THE GAMBIA NATIONAL MEDICINES POLICY

Department of State for Health & Social Welfare

July 2007

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ABBREVIATIONS

ADR	Adverse Drug Reaction
BI	Bamako Initiative
CMS	Central Medical Stores
DRF	Drug Revolving Fund
GEML	Gambia Essential Medicines List
GEMP	Gambia Essential Medicines Programme
GMP	Good Manufacturing Practice
GNF	Gambia National Formulary
GSTM	Gambia Standard Treatment Manual
IEC	Information Education and Communication
INN	International Non-proprietary Name
DoSH	Department of State for Health
MRA	Medicines Regulatory Authority
NMP	National Medicines Policy
NMQCL	National Medicines Quality Control Laboratory
NMP	National Medicines Policy
NGO	Non Governmental Organization
NPS	National Pharmaceutical Services
OTC	Over the Counter
RUM	Rational Use of Medicines
QC	Quality Control
TM	Traditional Medicines
WHO	World Health Organization

FOREWORD

The provision of adequate health care, which includes access to essential medicines, is the fundamental right of a country's citizenry. The investments is the health sector, including the pharmaceutical sector is therefore substantial. Notwithstanding, there is the constant challenge within the pharmaceutical sector of ensuring the availability and rational use of good quality and affordable essential medicines and supplies in the health service delivery system.

Since the adoption of its first National Drug Policy in 1995, the pharmaceutical sector in the Gambia has registered a number of achievements, ranging from the establishment of a National Pharmaceutical Services Unit, construction of three additional divisional medical stores, the provision of vehicles etc. Efforts to improve the management and utilization of pharmaceuticals had resulted to a number of training on "Rational Use of Drugs" and the "Management of drugs at health facility level" and the development and provision of the "Standard Drug Treatment Manual". All these had therefore contributed to improve the availability and accessibility of medicines in the country.

Despite these achievements, there are still constraints and challenges, e.g. storage facilities, medicines regulation, medicines quality assurance including laboratory facilities and human resources, some of which are currently being addressed. A number of global and national challenges such as the HIV /AIDS pandemic, the re-emergence of TB, and the increasing medicines resistance to infectious diseases including malaria, can also negatively impact on the pharmaceutical sector, as it obviously put further constraint to its limited resources, both financial and technical. This is further compounded by the problem of counterfeit, fake and sub-standard medicines, which is increasingly becoming a major concern world-wide.

The development of this policy, which is a tool to guide us through the process of strengthening our systems, resolving our problems and facing our challenges in a coordinated manner within the framework of the National Health Policy, is therefore timely.

On behalf of the Government of The Gambia, I wish to thank the World Health Organization (WHO) and the European Community for the technical and financial support provided for the update of this policy. I also wish to thank the technical team for the review and update of the policy document and the stakeholders for their endorsement during the consensus meeting.

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Secretary of State for Health & Social Welfare
July 2007

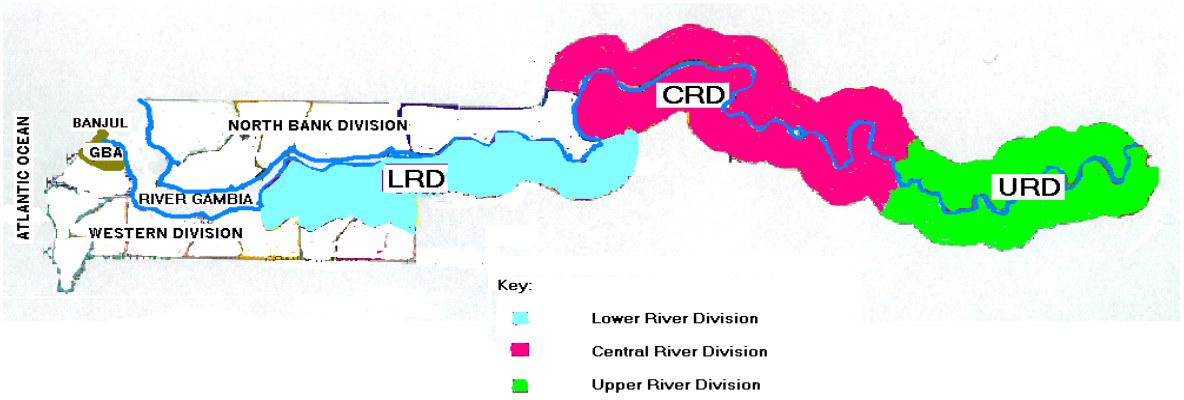
1. INTRODUCTION

Background

1.1 Country Profile

The Republic of The Gambia is located on the West Coast of Africa and is bordered on the East, North and South by Senegal and on the West by the Atlantic Ocean. It covers an area of approximately 11,000 Square Kilometres, with a length of 350 Km from East to West and a width of between 24 and 48 Km, with the west being the widest (see map of The Gambia). The land is generally low lying with the highest point less than 50 metres above sea level. It has a tropical semi arid Sahelian climate characterized by two seasons – a five month wet season (mid June to October) and a seven month dry season.

