies.

1.2.3 National development objectives

a. To improve the knowledge, efficiency and management skills of pharmaceutical personnel;
b. To reorient medical, paramedical and pharmaceutical education towards the principles underlying the National Medicines Policy;
c. To support the development of the local pharmaceutical industry and the local production of essential medicines;
d. To promote the acquisition, documentation and sharing of knowledge and experience through the establishment of advisory groups in rational medicine use, pharmaco- economics and other areas of the pharmaceutical sector.

1.2.4 Faith and culture objectives

To promote healthy behaviour, beliefs and moral values of the public to promote community well being.

2. REGULATORY FRAMEWORK

2.1 Establishment of the National Pharmacy Regulatory Board (NPRB)

The Minister of Health is vested with the powers of controlling the pharmacy profession and the trade in medicines and medical supplies. The Minister will therefore establish a Board to be called the National Pharmacy Regulatory Board (PRB). The PRB shall be the central reference point for regulatory control in order to achieve the objectives of the Essential Medicines Policy (EMP). The PRB will be responsible for quality control, evaluation, registration, pharmacovigilance, control of standards of production, importation and marketing.

2.2 Composition of the Pharmacy Regulatory Board

The Minister will appoint **five to ten individuals** to the PRB. The Board will be composed of;-

a) **Executive Chairperson**: - The Executive Chairman shall be a licensed health care professional (preferably pharmacist) with a minimum of 10 years experience in an area of public health. The chairman will preside over all meetings of the board and be a member of the various committees of the Board.

b) **Registrar/Secretary:** - The Minister will appoint a Pharmacist as the registrar/secretary of the Board. The registrar/secretary will manage the day to day operations of the board as a fulltime employee and report to the Board through the chairman. The tenure of the Registrar/Secretary shall be at the pleasure of the Minister based on the a dvice of the Board.

c) **Other members of the Board**: - The Minister will appoint other members of the board from various professional health associations including those of the pharmacists, doctors, nurses and any other relevant associations as per the advice of respective bodies/Institutions.

d) Every member of the board shall declare any conflict of interest he/she might have as regards the activities of the board

While constituting the board, the minister shall ensure that preferably at least two female members are appointed in order to maintain gender balance. Members appointed from section (a) and (c) above will serve for a period of three years but will be eligible for reappointment by the minister. The Board may formally or informally delegate some of its functions to professional associations, other branches of the government and private not-for-profit organizations.

2.3 CORE FUNCTIONS OF THE BOARD

2.3.1 Evaluation and Registration of Essential Medicines.

The following criteria shall be used for registration:

a) Priority will be given for the registration of Essential Medicines as indicated in the Essentials Medicine List provided the medicines are of proven quality, safety and efficacy.

b) New medicine entities and medicine combinations will be given considerations over the products that have already been registered provided they have an added advantage in terms of quality, safety and efficacy.

2.3.2 Quality Control of Medicines;

The Essential Medicines procured will be subject to basic screening using the mini lab (mobile laboratory) strategy, put in place by WHO, pending the establishment of quality control laboratories in the country. The present system of contracting with universities or WHO accredited quality control laboratories will be retained until a national quality control laboratory is established.

2.3.3 Quality Assurance

a) Medicines conforming to WHO quality control standards shall be permitted to be registered in the country. WHO guidelines on the bio equivalence of multisource products shall always be applied.

b) As additional safe guards, medicines will only be registered from licensed importers, manufacturers and suppliers. Companies which have been prequalified by WHO for the manufacture of essential medicines will be given preference.

c) For purposes of registration, relevant documentation, including registration in the country of origin, certificates of analysis for raw materials and finished products, will be carefully checked to ensure that quality of medicines that are being registered are of the required standard; and where necessary the medicines may also be subjected to further analysis by a quality control laboratory recognised by the Pharmacy Regulatory Board.

d) The PRB will institute a system for withdrawal of medicines from circulation, which have shown or demonstrated otherwise to be of unacceptable quality.

e) Expired medicines and medical supplies will not be permitted for purposes of evaluation, registration and sale.

