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GHANA NATIONAL DRUG POLICY

(SECOND EDITION)

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PREFACE

This document is the second edition of the National Drug Policy prepared by the Ministry of Health of Ghana in 1998. The revision was based on the second Programme of Work of the Ministry of Health, the World Health Organisation's guidelines for drug policy development and implementation and recent developments in World trade, including Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and its Public Health Safeguards. These reflect concerns raised regarding access to medicines for managing existing and emerging diseases of public health importance such as HIV/AIDS, tuberculosis malaria and buruli ulcer.

The policy document is to guide the pharmaceutical sector in Ghana. The various elements examined under the policy include, legislation and regulatory control, drug registration, selection of essential drugs, local manufacture, herbal medicines, drug procurement and supply management, quality assurance, co-ordination, monitoring and evaluation. In highlighting these areas, due cognizance has been given to available resources, potential of drugs in disease management and the socio-economic environment. The policy has also been formulated with an inherent flexibility to accommodate future developments and changes in the overall vision of attaining health for all.

This document has been developed following several consultations with all the stakeholders in the Pharmaceutical sector in order to ensure a coherent and a multi-sectoral platform for achieving the main goal of the national drugs policy.

This document shall therefore remain the official policy to guide the pharmaceutical sector in Ghana.

I wish to express my sincere appreciation to all the technical experts, World Health Organisation and the Royal Netherlands Embassy for their immense contribution and support towards the development of this policy and the pharmaceutical sector as a whole.

Dr Kwaku Afriyie
Honourable Minister of Health

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World Health Organisation Headquarters, Geneva

LIST OF ACRONYMS

ADR.....	Adverse Drug Reaction
ADRM.....	Adverse Drug Reaction Monitoring
CD.....	Controlled Drugs
CEPS.....	Customs Excise and Preventive Service
CMS	Central Medical Stores
DIS	Drug Information Section
DRS.....	Drug Registration Section
DTCs.....	Drugs and Therapeutics Committees
FDB	Food and Drugs Board
GDB	Ghana Drug Bulletin
GHS.....	Ghana Health Service
GMP	Good Manufacturing Practice
GNDP.....	Ghana National Drugs Programme
HDC	Hospital Drug Committee
IEC	Information, Education and Communication
INN.....	International Non-Proprietary Name
MOH	Ministry of Health
MTHS.....	Medium Term Health Strategy
NCB	Narcotic Control Board
NCPv	National Centre for Pharmacovigilance
NDC.....	National Drugs Committee
NDIC	National Drug Information Centre
NDP	National Drug Policy
NEDL.....	National Essential Drugs List
NMC.....	Nurses and Midwives Council for Ghana
NQCL	National Quality Control Laboratory
OTC	Over The Counter Medicines
P	Pharmacist-recommended Medicines
PC.....	Pharmacy Council
PNDCL.....	Provisional National Defence Council Law
POM	Prescriptions Only Medicines
TAMD.....	Traditional and Alternative Medicines Directorate
TMPC.....	Traditional Medicines Practice Council
TRIPS.....	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Programme

VAT Value Added Tax
VCG Veterinary Council of Ghana
WAHC..... West Africa Health Community
WHO..... World Health Organisation

INTRODUCTION

Pharmaceuticals are essential to the delivery of health care in any given population or country. Drugs (including vaccines) cut across all major areas of health care delivery. The absence or inadequate supply of drugs has always led to a loss of confidence in the health care system. Drugs are useful in promoting health, preventing and managing diseases but can be harmful when used inappropriately.

The inappropriate use of drugs has medical and social implications and may exert undue financial burden on the health care system as well as on patients. For example, drugs are estimated to constitute 60 - 80 % of the cost of health care in Ghana. It is the responsibility of the state to ensure that certain functions in the pharmaceutical sector are clearly defined and implemented. A national drug policy forms the basis of government's responsibility to ensure access of its citizens to good quality drugs at affordable prices, enacting drug regulations, developing professional standards, and promoting the rational use of drugs.

The government's responsibility to meeting the aims of the National Drug Policy cannot be delegated. It can be implemented by very different mechanisms with various forms of participation by the main stakeholders in the pharmaceutical sector.

The existence of this document is a sign of government's awareness of the problems facing Ghana in the pharmaceutical sector. It forms a basis for planning and implementation, monitoring and evaluation of interventions in the pharmaceutical sector.

In its efforts to achieve this, the Ministry of Health and other related ministries and agencies have faced a number of problems including the following:

- An under-developed machinery to ensure enforcement of existing laws and regulations resulting in poor compliance;
- Lack of qualified and experienced management and technical personnel, inadequate drug supply management procedures, unsuitable and insufficient distribution and storage facilities, often resulting in increased procurement costs and losses;
- Lack of systematic and continuing education coupled with inadequate reference and learning materials for various sectors of the healthcare delivery system have

contributed to poor patient care practices (including inappropriate use of drugs) and efficiency;

- The increasing cost of drugs and medical supplies with the expanding provision of health services and its effect on the national health budget; and
- The dramatic increase in the number of drug outlets in both the public and private sectors. In addition the number of drugs currently registered by the drug regulatory agency stands at 680 generics and 2100 specialities.

The Ministry of Health has taken a number of steps directed at addressing some of the problems. These include:

- The promulgation of the Food and Drugs Law 1992 (PNDCL 305B) and the Pharmacy Act, 1994 (Act 489), which have provided the legal framework for the control of pharmaceutical activities in the country;
- Development of Traditional Medical Practice Act 2000 (Act 575) and efforts to constitute TMP council;
- The establishment of the Ghana National Drugs Programme;
- Government's approval of the first edition of the National Drug Policy in August 1999;
- The publication and distribution of a National Essential Drugs List, Standard Treatment Guidelines; and
- The establishment of regional focal persons responsible for promoting the rational use of drugs and the training and deployment of clinical pharmacists.