Map of The Gambia



The Gambia is divided into five administrative divisions and two municipalities. The Population and Housing Census of 2003 reported a total population of 1,364,507 of which 676,726 (49.6%) were males and 687,781(50.4%) were females. The Capital, Banjul, has a population of 35,061 and the adjoining Municipality of Kanifing and Brikama have a population of 322,735 and 389,594 respectively. The geographical distribution of the population is 747,390 in Western Division (which includes the two municipalities), 72,167 in the Lower River Division, 172,835 in the North Bank Division, 185,703 in the Central River Division and 182,586 in the Upper River Division.

Four (4%) percent of the population is under one year, 20% under five years, 45% under fifteen years and 55% above fifteen years. Annual population growth rate is reported to be 4.9% for the period 1974 to 1983 and 3.4% for the period 1984 to 1993 and 2.8% for the period 1993 to 2003. The estimated life expectancy is 63.5 years, with 62.4 years for males and 65 years for females (2003 census).

The country is classified as a low income country, with a per capita gross national income of $310, well below the averages of $490 and $450 for Sub-Saharan Africa and other low-income countries respectively (World Bank Development Report 2004). The economy is based on agriculture, fisheries, tourism, trade and the country has as yet no commercially exploitable natural resources. The adult literacy rate is still relatively low at 37% nationally, with a male literacy rate of 48.5% and female of 29% (2003 Census).

The telecommunication network covers the entire country. The road network system is also relatively good, but had in recent years experienced some deterioration, and efforts are currently underway for road rehabilitation in various parts of the country.

1.2 Health Profile

The Public Health Sector is a three-tiered system based on the Primary Health Care (PHC) strategy. At the primary level, service is delivered through 492 health posts and trekking stations, with the main health care providers being Village Health Workers (VHW) and Traditional Birth Attendants (TBA) supervised by Community Health Nurses (CHN). This is further complimented by 38 village clinics out of which 29 are operational with medical doctors provided through Technical Assistance. At the secondary level, there are currently 36 health facilities comprising six major health centres, eighteen minor health centres and thirteen dispensaries. The tertiary level comprises four hospitals, with one currently under construction. The public health service is complemented by thirty-four private and NGO health facilities and clinics. In addition, there are also fourteen clinics operated by the Service institutions such as the Gambia National Army, Police Force and Fire Services and other clinics operated by community initiated projects.

The main causes of mortality in the under-fives are Malaria, Diarrhoeal Diseases, Acute Respiratory Tract Infections and Malnutrition. Maternal deaths are mainly due to sepsis, haemorrhage, eclampsia, prolonged and obstructed labour and unsafe abortion, with anaemia as a major contributing factor. About 40% of outpatients consultations reported in 2004 were due to malaria, whilst 25% were diarrhoeal diseases and acute respiratory tract infections (HMIS, 2004). Diabetes and Cardiovascular diseases are reported to be steadily increasing over the last ten years. The HIV prevalence rate had decreased from 2.1 to 1.1% for HIV 1 and 0.9 to 0.6% for HIV 2 based on results of the 2004 and 2005 sentinel surveillance respectively. The basic health indicators as below had shown an improvement over the years.

HEALTH AND OTHER INDICATORS

INDICATOR	1983 Census	1993 Census	2003 Census
Population	687,817	1,038,145	1,364,507
Life Expectancy	42	53	63.5
Male	40	52	62.4
Female	44	54	65
Infant Mortality Rate (per 1000 live births)	167	92	75
Under 5 Mortality Rate (per 1000)	260	137	99
Maternal Mortality Rate (per 100,000)	N/A	1050 (1990)	730

There was an estimated 4,365 health personnel in the health sector in 2005, with 2,386 in the public sector (divisional health facilities & referral hospitals), 152 at the central (department) level and 859 in the private/NGO sector (HRH Situational Analysis, 2005). The 968 Community Health Workers (CHWs) which comprises the Village Health Workers and Traditional Birth Attendants are not salaried personnel of DOSH, but under their purview with the Divisional Health Teams being responsible for their training and supervision. With the decentralization of health services, there are currently six Divisional Health Teams in the country responsible for the management and supervision of health facilities and services within their administrative divisions.

1.3 Pharmaceutical Profile

The National Pharmaceutical Services was established as a division under the Directorate of Health Services in 1996. Consequently four major functions were identified:

- **Essential Medicines Supply** - deals with the selection, procurement, storage, inventory control and distribution of drugs, medical/ surgical, dental and laboratory supplies.
- **Medicines Legislation and Regulation** – the activities of the Medicines Board, which regulates the import, distribution and sale of pharmaceuticals in the country.
- **Medicines Quality Control Services** – the laboratory analysis of drugs as part of quality assurance and the identification of narcotic and psychotropic medicines.
- **Planning and Management** of the pharmaceutical sector including human resource development.