2.3.4 Classification of Essential Medicines

a) Medicines will be scheduled according to the following categories. Packaging must carry indication of appropriate categories in bold letters.

   i) Prescription only medicines (POM)
   ii) Controlled medicines (CM).
   iii) Pharmacy only medicines (P)
   iv) General sales list of medicines (GSL)

b) Medicines which can be sold without prescription and used for short term relief of symptoms without prior medical consultation and precise diagnoses, or for the treatment of minor complaints, including pharmacy only (P) medicines and General sales list of medicines (GSL) will be drawn up by a committee which will be set up under the Board to make this selection after carefully defining the criteria for inclusion of these medicines in each list.

2.3.5 Licensing of Importers

All companies importing medicines for registration and marketing in the country are to apply for licensing of the company provided that the company or its principals abroad meet all the required conditions which will include Good Manufacturing Practice (GMP). All licenses will be reviewed periodically. Formal procedures for registration, based on quality; efficacy and safety will be upgraded through introduction or strengthening of:

i. A five-year re-licensing system for drugs
ii. Computerization of the evaluation system
iii. An evaluation report exchange system with reputable regulatory bodies in other countries
iv. Prioritization of registrations, based on need
v. Fast-track procedures for essential drugs
vi. Norms and standards for registration of medical devices.

2.3.6 Regulation of the Practice of Pharmacy

a) Licensing of Personnel and Premises

The Ministry of Health (MOH) will endeavour to build, the capacity of the public and private sector in the necessary legal procedures put in place in the form of registering and licensing of graduate pharmacists and pharmaceutical assistants.

Medical practitioners and nurses will be issued with dispensing licenses by the PRB to dispense medicines where the services of graduate pharmacists and pharmaceutical assistants are not available. Criteria for the granting of such licences will include *inter alia*, the application of geographical limits. All licences will be reviewed and renewed annually.

Retailing of essential medicines will be confined to licensed outlets. Where it is deemed to be in the interest of the public and provided that comprehensive pharmaceutical care is ensured, ownership of pharmacies by lay persons and other health care professionals will only be considered if they are under the supervision of a superintendent pharmacist in charge of a cluster of pharmaceutical outlets in a given geographical area. Uniform norms and standards pertaining to the dispensing of medicines by different service providers will be incorporated into one set of regulations.

b) Pharmaceutical Inspectorate

A pharmaceutical Inspectorate will be established to inspect outlets at regular intervals to ensure compliance with laws and regulations regarding storage and dispensing of pharmaceutical products. The inspectors will liaise closely with officers of the department of Customs and Excise in the monitoring of importation of medicines.

i) Authorized inspectors may make regular inspections of premises where dispensing operations are performed to ensure that the conditions for the granting and renewal of dispensing licenses are being adhered to in all aspects

ii) The inspectors will be provided with ID Cards to present them during inspection.

iii) The inspectors should have a pharmaceutical background and be given further training on issues of market surveillance, customer service and public relations.

iv) The inspectors should be persons of good conduct, proven integrity and maintain ethics and professional standards.

c) Professional Associations and Code of Ethics

All professional organizations involved in the supply of essential medicines shall maintain and enforce a specific code of ethics to regulate the conduct of their members. Codes of ethics for various professions dealing with medicines will be developed in collaboration with the Pharmacy Regulatory Board and the pharmaceutical societies already existing in the various zones. Disciplinary actions on unethical practices will be communicated to the PRB by the respective professional organizations for the necessary remedial action.

2.4 Advisory Role of the Board

The PRB will advise the government on any matters relating to the regulation of pharmaceutical products and services.

2.5 Funds of the Board

Funds will mainly be generated from registration of medicines, annual retention fees; and licensing renewals. The Board will be established with a financial autonomy. The Board will retain revenue, but be accountable to the Minister of Health.

2.6 Utilization of Funds

The funds will primarily be used for the following activities:

a) Payment of wages and salaries of the members of staff.
b) Purchase of office furniture, stationeries and equipment
c) Payment of utility bills e.g. water & electricity
d) Payment of meeting allowances for the members of the Board.
e) Testing of medicines for quality control.
f) Purchase of samples for post marketing surveillance.
g) Travelling expenses for board members and members of staff.
h) Manpower training and development including workshops and seminars.
i) Construction and maintenance of office space
j) Expansion of the infrastructure including, computerization of the administrative procedures.

2.7 Periodic Review of the Policy

The Board will regularly review legislation and regulations of the medicines policy in order to support the objectives of the NMP and liaise with relevant departments and stakeholders actively involved in the implementation of the policy.