Recent developments in the global pharmaceutical arena have implication for the national drug policy. These developments include the Trade-Related Aspects of Intellectual Property Rights/World Trade Organisation (TRIPS/WTO) agreement and how it affects generic drugs, drugs for emerging diseases and pharmaceutical trade. The HIV/AIDS pandemic and the inability of poor countries to pay the high prices of the multi-national pharmaceutical companies have also received great attention.

At the national level there is an emerging shift in health financing strategies from out of pocket expenditure by patients to health insurance schemes. The introduction of VAT and the implementation of the government's exemption policy will impact on the present drug policy. While these debates are ongoing and procedures/mechanisms are being developed, a document of this nature must capture these trends and provide for them. This constitutes the basis for the revision of the National Drug Policy.

GOAL

The overall goal of the policy is to improve and sustain the health of the population of Ghana by ensuring the rational use and access to safe, effective, good quality and affordable pharmaceutical products

OBJECTIVES

The objectives of the policy are to:

- ✓ Promote the rational use of drugs by prescribers, dispensers and consumers;
- ✓ Strengthen quality assurance by ensuring that only safe and effective drugs are sold or supplied to consumers by both the public and private sector;
- ✓ Establish financing mechanisms which ensure access and equity to essential drugs;
- ✓ Improve the system of supply and management of drugs by rationalizing the procurement system and improving the drug distribution and management systems at all levels of health care delivery; and
- ✓ Increase the quantity and quality of health human resources involved in pharmaceuticals at all levels of the health sector.

SITUATIONAL ANALYSIS

Pharmaceuticals make an important contribution to global reductions in mortality and morbidity. However, making drugs available to people and ensuring their safe, effective and rational use is often not without its accompanying problems. The emergence of National Drug Policies (NDPs) in the second half of the 20th century was a positive concept for achieving optimal availability and use of drugs. The policies have often been initiated with the support of the World Health Organisation as well as other bilateral and multilateral agencies and non-governmental organisations. NDPs have provided a framework for coordinating activities in the sector involving public, private, NGOs, donors and other stakeholders by specifying the goals, their relative importance and the main strategies for attaining them.

Following years of long planning and discussions among various stakeholders, Ghana launched its first national drugs policy in 1999 to serve as a reference guide for national pharmaceutical development. The specified goal of the policy was “to make essential drugs available and accessible to the population; to ensure the safety, efficacy and the quality of drugs and their rational use by prescribers, dispensers and consumers”. The components of the policy included drug selection and registration, drug procurement, local manufacture and drug storage and distribution. It also dealt with issues involving rational drug use, drug advertising and human resource development as well as drug financing, quality assurance, and traditional herbal medicines among others.

The policy specified a number of strategies for achieving the above goal. For example it sought to improve the supply of essential drugs in the public sector by increasing the drug budget and specifying the introduction of cost sharing and allocation of more resources to underserved populations and areas. It also spelt out procedures for drug procurement, supply and local manufacture. The policy was also formulated with an inherent flexibility to accommodate future developments and changes with the overall vision of attaining health for the entire population of Ghana. The following constitute a brief appraisal of some of the key components.

Drug legislation and regulation

The enactment of appropriate legislation and introduction of regulations to provide legal basis is necessary to make NDP enforceable. Such legislation specify the

various actors and their responsibilities in the system regarding those who can produce, or import pharmaceuticals as well as the range of prescribers, sellers and the type of products they can sell. It also specifies various institutions for monitoring and enforcing regulations and ensures product quality, safety and efficacy. The legislative models and structures in Ghana however, indicate that:

- Laws and regulations have been difficult to enforce due to lack of capacity and limited logistics.
- Penalties and sanctions have not been used.

There is therefore a need to review existing regulations and amend operations to make them adaptive to local realities and make them enforceable. The situation calls for a well organized and trained inspection unit and a system of quality control.

Drug selection, registration and supply

The selection of essential drugs that are safe, of high quality and effective and their proper registration are important components of NDPs. Since the essential drugs concept was introduced by the WHO in the late seventies, many countries have adopted it as a core component of their national drug supply system. The Ministry of Health of Ghana published its list of essential drugs with therapeutic guidelines in 1988. Since then the document has undergone reviews in response to new knowledge on drugs and diseases as well as changes in the epidemiology of disease in Ghana. The fourth editions of the Essential Drugs List (EDL) and the Standard Treatment Guidelines (STG) were published in 2000. The target of bi-annual review of the Standard Treatment Guidelines and the Essential Drugs List has not been achievable. However, a review of the procedure for selecting drugs for the Essential Drugs List was put into effect in the year 2000. This resulted in the selection of drugs based on evidence that they are the most appropriate for treating health problems in the country. While the application of the list in the public sector is commonly adhered to, in the private sector any drug registered by the Food and Drugs Board may be used.

Drug registration and licensing are therefore important tools of drug selection in Ghana's NDP. Apart from quality, safety and efficacy, other important regulatory aspects include drug advertisements, standards of practice for drug outlets, post-marketing surveillance and pharmacovigilance. The Ghana National Drugs Programme has funded activities in both FDB and the Pharmacy Council to improve on these factors including the establishment of a National Pharmacovigilance Centre. The preponderance of imported pharmaceutical products has on occasion resulted in the procurement of substandard products. A well-established and functioning

laboratory for the FDB or identification of local laboratories to carry out quality assessment of products is needed.

Procurement

Ghana has a state system for procurement in the public sector. A functioning Procurement Unit is now established for the health sector resulting in improvement in procurement procedures. In the procurement of pharmaceuticals, the use of international competitive bidding has resulted in good prices for the sector. Manuals on procurement procedures have been developed and nationwide training on their use conducted. Systems for quantification of drugs and inventory management however need improvement. There is also the need to upgrade the skills of trained staff in implementing standard operating procedures prepared for the management of medicines, supplies and equipment.

Local Manufacture

The growth and capacity of local pharmaceutical production is still marginal. Local manufacture has also been weighed down by the free market policy of the government and lack of tax exemptions for raw materials thereby adversely affecting production and competition.

