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Ministry of Health

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PREFACE

This document is the third edition of the National Medicines Policy prepared by the Ministry of Health of Ghana in 2017.

The overall goal of the policy is to ensure universal, equitable and sustainable access to priority, efficacious and safe medicines and other health technologies of acceptable quality for all people living in Ghana and promote their responsible use by healthcare providers and consumers. Access to essential medicines is part of the fulfillment of the human right to health. This policy document is intended to express the commitment of the Government of Ghana towards the goal of ensuring universal health coverage.
The policy is to provide direction and guidance for all stakeholders in the pharmaceutical sector in Ghana. Thus, all actions in the pharmaceutical sector would take alignment from this policy to ensure convergence of action and purpose, and to maximize our investments in health for better outcomes.

The revision has been informed by the need to strengthen pharmaceutical systems as a key component of health systems to meet the ever-changing health needs of the population. The urgent need to develop the local pharmaceutical industry to be responsive to health needs and ensure access to medicines for the poor and vulnerable also guided the revision. It is also driven by the Government's medium-term development strategy as outlined by the National Development Planning Commission, the Health Sector Medium-Term Strategy, the World Health Organization's guidelines for drug policy development and supply chain reforms in the health sector.

This policy covers broad areas such as selection, strategic purchasing, global trade and research and development, use of medicines, quality assurance and governance. New sections include health technology assessment, patient safety, risk management and good governance.
In highlighting these areas, due cognizance has been given to available resources, potential benefit of medicines in disease management and the socio-economic environment.

This document has been developed following a critical analysis of the evidence available and several consultations with stakeholders in the health and other sectors, in order to ensure a coherent and multi-sectoral approach for achieving the objectives of the national medicines policy.

The revised medicines policy shall therefore remain the official policy to guide the pharmaceutical sector in Ghana. It shall be implemented through an implementation plan, a communication and advocacy strategy and a framework for monitoring and evaluation.

I wish to express my sincere appreciation to the Technical Working Group of Experts, the Parliamentary Select Committee on Health, World Health Organization, United Nations Development Programme and other stakeholders whose immense contributions and support have made the review of this policy a success.

Hon. Kwaku Agyeman-Manu
Minister of Health

LIST OF ABBREVIATIONS

ADRs	Adverse Drug Reactions
APIs	Active Pharmaceutical Ingredients
ARVs	Antiretroviral medicines
BE/BP	Bioequivalence
CIF	Cost Insurance and Freight
CMS	Central Medical Stores
CSO	Civil Society Organisation
DGSL	Digicon Global Services Limited
DP	Development Partners
DQCL	District Quality Control Laboratory
DTC	Drug and Therapeutics Committees
ECOWAS	Economic Community of West African States
EML	Essential Medicines List
EMs	Essential Medicines
FDA	Food and Drugs Authority
FOB	Free on Board
GDF	Global Drug Facility
GDP	Good Dispensing Practices
GHS	Ghana Health Service
GMA	Ghana Medical Association
GMP	Good Manufacturing Practices
GNDP	Ghana National Drugs Programme
GPHA	Ghana Ports and Harbours Authority
GRA	Ghana Revenue Authority
GRNA	Ghana Registered Nurses Association
HT	Health Technologies
HTA	Health Technology Assessments
HTASC	Health Technology Assessments Steering Committee
INN	International Non-proprietary Name
ISO	International Standards Organisation
MeTA	Medicines Transparency Alliance
MIS	Management Information Systems
MOH	Ministry of Health
NCDs	Non-Communicable Diseases

NCPv	National Centre for Pharmacovigilance
NDIRC	National Drug Information Resource Centre
NHIA	National Health Insurance Authority
NHIL	National Health Insurance Levy
NHIML	National Health Insurance Medicines List
NHIS	National Health Insurance Scheme
NMPC	National Medicine Price Committee
NQCL	National Quality Control Laboratory
OTC	Over the Counter
PC	Pharmacy Council
POM	Prescription only Medicines
PPME	Policy Planning Monitoring and Evaluation
PPP	Public Private Partnerships
PS	Private Sector
PSGH	Pharmaceutical Society of Ghana
RMS	Regional Medical Stores
RUM	Rational Use of Medicines
SSFFCs	Substandard Spurious Falsified Falsely-Labelled Counterfeits
STG	Standard Treatment Guidelines
TB	Tuberculosis
TRIPS	Trade-related aspects of Intellectual property rights
VAT	Value Added Tax
WAHO	West African Health Organisation
WHO	World Health Organisation