3. THE ESTABLISHMENT OF A CONSORTIUM TO MANAGE A PUBLIC PRIVATE PARTNERSHIP SUPPLY CHAIN SYSTEM

3.1 PUBLIC PRIVATE PARTNERSHIP (PPP)

Continuous and adequate availability of safe and affordable essential medicines and medical supplies is at the heart of effective delivery of quality health care services. To meet this objective and in order to attain stability in public health service delivery, the management of essential medicines and medical supplies will be restructured and brought under the management of an independent organization. Through the mechanism of this consortium, application of sound and commercially oriented practices, a viable procurement and supply chain system will be established.

Most governments are increasingly seeking to develop financing mechanisms which encompass both the public and private sectors, not only to control budgetary expenditure but, also to pool these sectors' expertise together. This is being affected through the public private partnerships.

In the current competitive and dynamic world, it is almost impossible to do anything alone, thus, most organisations are opting for some sort of partnership to combine their skills and expertise for mutual benefit. For instance, the provision of health services nowadays is characterised by persistently rising prices, changing disease patterns, and increasing adoption of sophisticated technology for diagnosis and treatment. To make these services sustainable, a formal institutional partnership needs to be put in place. These partnerships may involve global partnerships ranging from partnerships between multinational

companies and multilateral donors to local private entrepreneurs and the local health authorities. A consortium established for medicine's supply through an act of parliament would ensure continuous and adequate availability of safe and affordable essential medicines and medical supplies to public health facilities and those in the private sector.

3.2 THE MANDATE OF THE CONSORTIUM

The Minister of Health will mandate the consortium to carry out the following functions relevant for the management and operations of procurement and supply chain management of Essential Medicines.

3.2.1 Procurement of Medicines

a) All public, private and Non-Governmental Agencies procuring pharmaceuticals should follow current Good Pharmaceutical Procurement Practices.

b) Essential Medicines as indicated in the Essential Medicines List will be procured by generic name (INN), and the products must be registered.

c) The consortium will carry out an annual needs assessment (Quantification) of essential medicines and medical supplies. The quantification will be updated periodically throughout the year, based on demand.

d) An annual procurement plan and schedule will be made according to actual resources available and realistic delivery times.

e) Medicines will be procured through a competitive tender process. Tenders will be open only to suppliers who have been pre-qualified by the Ministry of Health.

f) A formal supplier monitoring system will be established with objective standards for medicines quality and service performance. Suppliers whose products or services fall below international standards will be deleted from the list of approved suppliers.

g) Supply terms will be specific to Essential Medicines particularly with respect to specifications, shelf life, and labelling, packaging and related issues.

3.2.2 Storage of Medicines

a) The consortium will endeavour to ensure the provision and regular maintenance of adequately sized, suitably constructed and equipped storage facilities at every level of the distribution system. Where necessary, new stores will be constructed and existing ones, if needed, rehabilitated in order to ensure that medicines are stored in a secure, safe and systematic manner, so that losses due to deterioration, expiry or theft are minimized. Where appropriate, storage facilities will include air conditioning and properly maintained refrigeration to protect the heat sensitive products during the period of their storage

b) Regular spot checks on storage facilities and conditions, in order to ascertain their adequacy and suitability, will be carried out by authorized inspectors of the national Pharmacy and Regulatory Authority.

c) In order to encourage the correct maintenance and organization of medical stores throughout the country the consortium will develop a standards and operating procedures (SOPs and manuals) containing practical guidelines on the required procedures for all storekeepers.

d) All institutions providing pharmaceutical services will have physically separate areas designated - "Pharmacy". All institutions providing pharmaceutical services will have a pharmacy department managed by a pharmacist. Where there is no pharmacist, pharmaceutical assistants, nurses or any other health care providers may be authorized to manage pharmaceutical services provided they have received adequate training on the basic aspects of Good Storage & Distribution Practices of essential medicines.

3.2.3 Distribution of Medicines

a) The consortium will endeavour to maximise co-ordination between the different sectors in the transportation and distribution of essential medicines, particularly to the underserved and vulnerable groups.

b) Opening of retail pharmacies in rural and under-served urban areas will be encouraged through the provision of tax relief and other incentives.

c) To encourage cost awareness, all distributors will be required to provide their local wholesale price lists to the Pharmacy Regulatory Board according to an established timetable. The PRB will publish these official prices at least once yearly and more often as appropriate. In addition, a mechanism will be established to exchange information with other countries on prices of individual pharmaceutical products.