Drug Distribution

Drug distribution has improved essentially as a result of decentralisation of the health service and the revolving drug fund concept. The role of the Central Medical Stores in drug supply is yet to be fully clarified. A comprehensive distribution arrangement to move pharmaceutical products and other medical supplies from the medical stores to the service points is a major bottle neck to access to these items.

Rational drug use

The rational use of drugs is one of the major objectives of every drug policy. In Ghana, the recognition of the role of various health professions in achieving this objective has led to the establishment of a clinical pharmacy training programme, workshops for health personnel in various institutions and retraining of chemical sellers. The interventions introduced to improve the use of medicines have resulted in some gains including a reduction in the average number of drugs prescribed per out-patient encounter from 4.6 to 3.7. In addition, the proportion of out-patients receiving antibiotics and injections have reduced from 54% and 38% to 42% and 33%

respectively. However, as in most developing countries, inadequate control of drug promotion and drug dispensing by untrained prescribers has left a wide gap in the promotion of rational use of drugs. In general, while several activities have been carried out to promote rational prescribing and dispensing in the public sector, a lot remains to be done in the private sector. An important factor that hinders rational use of drugs is the lack of unbiased objective drug information. Through the Ghana National Drugs Programme an Information Resource Centre has been established to deal with this particular aspect of use of medicines for both health providers and clients.

Public education in rational drug use to provide individuals and communities with information and skills on appropriate, safe and judicious use have also lagged behind. Additional focused programmes also need to be carried out in both public and private sectors.

Financing drugs

The main challenge of drug policy is how to ensure stable and adequate financing. The public health care services in most countries of sub-Saharan Africa was characterised by state finance during the immediate postcolonial period. However, economic difficulties have compelled the introduction of user charges in recent years. The goal of this has been to maximize resources for drugs by ensuring continuous supply at low prices in order to improve economic accessibility. In Ghana mechanisms to increase economic accessibility has led to plans to implement health insurance and encourage generic prescribing. The drug policy has to date been unable to address abuses and problems associated with government suggested exemptions for specified groups of people who are considered incapable of paying for drugs at public health institutions.

Drug Pricing

Ghana has a long tradition of innovation and reform in the organization and delivery of its health services. The planned introduction of the National Health Insurance Fund (NHIF) follows earlier efforts to decentralize health service and drug management. The NHIF will replace the cash-and-carry system for financing health services medicines while maintaining local facility autonomy in managing their revolving drug funds (RDF). This autonomy increased local management's discretion over drug procurement and pricing, within clear guidelines. These guidelines state

that public facilities should buy first from the public sector and should mark up at a fixed 10 percent margin for Regional Medical Stores (RMS) and for Service Delivery points (SDPs). The MOH/Ghana Health Service (GHS) has been receiving reports of non-compliance with these guidelines within the public sector. RMS and SDPs have reportedly increased their procurement from the private sector while the considerable variation in drug prices indicate margins in excess of 10 percent. More therefore needs to be done to regulate retail margin.

Traditional Medicines

The role of traditional medicines and traditional medicine practitioners in the health care delivery system is recognised and the Traditional and Alternate Medicines Directorate of the Ghana Health Service has been established. Efforts are directed at bringing all traditional medicine practitioners under one national organisation; preparing guidelines for standards of practice and ethics, and a training manual for the profession. The Centre for Scientific Research into Plant Medicine and other research institutions like the Noguchi Memorial Institute for Medical Research continue to evaluate herbal medicines. The Food and Drugs Board has instituted a procedure for the registration of herbal products. The Traditional and Alternate Medicines Directorate will have to build the needed capacity to enable it forge links with partners and also exercise its mandate to ensure that traditional medicine products are safe, efficacious and of good quality.

Monitoring, evaluation and research

The need for routine monitoring of the NDP to evaluate its impact at regular intervals is also essential for the success of NDP. The institutional framework for monitoring the NDP in Ghana has, however, been inadequate.

Research to improve health services and health care include baseline studies of the pharmaceutical sector covering rational drug use, procurement and financing of drugs and Knowledge, Attitudes, Beliefs and Practices (KABP) studies on rational use of medicines in Ghana. The latter was geared towards the design of appropriate and effective strategy for meaningful information, education and communication on rational drug use. However, no research on the development of new products has been conducted.

This edition of the NDP differs from the earlier one in some significant respects. The current one incorporates an implementation plan to ensure that responsible organisations and individuals appropriately tackle all issues raised in the NDP. This edition also deals with intellectual property rights as contained in the Trade Related Aspects of Intellectual Property Rights agreement (TRIPS). It also covers local production of antiretroviral drugs necessitated by the importance of HIV/AIDS in the disease profile of the country. It is envisaged that the changes and improvements in content to this edition will accommodate the new challenges in the pharmaceutical environment in Ghana.

1.0 DRUG SELECTION

1.1 Preamble

The selection of drugs for use in a country is very crucial to the success of the main aim of making available, drugs of the required efficacy to the people. Drugs selected need to reflect the demographic and economic situations prevailing in the country at any time.

1.2 Objective

To ensure that drugs selected for incorporation into the Essential Drug List (EDL) are suitable for the appropriate treatment of prevailing diseases and that drug needs at different levels of the health care system are met.

1.3 Policy Statement

1.3.1 Essential Drugs

1.3.1.1 The Ministry of Health shall compile a selected list of drugs to be known as the Essential Drug List (EDL) which shall include programme and specialist drugs.

1.3.1.2 Selection of drugs shall be by generic name or International Non-proprietary Name (INN) only.

1.3.1.3 When several drugs are available with the same indication, or when two or more drugs are therapeutically equivalent, the pharmaceutical product and dosage form that provides the most favourable benefit/risk ratio shall be selected.

1.3.1.4 Fixed ratio combinations shall be acceptable if one or more of the following criteria are met:

- The clinical condition justifies the use of more than one drug;
- The therapeutic effects of the combination is greater than the sum of effects of each drug;
- The cost of the combination product is less than the total cost of the individual products;
- The combination form improves compliance.

1.3.1.5 The EDL, containing all the drugs selected for use in the health sector shall be produced and distributed to all health institutions and health care providers. Drugs on the EDL shall be categorised according to the level of use.