CONTENTS

CHAPTER 1

INTRODUCTION

This document is situated in the health-related Sustainable Development Goals (SDGs) towards Universal Health Coverage (UHC), SDG 3. (United Nations) It is also aligned to the Ghana Shared Growth and Development Agenda 1 and 2, which expresses the national vision and development agenda for wealth creation. (Ghana National Development Planning Commission, 2010)

The document also sits within the National Health Policy, Creating Wealth through Health, 2007. (Ghana Ministry of Health, 2007). The key strategic areas of the national health policy considered in this policy include bridging equity gaps in geographic access to health services, ensuring sustainable financing for healthcare delivery, improving efficiency in governance and management, intensified prevention and control of communicable and non-communicable diseases, and improving quality of health services delivery including mental health.

The document is also situated within the Ghana Health Sector Medium Term Plan, 2010-2013 and 2014-2017, with the goal of having a healthy and productive population that reproduces itself safely. (Ghana Ministry of Health, 2010-2013) (Ghana Ministry of Health, 2014-2017)

Based on an external independent assessment of the implementation of the 2nd edition 2004 drug policy in 2013, about 50% of the 60 key policy components of the 2004 policy are on track and that one third are at risk; and that in a small number of policy areas no action has been taken. (Hans, Cecile, & Annan, 2013) The implementation of the National Health Insurance Scheme (NHIS) with the coverage of essential medicines is one critical area that has improved access to medicines.

This success has been as a result of a concerted effort of all stakeholders in the health and other sectors. As a consequence of the NHIS and the related dramatic increase in government funding, the country is well on

track to achieving universal access to health and in particular, access to medicines, with increased patient numbers and high levels of patient satisfaction.

There are however some challenging areas requiring crucial policy interventions. There is the need to further improve efficiency in the pharmaceutical sector, through (1) improved procurement with economies of scale as well as quality assurance, and (2) improved analysis and processing of claims by the NHIS, to impact positively on prescribing and medicine costs. These necessary improvements as well as other policy interventions would ensure sustainable access to medicines in view of current health dynamics.
New areas to this document are based on global trends in health and pharmaceuticals and include Health Technology Assessment (HTA), risk management, governance and transparency, pricing, disposal of medicines and related health technologies.

This National Medicines Policy (NMP) focuses on strengthening key areas in the pharmaceutical sector, including public procurement, the Food and Drugs Authority (FDA), active monitoring and correction of prescribing behavior in line with Standard Treatment Guidelines (STG), and support to the local pharmaceutical industry within public health goals.

CHAPTER 2

SELECTION OF MEDICINES AND OTHER HEALTH TECHNOLOGIES

2.1 SELECTION OF ESSENTIAL MEDICINES AND HEALTH TECHNOLOGIES

Preamble

The selection of essential medicines for use in the country is crucial to the success of the main aim of making available, medicines of the required efficacy, safety and quality to the people. The selection must be evidence-based, the medicines must be the most cost-effective in their therapeutic group, and must reflect the demographic and economic situation prevailing in the country. This implies that attention will first be put on basic essential medicines for all people, before expensive medicines are selected, which may only benefit a small proportion of the population. The selection of medicines will also take into account the different skills of prescribers at different levels of health care.

Situation analysis

The Essential Medicines List (EML) and Standard Treatment Guidelines (STGs) were updated in 2004, 2010 and 2016. The 2010 version was used as the basis for the National Health Insurance Scheme (NHIS) reimbursement list (National Health Insurance Authority, 2010). The 2010 EML contains 334 medicines in 725 formulations, and was developed on the basis of the STGs (Ministry of Health-Ghana National Drugs Programme, 2010). Not all medicines listed on the STGs are included in the EML, and not all EML medicines are reimbursed by the NHIS. The current EML specifies the approved level of use and recommends the NHIS reimbursement status. The EML lists medicines

by their generic names or International Nonproprietary Name (INNs). (Ministry of Health-Ghana National Drugs Programme, 2010) The EML 2010 uses only INNs in the procedures and criteria in place for updating the EML.

There is a National Medicines Selection Committee with many contributors with a subgroup for evidence synthesis. Procedures and selection criteria are published with the EML. National disease control programmes are very positive about the inclusion of their (often changing) treatment guidelines in the STGs and EML.

The production of the STGs takes much time and printing is very expensive.

A 2008 survey revealed that 75% and 95% of facilities had copies of the 4th edition of STGs and EML respectively (Arhinful, Annan, & Gyansa-Lutterodt, 2009). The 5th edition of the STG and EML are available on the GNDP website (www.ghndp.org). About 17,000 copies of the STGs were distributed to all cadres of health professionals, students from health training institutions, NHIS claims managers etc. However, the number of copies in circulation is insufficient.