3.2.4 Inventory Control

a) The consortium will strive to improve and standardize inventory control procedures at all levels of the supply system. Minimum and maximum stock levels will be introduced, systematic stock rotation ensured, dead stocks and expired stocks will be identified and either disposed of, or, in the case of non-expired usable items, redistributed.

b) Manual and computerised inventory control procedures will be established. The training and implementation of these procedures will be carried out simultaneously at all levels of the health care delivery system.

3.2.5 Disposal of Pharmaceutical Waste

The Minister of Health, through the Pharmacy Regulatory Board (PRB) and in collaboration with the consortium will ensure that appropriate methods are applied for the removal and disposal of expired and returned stock of medical supplies and medical waste. The Pharmacy Regulatory Board will ensure that the removal and/or disposal of medicines, medical supplies and medical wastes takes place in such a manner that is neither harmful nor dangerous to the community or environment. Authorized inspectors shall carry out regular inspections to ensure that; the disposal of unwanted items takes place according to prescribed guidelines. Wherever possible returned non-expired stocks and reusable items shall be redistributed to needed localities.

4. LOCAL MANUFACTURE OF MEDICINES

1) The Government will stimulate the interest of national manufacturing companies in the production of medicines based on the Essential Medicines List through provision of incentives such as soft loans, tax relief, and allocation of sufficient foreign exchange.

2) The Ministry of Health will enter into negotiations with the department of Customs and Excise regarding the reduction to an acceptable minimum, of duties and taxes levied on raw materials and excipients required for the production of medicines.

3) The Government will promote the development of associated industries for raw materials, glass, plastics, paper, aluminium foil and other relevant equipment

4) The Government will promote the development of the national pharmaceutical industry as a multi-sectoral activity.

5. IMPORTATION OF MEDICINES

1) All companies importing medicines for registration and marketing in the country should apply for licensing of the company provided that the company or its principals abroad meet all the required conditions which will include Good Manufacturing Practice (GMP).

2) Importation of all Essential Medicines will strictly be limited to products registered by the Pharmacy Regulatory Board.

3) Importation of TB medicines shall be through only the government agencies and/or approved bilateral /multi lateral organizations.
4) There should be adequate designated storage facilities for medicines including cold storage, at all ports of entry. These facilities will have supportive services for inspection purposes.

5) The Ministry of Health in collaboration with the Ministry of Commerce and Treasury will maintain information on imports to help determine the national consumption requirements.

6. CHOICE OF MEDICINES

6.1 Adoption of the Essential Medicines concept

The private sector provides a substantial part of the health care delivery services. Therefore, health services provided by the private, as well as the public sector will be required to adopt the Essential Medicines concept and, specifically, to make use of the Somali Essential Medicines List. The Essential Medicines concept is clearly outlined in the Standard Treatment Guidelines and Training Manual and Use of Medicines at the Primary Health Care Level (WHO 2008), 2nd edition. Adoption of the Essential Medicines concept will ensure that health care providers, especially in the private sector are not confused by medicine regimens of patients crossing over from the public sector with chronic ailments such as TB, HIV, Diabetes, Hypertension and other chronic illnesses.

6.2 Essential Medicines List

The Essential Medicines List is a fundamental element in promoting rational use of medicines and controlling health care costs.

The Minister of Health will establish the National Pharmacy and Therapeutics Committee (NPTC) which will ensure the Essential Medicines List (EML) is updated regularly but not later than every five years.

The products in the list will be identified only by their generic names (INN- International Non-proprietary Name).

The criteria for selection of medicines in the EML are:

i. Quality, safety, efficacy and cost
ii. Intended level of care at which medicines will be utilized
iii. Epidemiological profile
iv. Therapeutic advantage.

The EML will be the basis for the following activities:

a) Public education and information,
b) Public sector procurement, prescribing, and dispensing,
c) Medical education,
d) In-service training programmes for health professionals,
e) Selective support for the local pharmaceutical industry,
f) Pricing policies
g) Control of donations of medicines.
h) Consumer protection

6.3 Level of Care

The EML will indicate the level of use of each item based on the following classifications: -

a) C = Medicines for use at central hospitals
b) R = Medicines for use at regional hospitals
c) HC = Medicines for use at health centres/Referral Health Centres
d) HP = Medicines for use at health posts.