1.3.1.6 The EDL shall be updated and published every two years.

1.3.1.7 Suggestions for amendments to the EDL shall be made in writing on a prescribed form to the Minister of Health, justifying each suggested amendment. New drugs shall only be introduced if they offer distinct advantages over existing drugs. If information on existing drugs shows they no longer have a favourable risk/benefit ratio, they shall be withdrawn and replaced with safer alternatives.

2.0 DRUG PROCUREMENT, STORAGE AND DISTRIBUTION

2.1 Preamble

Drugs shall be procured in such a manner as to ensure that the limited resources of the nation are utilized with care to economy, transparency, accountability and efficiency. The desire to eliminate wastage does not end with procurement, but continues with the storage and distribution of the drugs.

2.2 Objective

To ensure the availability of adequate, good quality, safe, effective and affordable drugs to all people in Ghana.

2.3 Policy Statement

2.3.1. Procurement

2.3.1.1 Procurement of drugs shall be restricted to items registered in the country of origin and registered for use in Ghana.

2.3.1.2 All drugs to be procured must satisfy Food and Drugs Board (FDB) labelling requirements (PNDCL 305B, 1992; Section 47).

2.3.1.3 Drugs shall be procured for the public sector in accordance with the Essential Drug List by INN or generic names only.

2.3.1.4 In the public sector, appropriate methods shall be adopted to procure best-priced and quality drugs in accordance with the procurement laws in Ghana.

2.3.1.5 Drugs for the public sector shall be centrally procured. However where the Central, Regional, and District Medical Stores cannot supply, health facilities shall be allowed to purchase from the private sector in accordance with laid down guidelines.

2.3.1.6 All procured and donated drugs shall conform to FDB specifications and guidelines.

2.3.2 Storage

2.3.2.1 The MOH through its drug regulatory agencies shall ensure the regular maintenance of suitably constructed and equipped storage facilities at every level in the public and private sector drug distribution system.

2.3.2.2 Regular monitoring shall be carried out on the quality of drugs at all levels to ensure that they have not deteriorated under the storage conditions prevailing at each location.

2.3.2.3 All facilities (private pharmacies, shops and government dispensaries) storing and dispensing medicines shall maintain records on all drugs at the facility at all times.

2.3.2.4 Deteriorated, obsolete or otherwise unwholesome drugs shall be disposed of in accordance with national guidelines.

2.3.2.5 Storage facilities shall be appropriately managed according to national standards.

2.3.3 Distribution

2.3.3.1 Only medicines registered in Ghana shall be distributed in the country.

2.3.3.2 All facilities from where drugs are distributed shall comply with the relevant laws of Ghana. Regular monitoring of public and private sector facilities for distribution of drugs shall be carried out to ensure compliance with the laws.

3.0 DRUG FINANCING

3.1 Preamble

The availability of finance for the procurement of drugs is the lifeline to the whole system of drug management. The financing of drugs can be provided by the government or the consumer, or by both in a certain proportion.

3.2 Objective

To establish a system that ensures joint responsibility between government and consumers for drug financing which will also provide for the vulnerable section of the population.

3.3 Policy Statement

- 3.3.1 Government shall continue to finance the procurement and management of adequate quantities of good quality essential drugs in the public sector.
- 3.3.2 Government shall collaborate with the private sector and donor agencies in the funding of drug supplies to the public sector.
- 3.3.3 Whilst the principle of cost recovery of drugs shall be retained, appropriate mechanisms shall be put in place to offer subsidies and exemptions for payment of drugs for specified categories of patients.
- 3.3.4 Health Insurance schemes shall be established to facilitate access to drugs at service delivery points.
- 3.3.5 Government shall exempt selected essential drugs from Value Added Tax (VAT) and other forms of taxation. Such exempted drugs shall be reviewed periodically, but not beyond two years.
- 3.3.6 Raw materials used for local manufacturing shall be subject to VAT exemption on conditions to be determined by parliament.
- 3.3.7 Government shall ensure that essential drugs are affordable and a national pricing policy put in place.

4.0 QUALITY ASSURANCE

4.1 Preamble

Quality Assurance applies to both locally manufactured and imported pharmaceuticals. It includes all plans, processes, and procedures that are put in place to ensure that products that are available for use are consistent in quality, safety and efficacy, and conform to all requirements as stipulated by regulation. Procedures for registration, importation, distribution, use, post marketing surveillance and advertisement monitoring shall be provided to assure the quality of products circulating in international and national commerce.

4.2 Objective

To ensure that drugs available for use in Ghana are safe, effective and meet approved specifications and standards.

4.3 Policy statement

4.3.1 Quality of Drugs.

4.3.1.1 The MOH shall establish and maintain an adequately equipped and manned National Quality Control Laboratory (NQCL) under the FDB. The NQCL shall carry out strategic testing of drug products moving through the drug supply system in both the public and private sectors. Where specific testing facilities are not available, other local and international QC testing facilities shall be used.

4.3.1.2 As additional safeguards, raw materials and finished products shall only be procured from reputable suppliers and the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce shall be applied.

4.3.1.4 All drug supplies shall be accompanied by relevant documentation, including certificates of analysis for raw materials and finished products.

4.3.2 Drug Registration

4.3.2.1 All drugs to be used in Ghana for both public and private sectors shall be duly registered with the national regulatory authority, the Food and Drugs Board (FDB) in accordance with the provisions of the Food & Drugs Law (PNDCL 305B) 1992, as amended by the Food & Drugs (Amendment Act), Act 523, 1996.

4.3.2.2 The FDB shall be duly notified of any variation in respect of source, documentation, packaging and indications for existing drugs and this shall be duly registered.

4.3.2.3 Drugs imported for the specific use of individual patients shall be exempted from registration requirements. Such requests shall be certified by a local medical specialist in the related field and an import permit obtained from the FDB.