A situational analysis of the pharmaceutical sector was conducted in 2005 as part of the process to review the National Medicines Policy. The main findings of this review included:

- The Plan of Action developed for the implementation of the policy was comprehensive, but not fully achieved due to limited funding, limitations in technical capacity and lack of integrated implementation according to the implementation plan.
- The establishment of the National Pharmaceutical Services resulted to the reorganization of the sector, but was still regarded as a supplier of pharmaceuticals and other medical items. The mandate of the National Pharmaceutical Services as the National Drugs Policy secretariat as not adequately strengthened with technical and financial resources.
- The budgetary allocation for pharmaceuticals had steadily increased from 15.6% to 19.8% of the health budget during the period of 2000 to 2004. The total health budget had also increased from 10.8% to 16.8% of the Government budget during the same period (PER Report, 2005). The budget on pharmaceuticals was further supplemented by donor funded health activities.
- Whilst the contribution of Drug Revolving Fund in financing medicines supplies is limited but significant, the contribution of the Bamako Initiative remains uncertain due to financial and management constraints.

- Investments made on the medicines supply system which included the construction of three divisional medical stores and the provision of vehicles further facilitated the decentralization of storage and distribution of supplies.
- Stock management still remains a problem at the Central Medical Store, mainly due to inadequate storage facilities, which is currently addressed with the newly constructed Central Medical Stores.
- Concerted efforts were made over the years on improving the management and utilization of pharmaceuticals through training of health workers on the "Rational Use of Drugs", "Management of drugs at health facility level" and the provision of the "Standard Drug Treatment Guidelines".
- Regulatory control in the private sector has improved but still significantly constrained by inadequacies of the medicines legislation, limited human and financial resources.
- The National Medicines Quality Control Laboratory which was established in 1991 was neglected over the years due to lack of human and financial resources.
- Human Resources Development was identified as a major constraint in the development of the pharmaceutical sector as no comprehensive training plan was implemented during this period. The existing personnel fall short of the estimated requirements, especially for pharmacists and pharmacy technicians.

2. THE OVERALL GOAL AND MAIN OBJECTIVES OF THE NATIONAL MEDICINES POLICY

Goal

The National Medicines Policy (NMP) aims to contribute to the attainment of quality health services for the population of The Gambia through ensuring the continuous availability, accessibility and affordability of essential medicines of appropriate quality, safety and efficacy and by promoting their rational use.

Main objectives are to:

- Ensure that essential medicines are made available to the population at affordable prices.
- Ensure that all medicines available in the country are safe, efficacious and of good quality.
- Promote rational use of medicines and provide objective information to health workers, patients and the general public.
- Ensure continuous education and professional training for pharmaceuticals and other relevant health workers for the effective implementation of the various components of the NMP.
- Institute a sustainable financing mechanism to ensure continuous availability of adequate quantities of the required essential medicines.
- Ensure adequate and updated legislation leading to effective regulation of pharmaceuticals.
- Promote the active participation of all stakeholders, especially the private sector, for the effective implementation of the policy
- Strengthen partnership at the national, regional and international levels in ensuring the full implementation of various components of the NMP through utilization of available resources, research, knowledge and expertise.

3. MEDICINES LEGISLATION AND REGULATIONS

Preamble

The legal framework regulating the movement and distribution of pharmaceuticals for both human and veterinary use are embodied in the Medicines Act 1984 and Medicines Regulation 1986. A review of the medicines legislation in 2005 identified a number of gaps and weaknesses which made regulatory control of pharmaceuticals difficult. The main weakness was that the legislation was a combined legal structure for the control of professional practice of pharmacy as well as the movement of the pharmaceutical products. However, whilst the control of pharmaceutical products was relatively addressed, the regulation of the professional practice was deficient in a number of critical areas. The Medicines Regulations requirement which allows for the sale of medicines in multipurpose stores was regarded as grossly insufficient, resulting to the proliferation of uncontrollable open market drug stores and drug peddling. The revised medicines legislation developed in 2005 is expected to address the key constraints of the Medicines Act.

Goal

Strengthening the legislative and regulatory framework to ensure that medicines are of acceptable safety and quality according to approved standards and specifications.

3.1 Medicines Regulatory Authority (MRA)

Objectives:

- To establish the MRA as an independent body, fully accountable for enforcement of relevant pharmaceutical laws and regulations.

- To institutionalize the activities and operations of the Medicines Regulatory Authority independent of the Medicines Supply System.

- To strengthen the operational and financial mechanisms for a sustainable and effective functioning of the MRA.
- To ensure that the pharmaceutical professional practices are effectively monitored and controlled by the relevant professional bodies according to the applicable statutes.
- To increase public awareness on the importance of appropriate controls in the handling of medicines.