7. RATIONAL USE OF MEDICINES

7.1 Prescribing and Dispensing

a) Prescribers will be encouraged to prescribe by generic name and use the Essential Medicines Concept.

b) A prescriber who wishes to dispense will be required to obtain a dispensing licence from the relevant licensing body.

c) At the dispensing level, a less expensive generic equivalent may be substituted unless the prescriber had indicated, "do not substitute" on the prescription. General Sales List Medicines will be made available through licensed outlets in approved packages carrying printed instructions for use as approved by the PRB. The literature should be both in English and Somali languages.

d) The dispensed medicines shall be put in packages, which shall bear the following information (in Somali language): Name of the patient, name of the product, instruction for use and precautions, name and address of the facility from where the medicine is dispensed.

7.2 Prescription Practices

All prescribers will be categorized based on their qualifications; and the respective range of medicines that they will be expected to prescribe will be specified. Prescriptions must contain the following information:

i) Name, age and sex of the patient;
ii) Name(s), dosage, and duration of all medicines on the prescription;
iii) The full name, initials, qualifications/designation and signature of the prescriber. His address and contact.

7.3 Generic Prescribing

All trainings on prescribing medicines in medical, nursing, and pharmacy schools will be based on the use of generic names.

7.4 Treatment Guidelines

Treatment guidelines for hospitals and outpatient health facilities will be regularly updated and made available to government, private and other health services. The use of these guidelines will be encouraged through information campaigns and pre service and in service training.

7.5 Education and Training

The curricula of institutions offering pharmacology and therapeutics training for medical, paramedical, pharmacy and nurses will be based on the Essential Medicines Concept. The curricula will also include detailed information on the National Medicines Policy, the Essential Medicines List, the use of generic names; the essential medicines supply system, and rational prescribing. Various licensing bodies shall establish continuing education programmes, attendance at which will be necessary for renewal of professional licences.

7.6 Pharmacy and Therapeutic Committees

Each health institution must have a Pharmacy and Therapeutics Committee (PTC). The PTC will be responsible for overseeing medicine selection, and formulary management, policies on prescription, medicine utilization review, and policies on dispensing and administration of medicines.

7.7 Medicines Information

To facilitate the promotion of rational use of essential medicines and dissemination of appropriate medicines information to the health care providers and the general public, all pharmaceutical products must be accompanied by product literature inserts with adequate information as to the indications, pharmacology, side effects, toxicology, special precautions and contra-indications. A Medicine Information Unit will be established under the Pharmacy Regulatory Board.

7.8 Medicines Advertising and Promotion

Promotion and advertising of medicines to health professionals must be ethical, factual, educational and balanced in approach and designed to impart non-exaggerated information to prescribers. These principles apply equally to symposia and other scientific meetings. Promotional materials must be in good taste and not in any way offensive to any segment of society. Major warnings as regards the dangers of using the advertised product must be given in the advertisement in a manner that ensures they are noticed and clearly understood. Medicines should not be advertised or launched before registration procedures are complete and the advert approved by the Pharmacy Regulatory Board.

Promotion and advertising of medicines to the general public must be limited to medicines legally available without prescription and should help people to make rational decisions on the use of medicines. Advertising must not be addressed directly or indirectly to children and should not encourage unnecessary or excessive use of medicinal products. Free samples of products registered for sale in the country may be provided only in modest

quantities to prescribers and only on request from the prescriber. Free samples should not be sold to the general public.

7.9 Patient Compliance and Self Medication

a) Patient Compliance
The PRB will promote research on the social and cultural factors, which facilitate the use of medicines and will endeavour through health education and provision of relevant information to alter any attitudes and beliefs, which are found to contribute to irrational use or non-use of medicines

b) Self Medication
Health education for the public on subjects including disease prevention, limited self-diagnosis, on what constitute appropriate and in appropriate self-medication and on suitable alternative non-medicine treatment will be promoted through the use of all available forms of mass media.