- 4.3.2.4 Drug donations shall be exempted from registration requirements; however, they must conform to the National Guidelines on drug donations.
- 4.3.2.5 The FDB shall compile a drug register, which shall be reviewed every 3 years with an annual update. Drugs in the register shall be classified as Prescription Only Medicines (POM), Pharmacist Recommended Medicines (P) and Over the Counter Medicines (OTC).
- 4.3.2.6 The FDB shall co-ordinate the preparation of a cross-index of generic and brand names for all medicines on the market.

4.3.3 Quality of service

- 4.3.3.1 The quality of service shall be in accordance with standards of professional regulatory bodies and MOH Quality of Service guidelines.
- 4.3.3.2 The MOH in collaboration with the relevant authorities shall ensure that patient's rights are protected.

4.3.4 Drug Advertisement and Promotion

- 4.3.4.1 All advertisements and promotion of drugs shall be of high ethical standards.
- 4.3.4.2 All drugs to be advertised or promoted shall be registered with the Food and Drugs Board (FDB).
- 4.3.4.2 The FDB shall be responsible for monitoring and ensuring ethical standards for drug advertisement and promotion in accordance with the Food and Drugs Law 1992 (PNDCL 305B) and shall collaborate with other agencies to achieve this objective.
- 4.3.4.3 Public advertising materials on drugs, whether in the print or electronic media shall be vetted by the FDB and the approval of the Board shall be obtained before the material is used.
- 4.3.4.4 Drug promotional activities shall be in line with the National Drugs Policy objectives. In this respect, whenever the brand name of a drug is used in any form of promotional or educational material, the generic name of the drug shall be given due prominence. In the case of printed materials, such as advertisements on billboards, posters and publications, the generic name shall be prominent and positioned underneath the brand name.
- 4.3.4.5 Promotion and advertisements of Prescription-only Medicines (POM) and Pharmacist recommended medicine (P) shall be restricted to health professional publications only.
- 4.3.4.6 Promotion and advertising of drugs shall not be permitted at public places including lorry parks and markets and in all modes of transportation except approved by regulations under the Food and Drugs Law 1992 (PNDCL 305B).
- 4.3.4.7 No advertisement shall be permitted for drugs and herbal medicines for disease conditions specified in schedule 2 of the Food and Drugs Law 1992 (PNDCL 305B).

5.0 LOCAL MANUFACTURE OF PHARMACEUTICAL AND TRADITIONAL MEDICINAL PRODUCTS

5.1 Preamble

Local development and manufacture of medicines, including herbal products, have been slow in Ghana and this has resulted in the continued dependence on imported drugs with a resultant drain on the country's scarce resources. While there may be local ability to reverse this state of affairs, the capability of local drug and traditional medicine product manufacturers to meet these demands, needs to be strengthened.

5.2 Objective

To promote self-sufficiency in the production, packaging and marketing of essential drugs, as well as herbal preparations, with the view to decreasing the dependency on imported drugs. The local manufacturer should however ensure the quality, efficacy, safety and affordability of these products.

5.3 Policy statement

- 5.3.1 A list of registered local drug and traditional medicine product manufacturers shall be compiled, published and reviewed by the FDB annually in accordance with the provisions of the existing laws.
- 5.3.2 Only drugs conforming to nationally accepted and/or internationally recognised quality standards shall be permitted to be manufactured and distributed in the country.
- 5.3.3 The regular and thorough inspection procedures for manufacturing and quality control facilities shall be instituted by the FDB.
- 5.3.4 The MOH through the FDB shall ensure that pharmaceutical companies institute product recall procedures. The FDB shall enforce the withdrawal from circulation of drug products, which have been shown by testing or demonstrated otherwise to be of unacceptable quality.
- 5.3.5 The manufacture, importation, exportation and distribution of counterfeit, substandard and expired raw materials and finished products shall not be permitted and shall be punishable by the provisions of the Food and Drugs Law 1992 (PNDCL 305B).
- 5.3.6 The Government shall support the private sector through various industrial funds and foreign grants available to it to develop the raw material base for the pharmaceutical and herbal industries.
- 5.3.7 The Government shall provide the needed finance and technical support to promote the development and growth of local pharmaceutical industries.
- 5.3.8 All local drug and traditional medicinal products shall comply with environmental laws of Ghana.
- 5.3.9 The export of locally manufactured pharmaceutical and medicinal products shall be encouraged and shall conform to local and international standards and specifications and be in accordance with existing laws and regulations.

6.0 RATIONAL DRUG USE

6.1 Preamble

There is a wrong impression among the public that the use of medicines or herbal products is the only way to manage all ailments.

For various reasons there is easy access, with or without a prescription, to medicines and traditional medicinal products in Ghana thereby increasing the possibility of misuse and the development of unwanted events related to these products.

The rational use of drugs requires that people receive medicines appropriate to their clinical needs, in doses that meet their individual requirements for an adequate period of time, and at the lowest cost to them and the community along with the requisite information.

There is therefore the need for the continuous monitoring and evaluation of the medicines and traditional medicinal products used in Ghana.

6.2 Objective

To ensure safe, efficacious and cost-effective use of medicines.

6.3 Policy Statement

6.3.1 Education and Training

6.3.1.1 The Government shall ensure that the WHO essential drug concept and the principles of rational use of drugs are incorporated in the curricula of all institutions involved in the training of health workers.

6.3.1.2 A systematic and comprehensive programme of in-service training and other suitable continuing education activities on medicines and herbal preparations shall be developed and implemented for all health workers.

6.3.1.3 The Ministry of Health shall collaborate with the Ministries of Education, Youth and Sports; Communication; and other public and private institutions responsible for schools, to integrate basic information on drug use into the educational curricula. This would lead to a better appreciation by the general public, of the benefits and limitations of the use of drugs in health care.

6.3.2 Drug Information

6.3.2.1 Government shall ensure the establishment and maintenance of a National Drug Information Centre (NDIC) with collaborative efforts of all stakeholders including Traditional Medicine Practitioners to facilitate the collection, compilation, processing, presentation and dissemination of information regarding appropriate drug use, among other things.