Strategies

- Update, adopt and enact the revised drug legislation for import, storage, distribution and use of medicines and related substances.
- Establish the Medicines Regulatory Authority (MRA).
- Support the activities of the Medicines Regulatory Authority and its associated committees.
- Strengthen the regulations, processes and procedures for the effective implementation of the legislation
- Provide the required human, technical, financial and logistical capacity for the effective application of the legislation
- Establish the Gambia Pharmacy Council to regulate the practice of the pharmacy profession.
- Use appropriate IEC tools for public awareness.

3.2 Medicines Registration

Objective:

- To ensure an effective and reliable medicines registration system.

Strategies:

- Establish and maintain a computerized medicines Registration System

- Ensure that all Medicines and related substances (herbal, homeopathic, nutritional supplements etc.) are registered and reviewed regularly.

3.3 Licensing of Persons and Premises

Objective:

- To ensure that all forms of medicines handling (manufacturers, pharmacy / medicines outlets / sellers) are appropriately regulated, duly authorized and licensed.

Strategy:

- Regular update and publication of the regulations for the licensing of persons and premises.
- Maintain the system so that only duly qualified and appropriately licensed persons are authorized to supply, sell and dispense medicines to the public

3.4. Inspection

Objective:

- To ensure an adequate and effective medicines inspectorate service under the direction of the MRA.

Strategy:

- Develop standards and guidelines for the inspection of manufacturing plants, public and private health facilities and medicines outlets

- Establish effective mechanisms for inspection of manufacturing plants, public and private health facilities and medicines outlets.

4. QUALITY ASSURANCE

***Preamble*:**

The quality of medicines in the public and private sector will be assured through adequate procedures for medicines registration, licensing, prequalification of suppliers, supplier monitoring, GMP inspection, pharmaco-vigilance and medicines quality control. The quality assurance system will include managerial, technical and legal aspects.

Goal:

To ensure that medicines reaching the patient are safe, efficacious and meet approved specifications and standards.

Objectives:

- To establish and maintain a comprehensive quality assurance system to ensure that the required safety, efficacy and quality of medicines and other medical products are maintained throughout the medicines supply chain.
- To promote and reinforce a good understanding of the need for effective quality assurance of medicines and other medical products by all those involved in the supply chain, including the consumer.
- To improve technical capacity on quality assurance.

Strategies:

- Strengthen and maintain an efficient and adequate Medicines Inspectorate to ensure that quality assurance policies are implemented in all aspects and at all levels of the medicines supply chain.

- Strengthen and maintain the effective and efficient operation of a reliable and comprehensive National Medicines Quality Control Laboratory (NMQCL).
- Establish collaboration between the NMQCL and other medicines quality control agencies to support further analysis and exchange of information.
- Ensure that all medicines received in the country conform to approved standards.
- Establish a system of post-marketing surveillance to effectively monitor the quality of medicinal products in circulation.
- Establish and maintain collaboration with other law enforcement agencies involved in importation control and medicines handling surveillance.
- Build capacity in medicines quality assurance for relevant staff involved in the medicines supply system.
- Establish counterfeit medicines surveillance in collaboration with other relevant agencies.

5. MEDICINES SELECTION

Preamble

The selection of medicines is in accordance with the essential drugs concept as defined by the World Health Organization. Essential medicines are those which are of utmost importance and necessary to meet the primary health care needs of the population. The Gambia Essential Medicines List (GEML) is used for the procurement of medicines in the public sector and also as a guide for registration and importation in the private sector.

Goal:

To ensure that medicines selected are both appropriate and affordable to meet the needs of the population according to the WHO Essential Drugs Concept.

Objectives

- To ensure that the medicines selected for use at all levels of the health care delivery system are most appropriate to meet the health care needs of the population.
- To increase the awareness of health workers, patients and the public on the essential medicines concept.
- To encourage use of the GEML of The Gambia as a guide for medicines procurement.

Strategies

- Formation of an Essential Medicines Committee for the periodic (2-3 years) review and updating of the GEML.
- Ensure the use of the GEML as a basis for procurement, prescribing and dispensing in the public health sector and promote its use in the private sector

6. ESSENTIAL MEDICINES SUPPLY SYSTEM

Preamble

The establishment of a secure, reliable and cost effective medicines supply system is a prerequisite for the availability of essential medicines on a sustainable basis. The public sector medicines supply system is complemented by the private sector. Earlier investments in the public sector which included the construction of divisional medical stores further facilitated the decentralisation of the supply chain. However, both public and private sector provisions are constrained by finance, logistics, human resources, infrastructure and also reliable data to support quantification.

Goal:

To strengthen and maintain a reliable and sustainable medicines supply chain at all levels of the health care delivery system, which will integrate and harmonise the supply management of various disease programmes.

6.1 MEDCINES QUANTIFICATION

Objectives:

- To improve the availability and reliability of required data for quantification.
- To enhance the capacity to process data and carry out quantification at all levels.