8. FINANCING AND SUSTAINABILITY

8.1 Government Financing

The Government will make an annual budget for medicines and medical supplies that is based on a rational and reasonable determination of Ministry's needs for pharmaceuticals and medical supplies. This determination will be established on a per capita basis. Year-to-year adjustments will be made on the per-capita requirement according to changes in the utilization of services and changes in the purchasing power of the shilling. The budget will be separated from other budgetary needs, such as salaries; and once voted, will be available for payment of supplies as and when needed.

The Ministries of Health, Finance, Interior, Commerce and the Central Bank, will coordinate prioritization of Essential Medicines in the allocation of foreign exchange.

8.2 Medical Insurance Schemes

Programmes will be developed to provide for payment of prescription medicines. The Government will promote viable and sustainable medical insurance schemes. The establishment of these medical insurance schemes will be determined by law.

8.3 Donor Assistance

All donated Pharmaceutical Supplies for the public sector will be channelled through the National Supply System. Clear guidelines on donation of medicines will be developed and circulated to all prospective donors. A central database of donations will be established in order to be able to cost the value of the donated products. Medicines donations from both international and local sources must comply with the provisions of this Policy.

8.4 Rationalization of the Pricing Structure

a) A Pricing Committee with clearly defined functions to monitor medicine prices shall be established within the Ministry of Health and it will be directly accountable to the Pharmacy Regulatory Board (PRB). The committee members shall compose of staff drawn from the Ministry of Health - (Health/Pharmaco-economists) and the Ministry of Commerce.

b) There shall be total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of medicines, as well as private clinics and hospitals.

c) Medicines at the primary health care level shall be supplied free of charge in the public centres.

8.5 Cost Sharing and Sustainability

a) At the secondary and tertiary levels a fixed affordable co-payment for medicines supplied by the government shall be levied.

b) A system of exemption shall be established for patients without the resources to meet such payment to ensure that they are not deprived of treatment.

c) A data base shall be developed to monitor the cost of medicines in the country in comparison with global prices.

d) Price increases of an item shall be regulated with selection and open tenders.

e) Where the government considers that the retail prices of certain medicines are unaffordable and the items are essential to the well being of any sector of the population, the Ministry of Health shall develop a system to make these medicines available to the private sector at acquisition cost plus the transaction costs involved.

9. TRADITIONAL MEDICINES

9.1 National policy and regulation

Not many countries have national policies for traditional medicines. Regulating traditional medicine products, practices and practitioners is difficult due to variations in definitions and categorizations of traditional medicine therapies. A single herbal product could be defined as a food, a dietary supplement or an herbal medicine, depending on the country. This disparity in regulations at the national level has implications for international access and distribution of products.

9.2 Technical Support

WHO, and the Ministry of Health, will cooperate to promote the use of traditional medicine for health care. The collaboration aims to:

a) Support and integrate traditional medicine into national health systems in combination with national policy and regulation for products, practices and providers to ensure safety and quality;

b) Ensure the use of safe, effective and quality products and practices, based on available evidence;

c) Acknowledge traditional medicines as part of primary health care, to increase access to care and preserve knowledge and resources; and ensure patient safety

9.3 Regulation and Control

The Ministry of Health will establish a taskforce to develop guidelines on traditional medicines and alternative therapy.
Meanwhile the Pharmacy Regulatory Board through its committees will determine the suitability of the medicines and provide specifications for the practice and utilization of the medicines.

9.4 National Reference Centre

A National Reference Centre for traditional medicines will be established. Its functions will include:

a) Development of a national database of indigenous plants that have been screened for efficacy and toxicity;
b) Testing for toxicity and efficacy;
c) Compiling a National Formulary of approved "Essential Traditional Medicines"
d) Dissemination of necessary information to the members of the public on the safety of these Traditional Medicines.

9.5 Research and Development

Herbal and other traditional remedies are extensively used in the country and are widely regarded as efficacious. The government will encourage and support research into these remedies with a view to identifying the most useful remedies for treatment of common endemic diseases, determination of the composition of their formulation into standardized products of reliable quality, and rationalization of their use.

10. DRUG AND SUBSTANCE ABUSE

Information on Drug Abuse will be disseminated to the public in a language easily understood by all members of the community. Educational efforts will be expanded to reach all the District Committees, and all susceptible groups (particularly youth and students). The PRB will organize multidisciplinary information seminars throughout the country to educate all cadres of health personnel. The use of all the media of communication including print and electronic as well as traditional media such as songs, poems, and drama will be deployed to prevent and control the rapid spread of Drug and substance Abuse. Mosques and religious leaders as means of communication will also utilized.