6.3.2.2 The National therapeutic guidelines for practitioners of orthodox medicine shall be revised and distributed to all registered orthodox health care practitioners every two years.

6.3.2.3 The Ministry of Health, through the Traditional and Alternative Medicine Directorate, shall ensure that treatment guidelines are developed for practitioners of herbal medicine.

6.3.2.4 The Ministry of Health shall ensure that mechanisms for discussion and dissemination of information on matters related to provision of pharmaceutical services and drug use in the country shall be instituted for health care providers.

6.3.2.5 Government shall undertake a comprehensive and sustainable Information, Education and Communication (IEC) programme to educate the general public on rational drug use.

6.3.2.6 Drug information provided by manufacturers to health care providers and consumers and the labelling of the original drug package should conform to the requirements detailed in the regulations of the Food and Drugs Law, 1992 (PNDC Law 305B) and the General Labelling rules, 1992 (LI 1541).

6.3.3 Prescribing

6.3.3.1 Prescribing of drugs shall be in accordance with the Pharmacy Act, (Act 489), 1994, the Medical and Dental Council Decree (N.R.C.D. 91) 1972 and the Nurses and Midwives Decree (NRCD 117) 1972.

6.3.3.2 Prescribing of drugs shall only be by duly registered practitioners who are in good standing with the appropriate regulatory body.

6.3.3.3 Professional Regulatory Bodies shall ensure that prescribers adhere to the Principles of Good Prescribing Practice as developed by the regulatory bodies.

6.3.3.4 The MOH shall develop a prescribing format that gives adequate information on the patient, disease condition, the drugs and the prescriber.

6.3.3.4 All drugs shall be prescribed by their generic name or International Non-proprietary Name (INN) only. Brand names may be inserted in parenthesis.

6.3.3.5 Prescribing practices in the country shall be constantly monitored by the appropriate professional and regulatory authorities in order to ensure efficient and cost-effective prescribing.

6.3.4 Dispensing

6.3.4.1 All medicines shall be dispensed and labelled using generic names or INN, and the brand name may be inserted in parenthesis.

6.3.4.2 The minimum information to appear on the label shall consist of the:

- name of the patient
- generic name of the drug
- strength of the active ingredient
- quantity of dispensed product
- complete dose regimen in written and/or graphic form
- name and address of the dispensing facility and dispenser.
- special instructions
- date of dispensing
- duration of use

6.3.4.3 Medicines shall only be dispensed by persons authorised by the appropriate authority to do so.

6.3.4.4 Authorised inspecting officers, appointed under the Pharmacy Act (Act 489 1994), shall make regular inspections of premises where dispensing operations are performed to ensure that the provisions of the Act are complied with.

6.3.4.5 Where a prescribed medicine for a given indication is not available, the Pharmacist shall contact the prescriber for necessary modification. Where a specified brand of a prescribed medicine is not affordable and/or available to a patient, a pharmacist may substitute an equivalent generic form after informing the patient and the prescriber where possible.

6.3.5 Patient Compliance and Self-Medication

6.3.5.1 Public information and education on medicines would be carried out to ensure that, while the public has ready access to sufficient unbiased and practical information on common ailments and the options for treatment, they are also made aware that medicines may be the cause of significant adverse events and disease.

6.3.5.2 Education of the public on subjects including disease prevention, health promotion, self-diagnosis, self-medication, first aid and suitable alternative non-drug treatments shall be promoted through all available communication media.

6.3.5.3 Research on the social and cultural factors, which affect the use of drugs, shall be promoted to provide information on attitudes and beliefs that contribute to inappropriate drug use or non-use.

6.3.5.4 Counselling on the use of medicines shall be instituted as part of the prescribing and dispensing process. Training curricula and continuing education programmes for all health professionals shall be revised where necessary to include a component on patient counselling on drug use.

6.3.6 Drug and Therapeutics Committees

6.3.6.1 The MOH shall provide guidelines and ensure the establishment of Drug and Therapeutics Committees (DTCs) in all major health facilities (government, quasi-government and private) in the country in order to ensure correct, efficient, and cost-effective management of drugs.

6.3.6.2 The membership shall include representatives of the medical, pharmaceutical, nursing and administrative services of the institution.

6.3.6.3 The committees, shall amongst other duties, be responsible for:

- Selection of drugs for use based on the National EDL;
- Accurate estimation of pharmaceutical requirements for both the hospital itself and any peripheral health units served by the hospital;
- Control and management of drug-related expenditure;
- Monitoring of the use of the therapeutic guidelines and overall drug utilisation;
- Institution of appropriate measures for the prompt, safe and efficient disposal of expired drugs;
- Instituting measures to be employed in cases of drug shortage; and
- Any other matters relating to the rational use of drugs.

6.3.6.4 The MOH shall ensure, through the DTCs and in collaboration with the Central Medical Stores (CMS) and other agencies where appropriate, the

redistribution of unwanted, but otherwise unexpired medicines, in public sector health facilities.

6.3.7 Disposal of expired drugs.

6.3.7.1 The FDB shall ensure in collaboration with other agencies where appropriate, that suitable measures are instituted for the regular identification, collection and safe disposal of expired drugs and drug waste.

6.3.8 Pharmacovigilance

6.3.8.1 The Ministry of Health shall support the setting up and maintenance of a National Centre for Pharmacovigilance (NCPv).

6.3.8.2 The NCPv shall be responsible for the regular collection of spontaneous reports from health care practitioners and the general public on adverse drug reactions (ADRs) occurring nationwide.

6.3.8.3 The NCPv shall be responsible for the identification of risk factors for, and mechanisms underlying, ADRs occurring in the country.

6.3.8.4 The NCPv shall continually process and disseminate information generated on ADRs to health care personnel, drug manufacturers and the general public.

6.3.8.5 Health care practitioners and the general public shall be encouraged to report all adverse drug reactions to the NCP.