Policy objective

To ensure that medicines selected for incorporation in the Essential Medicines List are suitable for the appropriate treatment of prevailing diseases, and that the medicines needs of the population at different levels of the health care system are met in the most scientifically sound and cost-effective manner.

Policy statements

2.1.1 The Ministry of Health shall compile a list of selected medicines and other health technologies to be known as the Essential Medicines List (EML), which shall include programme and specialist medicines.

2.1.2 Medicines listed on the EML shall inform procurement and reimbursements within the health system. For public health use, the Ministry of Health through/with the FDA shall ensure access

to such medicines of acceptable quality.

2.1.3 Selection of medicines and related health technologies shall be by generic name or International Nonproprietary Name (INN) only.

2.1.4 There shall be guidelines for the inclusion/deletions of medicines and other health technologies on the essential medicines list. These shall be based on evidence for safety and efficacy as well as evidence from economic evaluations.

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

2.1.6 Fixed ratio combinations shall be acceptable if 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.

2.1.7 The EML, containing all the medicines selected for use in the health sector shall be produced by the Ministry of Health and distributed to health institutions and health care providers. Medicines on the EML shall be categorized according to the level of prescribing to guide prescribing and reimbursements.

2.1.8 The EML shall be updated and published every two years. The official copy of the EML shall be the electronic copy made available on the internet. Printed copies would still be made available. An addendum or an amendment to the EML may be published if necessary within the two year update period.

2.1.9 Suggestions for amendments to the EML shall be made in writing on a prescribed form to the Minister of Health, justifying each

suggested amendment. New medicines shall only be introduced if they offer distinct advantages over existing medicines. If information on existing medicines shows they no longer have a favourable risk/benefit ratio, they shall be deleted and replaced with better alternatives.

2.2 HEALTH TECHNOLOGY ASSESSMENTS

Preamble

Health technology assessment (HTA) is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, and robust manner (World Health Organisation, 2015). Its aim is to inform the formulation of safe, effective, health policies that are patient-focused and seek to achieve best value. HTA must always be firmly rooted in research and the scientific method.

Situation analysis

Health Technology Assessment is not yet developed in Ghana. The selection of essential medicines is being done in a relatively systematic way, but is not informed by HTA. There is much potential for HTA to identify the most cost-effective diagnostic, preventive and curative interventions as well as support reimbursement decisions on vaccines, medicines, screening and preventive programmes. (Hans, Cecile, & Annan, 2013).

Policy objective

To strengthen the science and practice of HTA in support of evidence-based reimbursement decisions for the government and the NHIS.

Policy statements

2.2.1 There shall be a standing technical committee established by the Minister of Health responsible for Health Technology Assessments for the health system. The capacity of the standing

technical committee shall be built to perform HTA functions to meet the needs of the pharmaceutical sector.

2.2.2 There shall be developed and regularly updated HTA guidelines which shall detail methods, processes, benchmarks, perspectives and agreeable standards for the conduction, dissemination and use of HTA in-country.

2.2.3 HTA assessment reports shall be applied to evidence-informed context-based decisions on health technologies, with a focus on reimbursement decisions on new expensive vaccines, diagnostics and medicines.

2.2.4 The Secretariat on HTAs shall collaborate with other HTA groups regionally and globally, to contextualize existing knowledge when available.

2.2.5 Institutionalization of HTAs shall not usurp, but align with the statutory authority and functions of existing institutions such as the FDA, NHIA, GNDP (National Medicines Selection Committee) etc.

2.3 EMERGING DISEASES AND PHARMACEUTICALS

Preamble

An emerging disease is one that has appeared in a population for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range (WHO, 2016). Vaccines and medicines may play an important role in treating and containing the disease.

Situation analysis

The Ebola outbreak of 2014/2015 was a wake-up call for many governments globally, as the disease with a mortality of 60-90%, spread much more quickly and widely than on previous occasions. Although no treatment is available, the international vaccine industry was quick in developing and testing a new vaccine for rapid use.

Policy objectives

To ensure the rapid registration, procurement and distribution of any new vaccine, medicine and related-health technologies needed for the treatment and containment of an emerging disease.

Policy statements

2.3.1 A system shall be put in place to provide the needed pharmaceutical products and other health technologies for emerging diseases.