11. MANPOWER TRAINING AND DEVELOPMENT

The advent of the National Medicines Policy requires that the manpower imbalance in the pharmaceutical sector is addressed by the Government within a general policy of manpower development.

11.1 Manpower Substitution

As an interim measure, and until the availability of enough pharmacists, the MoH will depend on Manpower Substitution by allocating to other Qualified Health Personnel certain functions that would otherwise have been performed by pharmacists.

To ensure that such substitution achieves its purpose the MoH should ensure that the pharmacists are deployed fully in administrative roles to supervise, support and train the non-pharmacists health workers providing essential pharmaceutical services to the general public.

11.2 Continuous Professional Development

The Registrar/Secretary of the National Pharmacy Regulatory Board (PRB) shall collaborate with other stakeholders in establishing and modifying curricula for continuing education and developing of Manpower training and development programmes of the Pharmaceutical Sector.

11.3 Recruitment and Career Progression

The professional skills of pharmacists, pharmacy assistants and store managers are vital to the efficient and successful operation of Medical Supply System. The government will therefore ensure that adequate number of suitably trained pharmaceutical and stores management personnel are recruited to run and maintain public sector facilities. A suitable career structure will be designed to ensure that the skills and knowledge of staff will be regularly improved and updated through a continuing education and refresher training program.

11.4 Collaboration with the Ministry of Education

The Ministry of Health recognizes local Universities as key stakeholders in the implementation of the National Medicines Policy.

The Universities will therefore, be encouraged to identify the most important outcomes of the implementation programme that are related to pharmacy practice so as to develop training programmes that will address the existing imbalance of professional and skilled manpower at all levels of the pharmacy profession for the next five years and beyond.

Meanwhile the local Universities with the support of the Ministry of Education could enter into Memorandum of Understanding (MOU) with Universities in the region and other parts of the world for training of both general pharmacists and specialists. Such arrangements could also establish mechanisms whereby the training of Pharmacy Assistants and Certification of existing pharmacy practitioners is provided at the local universities in the country.

11.5 Training for Professionals

As part of continuous training for health care providers, the following professional training programmes should be used as courses for regular updates and also for renewal of practise licences;

11.5.1 Training of Pharmacists

a) Introduction to the principles of the National Medicines Policy, standard treatment guidelines, Essential Medicines concept in effective prescribing and rational use of medicines;

b) Organisation and management of decentralized health care systems

c) The management of Medicines supply and Hospital pharmacy administration.

d) Training on Pharmaco-epidemiology, Pharmaco-economics, Pharmaco-vigilance and Principles of Pharmaceutical care.

e) The disposal of Pharmaceutical waste

f) Training on the rational use of medicines

g) Update on Drug and Substance Abuse

11.5.2 Training of physicians and specialized doctors:

a. Introduction to the principles of the National Medicines Policy, standard treatment guidelines, essential medicines concept in effective prescribing and rational use of medicines;

b. Managing decentralized health care systems.

c. The management of Medicines supply and Hospital administration.

d. The disposal of Pharmaceutical waste

e. Training on the rational use of medicines

f. Update on Drug and Substance Abuse

11.5.3 Training of Nurses

a. Introduction to the principles of the National Medicines Policy, standard treatment guidelines and essential medicines concept in effective prescribing (in cases of substitution, when medical doctors are not available) and rational use of medicines;

b. Training on the rational use of medicines

c. The disposal of Pharmaceutical waste

d. The role of record keeping and data collection in pharmacy practice management information systems;

e. Introduction to dispensing (in cases of role substitution when pharmacy personnel are not available) and managing medicine supplies in clinics (in cases of role substitution when pharmacy personnel are not available).

f. Update on Drug and Substance Abuse

g. Updates on the diagnosis and treatment of common diseases

11.5.4 Training of Pharmacy Technicians – Assistance

a. Introduction to principles of the National Medicines Policy, concept of essential medicines, managing medicine supply.

b. The disposal of Pharmaceutical waste

c. Documentation and management of Health information systems.

d. The role of record keeping and data collection in pharmacy practice.

e. Training on the rational use of medicines

f. Introduction to dispensing (in cases of substitution role, where there is no pharmacy doctors).

g. In-service (on job) basic training for registration purposes.