6.3.8.6 All reports to the NCPv shall be treated in strict confidence.

7.0 GLOBAL TRADE AND PHARMACEUTICALS

7.1 Preamble

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the most relevant of all the various agreements of the World Trade Organisation (WTO) for the health sector. The TRIPS agreement introduces global minimum standards for protecting and enforcing nearly all forms of intellectual property rights, including pharmaceutical products and processes. The TRIPS agreement raises concerns about the major impact of this agreement on people's access to drugs and public health. Governments are required to bring their legislation on intellectual property rights to conform to the TRIPS agreement within a five-year transitional period.

7.2 Objective

To ensure that legislation and regulations developed maintain a balance between the minimum standard of intellectual Property Rights protection and the public health good.

7.3 Policy statement

7.3.1 In implementing regulations related to intellectual property rights, Government shall take advantage of all the safeguards within the TRIPS Agreement for the promotion of public health and ensuring access to pharmaceuticals.

7.3.2 Government shall not enact legislation and regulations more stringent than the TRIPS requirement.

7.3.3 The MOH shall actively collaborate with the Ministry of Trade and Industry, Attorney General's Department and other relevant agencies in the area of intellectual property rights in developing consistent legal framework that enhances access to essential drugs.

7.3.4 Parallel importation shall be permitted for pharmaceuticals when the protection of the health of the public is concerned.

7.3.5 The government shall grant compulsory licensing (e.g. local manufacture and generic version of patented products) to promote competition and access to drugs when the health of the public is at stake.

7.3.6 Regarding the exploitation of the rights conferred by patency on pharmaceuticals, the government shall design laws that prescribes a limited period immediately preceding the expiry of the patent for its agency or a third party to conduct tests on the product required for regulatory approval in the country.

7.3.7 The limited period in section 7.3.6 should also allow the agency or third party to manufacture and store the product, so that when the patent expires, a generic product can enter the market immediately.

8.0 EMERGING DISEASES AND PHARMACEUTICALS

8.1 Preamble

New diseases may emerge at any time in the world, while existing diseases may pose new challenges at one time or the other. Such diseases usually become issues of concern when treatment is very expensive and out of the reach of most of the people, or the treatment or control is simply difficult or not available at all.

8.2 Objective

To provide needed drugs to adequately treat and control such diseases, and also make other resources available where there are special needs.

8.3 Policy statement

- 8.3.1 A system shall be put in place to provide needed drugs for new diseases and existing ones posing new challenges. Both the public and private sectors shall be involved.
- 8.3.2 The Ministry of Health shall collaborate with the relevant international bodies to mobilise resources for these cases, where they cannot be provided from the country.
- 8.3.3 Where emerging diseases with no previously known treatment have been identified, the Government shall support and fund the research, development and local manufacture of the needed drugs and herbal preparations.

9.0 HUMAN RESOURCE DEVELOPMENT FOR DRUG MANAGEMENT

9.1 Preamble

Human resource development is paramount and shall be given a major focus in the Health Sector. The aim of human resource development policy shall be to develop and place staff with specified skills, in the right mix and numbers at all levels. This will ensure the achievement of efficiency and the goals of the health sector. This is in reference to both administration/management and service delivery points in the health sector.

9.2 Objectives

To embark on human resource development programmes that will ensure that adequate, appropriately trained and well-motivated personnel in pharmaceuticals are available in the health sector to provide effective and efficient services.

9.3 Policy statement

- 9.3.1 Appropriate client-oriented continuing education and postgraduate training programmes shall be instituted to improve on performance for both public and private sectors.
- 9.3.2 The Ministry of Health shall define and ensure the development of programmes that aim at providing clear career prospects and opportunities for attracting and maintaining qualified personnel.
- 9.3.3 Formal and structured training for auxiliary pharmaceutical providers especially those at the first point of call in the pharmaceutical delivery system of the health sector shall be actively pursued.

10.0 TRADITIONAL MEDICINAL PRODUCTS

10.1 Preamble

Although widely believed to be effective and potentially accessible to many Ghanaians, documentation of the constituent herbs as well as the active ingredients of local herbal medicines remain poor. Additionally, traditional medicine practice in the country is at present largely unregulated and shrouded in secrecy.

10.2 Objective

To promote the proper use of traditional herbal medicines in Ghana.

10.3 Policy Statement

- 10.3.1 The MOH shall promote and encourage research, development and rational use of herbal medicines that are widely believed to be efficacious, safe and of good quality.
- 10.3.2 The MOH, through the Traditional Medicine Practice Council (TMPC), shall supervise training and register herbal practitioners and regulate their activities to ensure that they conform to the standards set by the TMPC.
- 10.3.3 All traditional medicine products shall be subjected to the regulations and standards provided for under the Food and Drugs law.
- 10.3.4 The Government shall encourage and support financially, where necessary, research by the Centre for Scientific Research into Plant Medicine and other research institutions, including the country's universities. This will be in the areas of identifying the useful components of herbal medicines for treatment of endemic diseases, their formulation into standardised products of reliable quality, and rationalisation of their use.
- 10.3.5 The Government shall promote the exchange of research findings with other countries and international agencies such as the WHO, UNDP, and shall encourage and support the participation of local drug research institutions in international drug research activities.
- 10.3.6 The Government in collaboration with the Ministry of Food and Agriculture, Ministry of Lands, Forestry and Mines and any other related sector; shall encourage the cultivation and sustainable harvest of medicinal plants.

11.0 RESEARCH AND DEVELOPMENT

11.1 Preamble

Although significant knowledge about the pharmaceutical sector has accrued over the years, numerous questions still remain unanswered. Research capacity would be built to provide sound, scientific and reliable information that will influence and guide policy management and practice of drug use.

The abundance of medicinal plants in Ghana requires a well co-ordinated and intensified research programme to identify, classify and document their uses and potency in the management of disease conditions in the country. These research findings shall be used to improve drug management at all levels.

11.2 Objective

To identify and support scientific and operational research and development activities in the pharmaceutical sector and in traditional medicines.