Strategies:

- Establish and maintain a reliable medicine management information system integrated into the Health Management Information System

which will ensure the ready availability of accurate morbidity and medicines consumption data.

- Develop guidelines for quantification and distribute to all levels.
- Develop capacity at all levels for data collection, processing and quantification of needs.
- Conduct regular data collection and processing.
- Conduct periodic and regular quantification exercises at all levels.

6.2 MEDICINES PROCUREMENT (INCLUDING DONATIONS)

Objectives:

- To improve procurement capacity at all levels of the health care delivery system.
- To ensure an appropriate, efficient, timely and transparent procurement system in the public sector according to The Gambia Public Procurement Act, 2003 and Regulations and any other relevant procurement regulation.
- To ensure procurement of generic medicines according to the GEML and encourage the practice in private sector.
- To ensure that donation of medicines to the public sector conforms to the GEML and/or approved by the MRA. Similarly, donations to the private sector and communities shall be subjected to approval by the MRA.

Strategies

- Conduct training on procurement regulations and procedures for staff at all levels.
- Coordinate and harmonize all forms of medicines procurement for the public sector with all other key stakeholders.

- Ensure that medicines procurement for the public sector is based mainly on the GEML and encourage the practice in the private sector.
- Develop guidelines and statutory instruments for medicines donations.
- Improve procurement efficiency through adequate provision of the required logistics including computerisation and capacity building.

6.3 MEDICINES STORAGE AND INVENTORY CONTROL

Objectives:

- To maintain quality and security of medicines and ensure the accurate and systematic recording and monitoring of stock levels from the time of arrival into the country to the time of issue to the patient.
- To ensure adherence to recommended storage and inventory control procedures.
- To ensure that adequate financial, physical, technical and human resource capacity is available to develop and maintain the required storage and inventory control system throughout the medicines supply chain.

Strategies

- Review and improve relevant record keeping procedures to ensure that the required data is accurate and readily available at all levels.
- Update and implement the standard operating procedures for storage and inventory control at all levels.

- Develop guidelines for good storage practices and ensure its adherence at all levels.
- Build capacity of staff on good storage and inventory control practices and institute adequate supervision and monitoring.
- Strengthen and maintain the computerized inventory control system.

6.4 MEDICINES DISTRIBUTION

Objectives:

- To ensure that only medicines registered or approved for use will be allowed to be distributed in the country.
- To ensure the establishment of and adherence to good distribution practices.
- To ensure equitable and timely distribution and redistribution where necessary of medicines and medical supplies.

Strategies:

- Ensure the provision of adequate and appropriate transportation, maintenance and communication facilities and the personnel necessary to maintain the efficient operation of the public sector distribution system.
- Improve and maintain the decentralization of the public sector medicines distribution system.
- Institute an efficient and practical system for the identification, collection and redistribution of excess stocks of medicines and medical supplies in the public sector.
- Develop guidelines on good pharmaceutical wholesale and distribution practices.

6.5 DISPOSAL OF EXPIRED AND UNWANTED ITEMS

Objective:

To strengthen and maintain the system for the safe effective and controlled disposal or destruction of expired or otherwise unwanted items of medicines and medical supplies.

Strategies:

- Collaborate with all relevant stakeholders for the proper disposal of unwanted and expired items.
- Develop and implement guidelines for suitable methods of disposal or destruction of medicines and unwanted items.
- Ensure adequate investments in the required equipment, technology and training for the proper disposal of expired and unwanted items.

7. RATIONAL USE OF MEDICINES

Preamble

The Rational Use of Medicines is essential to maximize the therapeutic benefit to the patient and reduce loss, wastage and hazards arising from irrational practices. The issue of RUM has always been a major concern especially in view of the fact that a wide range of personnel are involved in the prescribing and dispensing of medicines. Concerted efforts were made over the years on improving the management and utilization of pharmaceuticals through training of health workers on the Rational Use of Medicines, Management of medicines at Health Facility Level and the provision of the Standard Treatment Manual (STM).

Goal:

Ensure that medicines are managed, prescribed, dispensed and used rationally by health personnel, individuals and the community.

7.1 EDUCATION AND TRAINING

Objectives:

- To ensure that all individuals involved in diagnosis, prescribing and dispensing of medicines receive adequate and relevant training to enable them to perform these activities in accordance to guidelines and standards.
- To ensure that the necessary structure and process required promoting rational medicines use are established.

- To review and update the curricula of all health training institutions to provide adequate coverage on the essential drugs concept, and the rational use of medicines.
- To institutionalize continuing educational activities for the training of practising health workers in the afore-mentioned areas.
- To support the provision of relevant educational materials such as the GSTM and GNF as part of the continuing education process.
- To develop and implement Community IEC strategies on RUM.