2.3.2 The Ministry of Health shall collaborate with the relevant international organizations to mobilize resources for emerging diseases, where they cannot be provided in-country

2.3.3 Where emerging diseases with no previously known treatments have been identified, the government in collaboration with international organizations shall support and fund the research, development and local manufacture of the needed pharmaceutical products.

CHAPTER 3

STRATEGIC PURCHASING

3.1 FINANCING

Preamble

In recent years, government has implemented important policies towards achieving universal health coverage for all people in Ghana. This has implied considerable and annually increasing financial investments in health. In order to sustain the system, careful planning of financial investments and continuous attention to cost-containment are needed.

Situation analysis

The MOH with support from development partners centrally procures anti-retroviral (ARVs), psychotropics, family planning products and vaccines. Most of the ARVs and the TB medicines (90%) are donations and/or products received through the voluntary pooled procurement mechanism from Global Fund and the Global Drug Facility (GDF), the United States Agency for International Development (USAID) – President's Emergency Plan for AIDS Relief (PEPFAR), and the Global Alliance for Vaccines and Immunizations (GAVI); the rest are paid for by the MOH or GHS. The MOH centrally procures very few general essential medicines, and mostly in insufficient quantities. In May 2013, only 27 out of a sample of 100 general EML-listed products for maternal and child health (MCH) and non-communicable diseases (NCDs) were in stock, plus 7 non-listed alternatives (usually different strengths of EML medicines). General essential medicines are largely procured by the RMS directly; and to a lesser extent by tertiary and district facilities themselves. The absence of central procurement of general EM leads to inefficiencies in price through loss of economies of scale, and to less stringent quality assurance.

Until recently, medicines for children <5 and the elderly were supplied

free, against erratic reimbursement or replenishment by the CMS. This situation has drastically improved by the introduction of the health insurance with free medicines listed on the EML. Some programme medicines are supplied free of charge like ARVs and TB medicines (see above).

Since the NHIS was established, coverage has increased to 62% of the population in 2010, and to 80-95% of consultations in public facilities in 2013. Over 50% of NHIS expenditure is on medicines and medical products. The insurance package is perceived by some as too generous in relation to the available funds, creating a sustainability risk. For example, in 2012 the World Bank estimated that the NHIS will be insolvent in 2013. Addressing the cost-inefficiencies of the pharmaceutical sector is essential for the future sustainability of the NHIS.
The introduction of the health insurance scheme has made essential medicines affordable to over 62% of the population (80-95% of outpatient visits); they do not worry about medicine prices anymore. For the non-insured, large variations in retail price have been reported (up to 20 times the ex-factory price), sometimes because of large margins. No pricing policy is in place. Facility prices tend to drift towards the reimbursement price. The proportion of rich uninsured patients that are willing to pay extra for non-EML medicines is small (anecdotally, 2% has been mentioned; in urban areas the percentage may be higher).

Policy objective
To ensure the joint responsibility between government and consumers for a fair system of medicine financing, which will ensure universal access to essential medicines, including the vulnerable section of the population.

Policy statements

3.1.1 Government shall continue to provide financing mechanisms for the procurement and management of adequate quantities of good quality essential medicines in the public sector, and ensure adequate stock and constant supply of these at central and regional depots.

3.1.2 Government shall partner with the private sector and donor

agencies in the funding and supply of medicines.

3.1.3 Government shall put adequate and timely measures in place to take over funding in the event of a discontinuation of donor support.

3.1.4 Mechanisms shall be put in place to offer subsidies and exemptions for payment of the cost of medicines for specified categories of patients and diseases of public health interest.

3.1.5 The National Health Insurance Scheme (NHIS) shall continue to provide financial access to medicines at service delivery points for all subscribers in line with the Benefits Package.

3.1.6 The government shall strengthen the NHIS to institute measures that promote efficiency of processes, procedures and medicines expenditure to ensure sustainability of the scheme.

3.2 PRICING

Preamble

Improved and sustained access to medicines continues to remain an agenda of the government of Ghana, in the quest to promote the access to healthcare for all persons living in Ghana.

In order to improve access and specifically financial access, there have been several advocacy efforts towards removal of some of the taxes and tariffs, which inflate prices of medicines in Ghana over the years.

Situational analysis

These advocacy actions are informed by previous medicines price and availability surveys, which reveal duties, tariffs and markups significantly contributing to the final price of medicines (30-40% for taxes and tariffs, and 50-200% for markups). Thus, for a basic monthly treatment for peptic ulcer (using ranitidine 150mg twice a day for 30 days-60 tablets) in the Private Retail Pharmacy, the price would require 86.6 days' wages for an innovator brand treatment and 10.9 days wages for treatment with its generic equivalent.