11.3 Policy statement

- 11.3.1 Research institutions shall be strengthened and supported to ensure the achievements of the objectives of the pharmaceutical sector.
- 11.3.2 The Government, through its tertiary institutions and other research centres shall encourage and support collaboration between local drug manufacturers and herbal industries.
- 11.3.3 Research priorities shall be determined on the basis of major health problems encountered in the country.
- 11.3.4 Research shall be aimed at supporting essential drugs programme and rational drug use.
- 11.3.5 The government shall support areas of health research that have bearing on the National Drug Policy.
- 11.3.6 The Government shall encourage the development of high level multidisciplinary research in disciplines such as medicine, pharmacy, pharmacology, medicinal chemistry and the training of research personnel into the relevant areas of interest.
- 11.3.7 Exploratory and developmental research into local raw materials as sources for excipients shall be actively supported in order to achieve the objective of increased national self-sufficiency in essential drug requirements.
- 11.3.8 The MOH shall make use of research findings in making necessary adjustments in its strategies to ensure achievement of the objectives of the NDP.
- 11.3.9 Government shall establish a co-ordinating centre to collaborate with recognised research institutions for drug research for the purpose of the appropriate use of their findings.

12.0 NATIONAL DRUG POLICY IMPLEMENTATION

12.1 Preamble

Drug administration in Ghana is multi-sectoral and it is imperative that the various stakeholders all work towards the same goal. For the successful implementation of the objectives of the National Drug Policy, there is the need to establish a platform that would bring together all stakeholders.

The Government therefore, shall support the activities of the professional and regulatory bodies and establish a unifying platform for the implementation of the Policy. All bodies whose functions are to ensure compliance with all aspects of the policy shall be included.

These bodies include the Food & Drugs Board, Pharmacy Council, Medical and Dental Council, Nurses and Midwives Council, Narcotics Control Board, Traditional Medicines Council, Veterinary Council of Ghana, Private Hospitals and Maternity Homes Board, Pharmaceutical Society of Ghana, Ghana Medical Association, Ghana Registered Nurses Association, Ghana Registered Midwives Association, and any other such body.

12.2 Objective

To ensure the successful implementation of the NDP through the establishment of systems for monitoring and evaluation of outcomes.

12.3 Policy statement

12.3.1 Operationalisation of Policy

12.3.1.1 The MOH shall set up a unit that shall be responsible for translating the policy into action through the development of a pharmaceutical master plan and a priority action plan.

12.3.1.2 The MOH shall be the focal point for the promotion of inter and intra-sectoral collaboration and co-operation.

12.3.1.3 All pharmaceutical legislation shall be regularly reviewed to conform to the policy.

12.3.2 Monitoring and evaluation

12.3.2.1 The MOH shall define indicators for monitoring and evaluation of the implementation of the Policy.

12.3.2.2 The MOH shall set up a system for co-ordinating and monitoring the agencies responsible for implementing the Policy.

12.3.1.2 Mechanisms for support, monitoring and evaluation of performances and sanctions under the policy shall be strengthened at all levels.

ANNEX A: DEFINITIONS

Prescription Only Medicine (POM) - means a drug that can only be made available to the consumer through a written order signed by a duly qualified and registered prescriber and dispensed by a registered pharmacist.

Pharmacist Recommended (P) - means drugs that may not require a medical practitioner's prescription, but may only be supplied on the recommendation of a pharmacist on professional judgement who shall maintain proper records relating thereto.

Over The Counter Drugs (OTC) – are drugs that are generally regarded as safe for the consumer for use by following the required label directions and warnings. They may be purchased without a prescription.

Pharmacovigilance is concerned with the early detection of unknown Adverse Drug Reactions (ADRs), and the frequency of known ADRs, and would be a major resource for ensuring the safe and rational use of medicines in Ghana.

Efficacy: refers to the ability of a drug, whether orthodox or herbal, to treat or control a disease.

Drug, Medicine, Medicinal product, Pharmaceutical products are terms used interchangeably in this document and include herbal medicines and any substance included in any publication mentioned in the Food and Drugs Law 1992 (PNDCL 305B), or any substance or mixture of substances prepared, sold or represented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state, or symptoms thereof, or restoring, correcting or modifying organic functions in man.

Auxiliary Service Providers here refers to Chemical Sellers, Dispensing Assistants and Dispensing Attendants.

Health practitioner and Health professional, used interchangeably, here refers to one who practices medicine or an allied health profession such as nursing, pharmacy, radiography, etc.

Pharmaceutical inputs refer to the totality of all components of production or manufacturing within the pharmaceutical sector, other than the human resource.

Programme Drugs refers to drugs used in public health programmes of the Ministry of Health, within the guidelines of the specific programmes. E.g. TB drugs, ARV drugs, etc.

Specialist Drugs refers to drugs or medications that are restricted for use by qualified specialists (consultants) who may request for them. E.g. anti-cancer drugs.

Pharmaceutical sector refers to the sector of health care concerned with the knowledge or art of pharmacy and its practice according to specific rules and formulas. It includes the public sector (pharmacies and dispensaries), the manufacturing sector and the private sector (pharmacies, chemical shops and dispensaries).

ANNEX B: RELEVANT REGULATIONS ON PHARMACEUTICALS

The Food and Drugs Law (PNDCL 305B) 1992

The Pharmacy Act (Act 498) 1994

The Standards Decree (NRCD 173) 1973

The Narcotics Drugs (Control Enforcement and Sanction) Law (PNDCL 236) 1990

The Centre for Scientific Research into Plant Medicine Decree (NLCD 344) 1975

The Environmental Protection Agency Act (Act 490) 1994

The Traditional Medicine Practice Act (Act 575) 2000

The Veterinary Surgeons Law (PNDCL 305C) 1992

The Private Hospitals and Maternity Homes Board Act (Act 9) 1958

The Private Hospitals and Maternity Homes Board Amendment Decree 395, 1969

The Private Hospitals and Maternity Homes Board LI 295, 1959

The Medical and Dental Council Decree 91, 1972

The Nurses Regulation (LI 683) 1971

The Nurses and Midwives Decree (NRCD117) 1972

The National Health Insurance Act, 2003 (Act 650)