h. Update on Drug and Substance Abuse

i. Updates on the diagnosis and treatment of common diseases

12. RESEARCH AND DEVELOPMENT

12.1 Training

Research is a multidisciplinary activity involving medicine, pharmacy, pharmacology and medicinal chemistry. The government will encourage the development of high level research in these disciplines, and the training of research personnel in the relevant area of interest. Research will focus particularly on the following areas:

a) The impact of the National Medicines Policy and its core principles on health service systems and delivery problems related to prescribing and dispensing at different levels of the health system;

b) The economics of medicine supply and the socio-cultural aspects of medicine use, including self-medication, acceptability and use of supply systems, and knowledge, attitudes and practices of users of essential medicines.

c) Evidence based community surveys in health seeking behaviours

12.2 Types of Research

Research may take a variety of forms including basic research in the natural science, applied research for conversion of scientific knowledge to technological advancement, and operational research to utilize tools identified through applied research for disease control. The government will encourage, support and co-ordinate these various forms of research and would make them available to research workers in other areas. The various forms of research to be used are listed below:

12.2.1 Basic Research: Investigation and analysis focused on a better understanding of a subject, phenomenon, instead of on a specific practical application of the results.

12.2.2 Applied Research: Scientific study and research that seeks to solve practical problems. Applied research is used to find solutions to everyday problems, cure illness, and develop innovative technologies.

12.2.3 Exploratory and development research into local raw materials as sources for new medicines and for excipients will be actively supported in order to achieve the objective of increased self-sufficiency through promotion of local manufacturing capabilities.

12.2.4 Operational research: Analytical method of problem-solving and decision-making that is useful in breaking down problems into basic components and then solved in defined steps.

13. CLINICAL TRIALS

13.1 The Role of Clinical Trials

Clinical trials are sets of tests in medical research and drug development that generate safety and efficacy data (or more specifically, information about adverse drug reactions and adverse effects of other treatments) for health interventions. The National Pharmacy Regulatory Board will advise the relevant government research institutions on the need for establishment of proper clinical trial protocols which will ultimately provide scientific evidence on safety and efficacy of medicines that have been subjected to clinical trials. This information may be used for purposes of registration of new molecules/medicines/formulations.

13.2 Protocols for Clinical Trials

The PRB will approve protocols for clinical trials for new medicines and establish guidelines for clinical trials involving medicines already in the country. This will be achieved through the Ministry of Health, supporting important areas of the various forms of research that can promote the successful implementation of the National Medicines Policy. The findings of such research will be used to make necessary adjustments in strategy and to ensure that policy objectives are achieved.

14. INTERSECTORAL AND TECHNICAL COOPERATION

14.1 Intersectoral Collaboration

The Ministry of Health in collaboration with Bilateral and Multilateral Agencies, should establish a forum of stakeholders to enhance the exchange of information between the concerned Ministries, Institutions, Donor Agencies and NGOs on matters pertaining to the National Medicines Policy.

14.2 Technical Cooperation

Meetings of the stakeholders should be held at least once every three months. The following areas will form part of the terms of reference of a taskforce to be established by the Ministry of Health as indicated above;

a) Evaluation of medicines and quality control

b) Regional procurement systems and the exchange of information on pharmaceutical supply sources;

c) Computerization of stock control, medicine registration and utilization;

d) Transfer of appropriate technology and exchange of medicine information;

e) Training and human resources development;

f) Management of emergency situations, such as epidemics and disaster.

15. MONITORING & EVALUATION

The Ministry of Health will establish a taskforce of stakeholders to maintain a monitoring and evaluation committee. The committee shall oversee the implementation of the NMP and define indicators for measurement of progress towards achieving the objectives of the National Medicines Policy.

The aim will be achieved through coordination, supervision, monitoring and evaluation of the implementation of the National Medicines Policy by the Ministry of Health. 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. Progress in National Medicines Policy implementation will be monitored at regular intervals. A full evaluation of the National Medicine Policy will take place every three years.

The implementation programme of the NMP should be very participatory and involve all the stakeholders in its activities, including, especially those outside the Ministry of Health. This in effect means that the taskforce and the National Medicines Policy Implementation Programme secretariat will have representatives from the public and private sectors; and they will be responsible for the planning, monitoring and evaluation of the various activities of the National Medicines Policy.