Clearly medicines prices could be considered high in Ghana; justifying efforts and interventions that seek to reduce medicines prices for out-of-pocket payments and health insurance payments.
Price component studies have revealed the contributions to the final patient prices paid out-of-pocket payments or through health insurance payment models. Such studies have indicated that the manufacturers' component to the patient price ranged from 5.5 to 42.67% in the rural areas and 5-53.2% in urban areas. Also wholesalers contributed 14.1-55.42% in rural areas and 10.5-77.72% in urban areas. Retailers contributed 20.1-74.99% in rural areas and 4.03-69.98% in urban areas. Importation typically added up to 36% to the ex-factory price of medicines.
Port taxes and tariffs includes the following, import duty 10% of CIF, import VAT 12.5% of (CIF+import duty), import NHIL 2.5% of (CIF+import duty), ECOWAS levy 0.5% of CIF, Export Development Levy 0.5% of CIF, Interest Charges 0.5% of FOB, Network Charge 0.4% of FOB, Net Charge VAT+ NHIL, DGSL 1% of CIF, and GRA Tax Deposit 1% of CIF. Other fees include shipping line release fee, Ghana Ports and Harbours Authority (GPHA) rent and handling, clearing agent fees.

The general observation of relatively high prices for medicines in Ghana was also true for child medicines. Meanwhile a comparison of medicines prices for children and adults revealed that prices of children's medicines were compared to the respective adult formulation. It is widely known that paediatric formulations are more expensive than adult formulations and this was also the case in Ghana. Co-trimoxazole syrup was 46% more expensive than the respective tablets, paracetamol syrup 22% and erythromycin syrup 13%.

Policy objective

- To improve the medicines pricing governance mechanisms and promote affordability of medicines in Ghana
- To promote sustainability of the National Health Insurance as well as efficiency and value for money
- To sustain the role of the private sector in assuring medicines availability and supply

3.2.1 A National Medicine Price Committee (NMPC) shall be established by the Minister of Health to manage the medicine pricing system in Ghana.

3.2.2 For new and/or expensive single-source products and medicines under patent the government will set and publish maximum sales prices for the public and private sector. This shall be guided but not defined by external reference pricing in a minimum of three similar pharmaceutical markets.

3.2.3 With regard to pharmaceutical reimbursements, the NHIS, in consultation with the NMPC will set the maximum reimbursement prices for all medicines reimbursed. This way the NHIS will become price-setting, rather than price-following.

3.2.4 For large volume general essential medicines supplied in the public sector, the government will publish the tender results of the annual framework ("rate") contracts, and the RMS sales price based on a fixed distribution margin. This information will also guide the NHIS reimbursement price.

3.2.5 Government shall in consultation with stakeholders develop and implement a scheme of recommended mark-ups for medicines along the distribution chain; this will also inform the final reimbursement price by the NHIS.
The standard mark-up schedule for pharmaceuticals;

- shall be regularly updated based on evidence (from the supply chain, medicines market, etc.), and through transparent stakeholder consultative processes,
- shall be implemented in line with MOH guidelines, and
- shall include incentives for rural markets
- shall decouple administrative component and overheads from the prices of medicines

3.2.6 Competitive strategies shall be promoted in the procurement and supply of general essential medicines for the public sector

3.2.7 Health technology assessments shall be done with country level

data to inform listing of medicines, devices and technologies for public health benefit. This shall be in line with HTA guidelines defining the benchmarks and standard methodology applicable to Ghana.

3.2.8 Government shall exempt selected essential medicines from Value Added Tax (VAT) and other forms of taxation. Such exempted drugs shall be reviewed periodically, but not beyond two years.

3.2.9 Government shall exempt raw materials used for local pharmaceutical manufacturing from VAT on conditions to be determined by Parliament.

3.3 PROCUREMENT OF MEDICINES AND MEDICINE-RELATED HEALTH TECHNOLOGIES

Preamble

Procurement of safe, effective medicine of good quality is a complex process that needs standard procedures, dedicated professionals, good governance and full transparency of process and outcomes. In general, this can only be guaranteed by pooled procurement concentrated in a small number of large professional procurement agencies. Decentralized procurement always leads to higher prices and lower quality, and should be restricted to emergency procurements and small volumes only, from prequalified entities. The supply chain of health commodities must be guarded and protected for the sake of the entire public health system.