Strategies:

- Review and update the curricula of all health training institutions to provide adequate coverage on the essential medicines concept, the rational use and management of medicines.
- Institutionalise continuing education activities for the training of practising health workers.
- Support the regular update, production and distribution of the GSTM.
- Support the development and distribution of The Gambia National Formulary (GNF).
- Develop and implement Community IEC strategies on RUM.

7.2 PRESCRIBING

Objectives:

- To ensure that medicines are prescribed correctly by appropriately trained and duly authorized personnel.
- To ensure that all prescribing conforms to agreed recommended standards.

- To ensure the provision of appropriate prescribing information and guidelines.

Strategies:

- Enforce that prescription of medicines in the public sector is by generic name only and actively promote this practice in the private sector.
- Promote the use of the GSTM and NMF through regular distribution and training of all relevant health workers.
- Establish functioning therapeutic committees in all hospitals and major health centres.
- Promote good prescribing practices.

7.3 DISPENSING

Objectives:

- To ensure that dispensing at all levels comply with recommended standards of good dispensing practices.
- To improve the availability and performance of suitably trained dispensing staff
- To institute generic substitution where necessary as a means of improving access and affordability

Strategies:

- Develop and distribute guidelines on good dispensing practices for all dispensing personnel
- Ensure adequate training of sufficient numbers of the required dispensing staff
- Establish a sustainable mechanism for the regular monitoring of dispensing practices

- Ensure the regular inspection of premises and personnel where dispensing of medicines are performed.
- Institute the practice of appropriate generic substitution in dispensing in the public sector and encourage the same in the private sector.

7.4 PATIENT USE

Objectives:

- To encourage patient compliance through the provision of relevant and adequate information.
- To ensure that the public has ready access to sufficient unbiased and practical information prior to embarking on self-medication.

Strategies:

- Design a system of producing and disseminating objective, relevant and practical information to the public on self medication, prevention and treatment of common conditions
- Provide adequate public information on disease prevention, limited self diagnosis and on suitable alternative non-medicines treatment.
- Ensure that adequate patient counselling on the correct use of prescribed medicines is given as part of the prescribing and dispensing process.
- Increase awareness on rational medicines use and adverse medicines reactions

7.5 MEDICINES INFORMATION, PROMOTION AND ADVERTISEMENT

Objectives:

- To ensure the availability, accessibility and the correct application of consistent and appropriate information on medicines and therapeutics for health workers, patients and the general public
- To ensure that information used in the promotion and marketing of medicines is unbiased, accurate and not misleading

Strategies:

- Establish and maintain a Pharmaco-vigilance system which will include a Medicines and Poisons Information Centre and Adverse Medicines Reaction Monitoring Service.
- Establish functional Medicines and Therapeutic Committees (MTC) at hospital levels.
- Create appropriate committees to promote rational use of medicines at national and facility level.
- Provide and disseminate reliable and scientifically-based literature on medicines.
- Establish a suitable body representing all stakeholders for the harmonization and coordination of relevant medicines information.
- Produce and distribute guidelines for medicines promotion and marketing
- Ensure that advertising and promotion of medicines conform with the requirements of the appropriate legislation for the control of medicines advertisement
- Ensure continuous review and periodic publication of all relevant national pharmaceutical literature.
- Ensure that scientific studies and surveillance on medicines are not misused and /or disguised for promotion.

8. MEDICINES FINANCING & PRICING

Preamble

The Government of The Gambia is responsible for the financing of pharmaceuticals and other medical supplies as well as pricing policy in public health facilities. The procurement of pharmaceuticals for the public sector is financed mainly by Government budget and further supplemented by bilateral and multilateral donors through specific health programs. The two financing strategies in place are the Drug Revolving Fund (DRF) and the Bamako Initiative (BI). The current pricing policy adopted by government is based on flat fees for both consultation and treatment. There is no pricing policy in the private sector.

Goal

To ensure that sufficient funding is made available to provide adequate quantities of good quality essential medicines at affordable prices and promote equity in access.

Objectives

- To develop and support suitable and sustainable medicines financing mechanisms.
- To encourage private sector investment in pharmaceutical service provision
- To ensure that prices of essential medicines are maintained at levels affordable to the population

Strategies:

- Demand for increased government budgetary allocation to health

- Allocate sufficient funding for the financing of the public sector medicines supply
- Encourage partner involvement in medicines supply financing
- Encourage and support the development and strengthening of national and community financing mechanisms which contribute to the sustainable financing of essential medicines.
- Identify and maintain incentives to promote private sector involvement and investment in the provision of pharmaceutical services
- Support the cost sharing policy of the public sector.
- Actively encourage the concept and practice of generic prescribing and dispensing as a means of providing medicines at affordable prices
- Apply the appropriate provisions of the WTO/TRIPS Agreement that the country can use to safeguard health and access to medicines in relation to the manufacture and importation of patented medicines.
- Review the current charges and institute a sustainable cost recovery system.
- Monitor medicines prices at public and private sector and use pricing information to promote affordability.