Situation analysis

Central procurement by the procurement units of the MOH and the Ghana Health Service is restricted to registered products. RMS and tertiary hospitals procure about half of the EMs themselves, mostly through private wholesalers; district hospitals probably procure about one quarter, from wholesalers and private pharmacies. They all assume that the products they procure are registered and approved. There are no survey data on the percentage of unregistered products in RMS and district hospitals. Teaching Hospitals occasionally import specialist drugs directly through medical representatives of the manufacturers.

In recent years there is little general EM procurement due to decapitalization of CMS. RMS focus on EML medicines but there is no maximum percentage set for non-EML purchases, and no accessible procurement information to verify the percentage of non-EML medicines. 2008 national survey data showed that 87.5% of prescriptions follow the EML, so procurement of non-EML medicines was apparently not a major problem at that time. Anecdotal information suggests that non-EML medicines are now only prescribed for non-insured patients – but these are increasingly few as most patients (60-95% of district hospital visits) are insured.

There is no information whether RMS, TH and facility procurement follows FDA specifications. There is no central oversight on RMS and Tertiary Hospital procurement and distribution. There is no information flow between the RMS and CMS level. There is no inspection system for RMS facilities and performance. A national Health Commodity Supply Chain Master Plan has been developed in 2012, but has only partially been implemented (as at 2017).

Occasionally the MOH monitors the quality of essential medicines in the public sector, but not often enough as only 1000 samples are tested per year. There are long quarantine times for medicines at CMS and RMS pending the central drug quality control, which is required but in practice often omitted.

The MOH and the FDA have not been very clear about supply chain roles and responsibilities in relation to the oversight of medicine and medical supplies, especially for the latter.

The Public Procurement Act of 2003, (Act 663) and (Act 914) as amended, designed for all government Ministries, Departments, and Agencies unintentionally created unnecessarily high procurement prices for clients of the MOH/GHS and for NHIA as an insurer by allowing all health facilities to conduct procurements locally from pharmaceutical suppliers. Many health commodity purchases are small in volume and, therefore, high in price.

There is weak deployment of ICT infrastructure throughout the supply chain and therefore the current environment for automation within the health sector and poor data visibility for policy makers and operational

leaders regarding commodity information has also not been a priority. The current systems, mechanisms, and inspection resources do not seem to be adequate to ensure that inferior medicines and medical devices and supplies do not enter the public sector supply chain system.

Policy objective

To ensure that good quality health commodities are available, accessible, and affordable to all people living in Ghana, and anchored by a sustainable, reliable, responsive, efficient, and well-coordinated supply chain system.

Policy statements

3.3.1 The MOH shall clearly define management roles and responsibilities for procurement of medicines and other health technologies.

3.3.2 Medicines and other health technologies that have high financial impact and high supply risk such as programme medicines shall be aggregated, procured and managed centrally.

3.3.3 Procurements shall be consolidated and made under international/ national competitive tender and other procurement methods as permitted by government procurement rules in order to achieve good quality products and economies of scale.

3.3.4 Public procurement and reimbursement by the NHIS will be limited to products which are registered with the FDA and which are listed on the national EML. This also applies to donated products, for which the existing national guidelines will be updated.

3.3.5 There shall be a robust Information Management System to coordinate and manage medicines and other health technologies.

3.3.6 Organizational relationships between CMS and RMS will be simplified

CHAPTER 4

QUALITY ASSURANCE

4.1 QUALITY ASSURANCE OF PHARMACEUTICALS

Preamble

The assurance of the quality, safety and efficacy of medicines and medical technologies in the market is increasingly important. This is in view of the need for cost-effective public procurement, fair competition between generic products, and the threat (or risk) posed by unregistered and potentially substandard and falsified medicines (SSFFCs) in the market. In addition, a strong regulatory agency is essential for strengthening the local pharmaceutical industry.

Situation analysis

The National DQCL is fully functional. The laboratory is accredited to the ISO/IEC 17025-2005 standard by ANSI-ASQ National Accreditation Board/ANAB of the United States of America. The laboratory has applied for WHO prequalification and has already undergone a WHO peer review audit in June 2015. The total number of samples tested in 2014 is 3072. This number excludes program testing and field minilab tests. The laboratory annually carries out in collaboration with USP, the Antimalarials and Analgesics Survey as well as Uterotonics Survey. The 2015 Uterotonics Survey was completed in September 2015.

The percentage of unregistered medicines is not known but the problem is acknowledged by the FDA. Incidental reports of unregistered medicines available in the market are worrying (e.g. 28 of 46 oxytocin samples taken). The high proportion of medicines reported as "registration in process" is a source of concern. The FDA has implemented a web-based list of registered products which is searchable.

Mechanisms are in place for reviewing drug scheduling (POM, OTC) to be reviewed every 3 years. Regulations on the quality of pharmaceutical service are in place, but they are not enforced. There is no specific policy for patient safety.

There are no advertisements of POM medicines to the general public. A mechanism for vetting OTC advertisements is in place. Vetting of adverts are conducted centrally for applications received from all the regions and covers adverts intended for all media platforms - electronic, print and others. A problem remains with a large number of regional radio station advertisements, especially for traditional medicines, which are very difficult to monitor.

There is regular FDA inspection of manufacturing plants. A roadmap has been developed to assist local pharmaceutical manufacturers to attain minimum WHO GMP status by 2018.

Policy objective

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

Policy statements

4.1.1 The FDA shall be responsible for approving advertising materials and their monitoring to ensure that ethical standards for advertisement and promotion of medicines and health technologies are in accordance with the provisions of the Public Health Act, 2012 (Act 851) and shall collaborate with other agencies to achieve this objective.

4.1.2 All biological products manufactured locally, imported, exported, distributed and used in Ghana for both public and private sectors shall be duly registered with the national regulatory authority, the Food and Drugs Authority (FDA) in accordance with the provisions of the Public Health Act, 2012 (Act 851)

4.1.3 All clinical trials conducted on medicines and health technologies in Ghana for both public and private sectors shall be duly approved

by the Food and Drugs Authority (FDA) in accordance with the provisions of the Public Health Act , 2012 (Act 851)

4.1.4 All controlled substances manufactured locally, imported, exported, distributed and used in Ghana for both public and private sectors shall be duly registered with the Food and Drugs Authority (FDA) in accordance with the provisions of the Public Health Act, 2012 (Act 851) Part Seven, Section 126

4.1.5 The FDA shall ensure that medicines and health technologies are consistently manufactured to meet requisite quality standards in accordance with the provisions of the Public Health Act, 2012 (Act 851)

4.1.6 The MOH shall establish and maintain an adequately equipped and manned National Quality Control Laboratory (NQCL) under the FDA. The NQCL shall carry out strategic testing of medicines and Health Technologies moving through the health 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.

4.1.7 The FDA shall ensure continuous monitoring of all medicines and health technologies to be used in Ghana for both public and private sectors in accordance with the provisions of the Public Health Act, 2012 (Act 851)

4.1.8 All medicines and health technologies manufactured locally, imported, exported, distributed and in Ghana for both public and private sectors shall be duly registered with the national regulatory authority, the Food and Drugs Authority (FDA) in accordance with the provisions of the Public Health Act, 2012 (Act 851)

4.1.9 The Authority shall continually monitor the safety of medicines and health technologies granted marketing approval under the Public health Act 2012 (Act 851) by analysis of the adverse effect or event reports and by any other means and take appropriate

regulatory action when necessary.

4.1.10 All tobacco and tobacco products manufactured locally, imported, exported, distributed and used in Ghana shall be duly registered with the Food and Drugs Authority (FDA) in accordance with the provisions of the Public Health Act, 2012 (Act 851) Part Six, Sections 58 -79.

4.2 LOCAL MANUFACTURE

Preamble

Local manufacture of pharmaceuticals is developing in Ghana and may, in the long run, reduce the need for imported medicines. At the same time, there is strong international competition in essential medicines market, leading to improved availability of good quality products at very reasonable prices. Support to the national industry will focus on essential medicines where the local industry may have an advantage.

Situation analysis

The FDA maintains a web-based list of national manufacturers. Tracking the progress in the registration process is a challenge. There are no mechanisms to allow applicants to know how their application is proceeding and there is no maximum processing time for the various steps of the registration process.

There is regular FDA inspection of manufacturing plants. An earlier system of categorizing manufacturers at different levels of adherence to GMP and production quality is unfortunately not used anymore. There is a strong perception that GMP standards are not uniformly applied and enforced.

Modest training support for APIs was given through the WHO prequalification programme. Government also supports herbal industries.

Policy objective

To strengthen the local pharmaceutical industry with a focus on the cost-effective production of good quality essential medicines and health

products as part of an industrial policy of government.

Policy statements

4.2.1 The pharmaceutical manufacturing sector will be assisted with low interest rate and long-term capital.

4.2.2 Pharmaceutical companies will be supported by the medicine regulatory authorities to acquire international GMP certification.

4.2.3 Government shall provide general and specific short-term incentives to the pharmaceutical production sector in Ghana.

4.2.4 Information systems shall be improved to be able to capture data on local production, importation and medicines use, to assist decision-making, policy formulation and investments into the sector(s).