9. TRADITIONAL MEDICINES

Preamble

Herbal medicine is defined as plant-derived material or preparations with therapeutic or other human health benefits, whilst traditional medicine is described as the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illnesses (National Policy on Traditional Medicine and Regulation of Herbal Medicines, WHO, 2005)

There are currently no laws or regulatory systems on traditional, herbal or homeopathic medicines. No registration system exists and these traditional medicines are not included on the Essential Medicines List. There are currently no restrictions on the advertisement and sale of traditional medicines in The Gambia, and this is considered a major gap in the regulation of health services, as advertisements on traditional medicine and practitioners are quite common. Efforts to streamline activities relating to traditional medicines had resulted to the establishment of the Traditional Medicine Program in the Department of State for Health. There is currently a draft policy formulated on the practice of Traditional Medicines. The revised drug legislation is also expected to address the regulation and control of traditional medicines in the country.

Goal:

To maximize the benefits and minimize the hazards associated with the use of Traditional Medicines (TM).

Objectives:

- To regulate the production, distribution and marketing of TM
- To collaborate with other countries in the exchange of information and experiences on TM
- To support research in TM

Strategies:

- Establish and maintain a regulatory mechanism for the control of TM
- Support the development and implementation of the TM policy
- Facilitate collaboration with TM agencies for the exchange of useful information and experiences.

10. RESEARCH AND DEVELOPMENT

Preamble:

Various types of research notably operational research, drug development and clinical research are generally indicated on medicines policies. The potential for further operational and clinical research exists, but limited research has so far been conducted mainly due to human and financial resources constraints.

Goal:

To promote all forms of research necessary for the effective implementation of the NMP

Objectives:

- To identify the key areas of NMP where research will be required
- To support and encourage health professionals to undertake relevant research
- To ensure widespread dissemination and application of research findings in further development of health policies and practices
- To enhance overall research capacity

Strategies:

- Encourage and support health professionals to undertake medicines related research
- Identify and support both operational and clinical research on key areas of the NMP
- Encourage the continuous collection of accurate and useful information and data on medicines and medicine utilisation for evaluation and dissemination to health professionals using and adopting available measurement tools and indicators.
- Promote and support relevant research on traditional medicine

- Improve capacity of interested health professionals to conduct relevant research
- Develop and implement statutory requirement and guidelines for conducting medicines related clinical trials.
- Establish a system to facilitate dissemination of useful research findings to all stakeholders and other interested parties

11. HUMAN RESOURCE DEVELOPMENT

Preamble

The health sector has rapidly expanded from 1994 to date due to rehabilitation and upgrading of existing facilities, construction of new facilities (hospitals and village clinics) and the addition of medical staff, mainly through technical cooperation. This has therefore resulted to increased demand on the health care delivery system, which directly impacts on human resources. The Pharmaceutical sector comprises Pharmacists, Pharmacy Technicians and Pharmacy Assistants, with the store cadre as the support staff. The training of pharmacists and pharmacy technicians is external whilst that of pharmacy assistants is conducted locally. The trainings which are not well-coordinated are highly dependent on external funding and carried out on an ad-hoc basis. Furthermore, due to the limited number of pharmacists and pharmacy technicians, the pharmacy assistants who should mostly be in the health centres are currently at the divisional and central level with nurses mainly responsible for the management and dispensing of pharmaceuticals in the health facilities.

Goal

To develop, strengthen and sustain an adequate human resource base to improve pharmaceutical health service delivery; management and NMP implementation.

Objectives

- To significantly improve the human resource capacity at central level to reflect the importance of pharmaceuticals in health service provision and to provide for the required development of the National Pharmaceutical Services (NPS)

- To ensure that adequate numbers of suitably trained personnel are available throughout the healthcare delivery system for effective implementation of the NMP
- To ensure the continued motivation, retention and further development of pharmaceutical cadres in the public health sector
- To ensure equitable distribution of trained personnel in the provision of pharmaceutical services

Strategies

- Support and strengthen the NPS to enable it to perform its core functions in relation to the implementation of different components of the NMP
- Develop a strategic plan on human resource development for the pharmaceutical sector.
- Identify and actively promote the recruitment and training of the required pharmaceutical and other relevant human resources at all levels for the implementation of key pharmaceutical components and ensure their continued motivation and retention.
- Ensure the development and strengthening of a pre- and in-service training program on the essential medicines concept and for effective implementation of NMP
- Strengthen the capacity in hospitals and divisional level to carry out relevant NMP activities.
- Conduct supportive supervision and monitoring to identify gaps, deficiencies and suitable solutions for the pharmaceutical human resource for the effective implementation of the NMP
- Facilitate collaboration with other stakeholders for pharmaceutical human resource development

12. LOCAL PRODUCTION

Preamble

There is currently no industrial production of pharmaceuticals in the Gambia although there have been a number of proposals submitted to the Medicines Board in recent years. These proposals were not considered viable as they did not meet the minimum requirements for setting up medicines production plants according to WHO Guidelines on Good Manufacturing Practices (GMP). However, there is limited production of eye drops and some external preparations in the teaching hospital. It is envisaged that any future development on local production of pharmaceuticals will require financial investments and the transfer of appropriate technology.

Goal

Encourage and support appropriate development of local production of good quality, safe and efficacious essential medicines.

Objectives

- To create an enabling environment for the establishment of increased national capacity for the production of essential medicines
- To ensure that local production complies with current GMP and statutory requirements

Strategies

- Adhere to the established system of incentives for investments in the manufacturing of pharmaceuticals
- Conduct regular and systematic inspection of premises and ensure adherence to licensing conditions.
- Develop and strengthen technical capacity in the areas of pharmaceutical production techniques, quality assurance and GMP

13. INTERSECTORAL AND TECHNICAL COOPERATION

Preamble

Inter-sectoral cooperation and collaboration is necessary to achieve the overall goals of an efficient and cost-effective pharmaceutical services which contributes both to the health of the population and the socio-economic development of the country. Likewise, Technical Cooperation with other countries and international agencies is required to maximize the efficient utilization of the resources available in the implementation of the drug policy. In the country, the direction for both inter-sectoral and technical cooperation has been well articulated in the health policies. As problems of medicines supply and utilization affect many countries, the government will encourage exchange of findings and experiences with other countries and international agencies.

Goal

Actively pursue and effectively utilize all forms of Technical Cooperation, nationally and internationally, to ensure the full implementation of the medicines policy.

Objectives

- To strengthen and maintain existing technical cooperation arrangements
- To explore and foster the relationships between national and regional technical centres

Strategies

- Strengthen and maintain regular working relationships with national, regional and international agencies and institutions.
- Facilitate ongoing technical cooperation and the exchange of required information and experience
- Promote the optimal use of existing resources and encourage national and regional specialization.
- Build capacity in priority areas of required competence.

14. NATIONAL MEDICINE POLICY IMPLEMENTATION

The Government of The Gambia through the Department of State for Health & Social Welfare has the responsibility to strengthen the pharmaceutical capacity to reflect the fundamental role of pharmaceuticals in health services provision.

Goal:

To coordinate the adequate implementation of strategies for each pharmaceutical components

Objectives:

- To ensure the implementation of the various components of NMP
- To provide adequate staffing and allocation of resources for all implementing agencies
- To suitably equip the National Pharmaceutical Service to co-ordinate and supervise the implementation of the National Medicines Policy.
- To separate the medicines regulatory function from the medicine supply management

Strategies

- Establish the NMP Consultative Committee for regular meeting and discussing of issues.
- Develop a Plan of Action for the NMP (medium/long term and/ or annual / biennium).
- Identify financing mechanisms and mobilize resources

The National Pharmaceutical Services shall be established as a Directorate in the Department of State for Health to coordinate and provide secretariat for the overall implementation of the NMP, including Pharmaceutical Services Planning and Management.

The implementing agencies within the Pharmaceutical Sector will be:

I. National Pharmaceutical Services Directorate (NMP Secretariat)

i. Responsible for Pharmaceutical Policy Planning and Management

ii. Coordinate meetings of NMP Committee and functions of various stakeholders

iii. Coordinate monitoring and evaluation of pharmaceutical sector status and impact of NMP implementation.

iv. Coordinate dissemination of component reports and the pharmaceutical sector assessment reports.

v. Coordinate Human Resource Development,

vi. Conduct regular update of EML & NMF

II. Essential Medicines Supply Management (Central & Divisional Medical Stores)

i. Procurement of medicines and other medical supplies

ii. Logistics Management (Storage, inventory control, distribution and transportation)

iii. Rational Medicines Use and Management

III. Medicines Regulatory Services (MRA)

i. Registration of medicines & other related substances

ii. Licensing of persons and premises

iii. Inspection of licensed outlets

iv. Medicines Quality Control &Laboratory services

IV. Medicines Information Services

i. Medicines Information

ii. Poisons Information

iii.Pharmaco-vigilance

15. MONITORING AND EVALUATION

Goal

To ensure that the progress and impact in terms of meeting the goals and objectives of NMP implementation is assessed.

Objectives

- To establish and maintain an effective Monitoring & Evaluation (M&E) system
- To utilize and disseminate M&E findings in support of planning and necessary improvement and adjustment of strategies to implement different components of NMP.

Strategies

- Identify and build capacity for M&E at all levels
- Develop guidelines and indicators for monitoring of NMP implementation.
- Undertake monitoring and assessment of country pharmaceutical situation and specific components using tools that will allow comparison of performance and measurement of progress over time.
- Ensure optimal use of M&E findings for the improvement of pharmaceutical service delivery and management as an input to developing implementation plans and reviewing policies.
- Establish the mechanism for external assessment