4.2.5 Public Procurement of Medicines shall be used to support local pharmaceutical production.

4.2.6 Government shall promote marketing of local pharmaceutical products and services through regional trade shows and with bilateral and multilateral diplomacy.

4.2.7 Government shall promote innovation and technology transfer to the sector through south-south cooperation.

4.2.8 Tertiary pharmacy schools will be supported to design curricula and training to support the sector's human resource needs.

4.2.9 Government shall pursue regional medicines regulatory harmonization at WAHO level to support the sector.

4.2.10 Government shall strengthen the capacity of the regulatory agencies to be able to provide enhanced and sustained regulatory

oversight of the sector.

4.2.11 Public Private Partnership (PPP) shall be used to improve research and development infrastructure in the sector, e.g. bioequivalence and bio BE/BP centre.

4.2.12 Government will improve logistics infrastructure like roads to assist distribution.

CHAPTER 5

USE OF MEDICINES

5.1 RATIONAL USE OF MEDICINE

Preamble

The responsible use of medicines 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. More than half of all prescribed, dispensed, sold and consumed medicines are inappropriate, leading to waste and undesirable health outcomes. About half of all patients do not take the medicines as prescribed. The combination of irrational prescribing and lack of patient adherence to treatment leads to undesirable health outcomes and considerable economic waste. The economic waste is of such magnitude that the sustainability of the NHIS is threatened.

Situation analysis

Professional bodies and training institutions use the EML and STG in their basic curricula. No medicine use information programmes are in place in the basic school curriculum.

There is a National Drug Information Resource Centre (NDIRC), which produces a Medicines Information Handbook (MIH) as part of its work. The Centre has identified and trained drug information (DI) officers in the regions and this has gradually reduced queries for information on medicines at the national level. The Centre continues to support the DI services in the regions.

The Center publishes a drug information journal but that has stopped since 2010 due to lack of funds. The Center does not collaborate directly with the National Pharmacovigilance Center. There is no 24-hour

information service for questions on intoxications at the Centre; but this is reported to be available at a separate Poisons Centre.

The STGs are not always indicating first- and second-line choices (e.g. for diabetes and hypertension many possible treatments are listed, without indication of first priority or cost). A first national formulary of traditional remedies was also developed and published.

A 2008 survey showed that 59.9% of public sector prescriptions use INNs. This is a reasonable percentage, in view of the fact that generic substitutions are allowed and practiced.

The medicine use survey of 2008 also found that 87.5% of public sector prescriptions are based on the EML, 43.3% of public sector prescriptions contain one or more antibiotics and 13.3% of public sector prescriptions contain one or more injections. Especially the latter is a large improvement, as it used to be in the 50% range (the reduction is largely due to reduced use of chloroquine injection). There is no system of regular RUM surveys nor a dedicated national body to monitor use.

Over half of the major hospitals do not have a Drugs and Therapeutic Committee in place; including some district hospitals. The level of functioning is not very well known. DTC guidelines were prepared and disseminated by the MOH.

Some ad-hoc arrangements take place to redistribute unused medicines, but there is no systematic approach as there is no exchange of inventory information between facilities, RMS and CMS.

A national pharmacovigilance (PV) center has been established at the FDA, performing routine PV monitoring and cohort surveys. Spontaneous reporting is still rather low. Another pharmacovigilance center for training has been established and has been recognized as a regional WHO Collaborating Centre. Adverse Drug Reaction (ADR) reports are acknowledged within 7 days, and then reviewed by a committee of experts under the FDA. In 2013 the center started issuing a 6-monthly bulletin (electronic and hard copy) with general ADR reports and guidance for prescribers.

Policy objective

To ensure the scientifically sound and cost-effective use of medicines by health care providers and consumers, in order to maximize the health

outcomes and reduce unnecessary expenditure for the government, the NHIA and the public.

Policy statements

Prescribing

5.1.1 Prescribing of medicines shall be in accordance with the Public Health Act 2012, (Act 851) and Health Professions Regulatory Bodies Act 2013, (Act 857). Prescribing of medicines shall only be by duly registered practitioners who are in good standing with the appropriate regulatory body.

5.1.2 Professional Regulatory Bodies shall ensure that prescribers adhere to the Principles of Good Prescribing Practice.

5.1.3 The MOH shall develop a standard prescribing format that gives adequate information on the patient, disease condition, the medicines and the prescriber details in accordance with relevant laws. Such prescription format shall be colour coded for the different levels of care.

5.1.4 All medicines shall be prescribed by their generic name or International Non-proprietary Name (INN) only.

5.1.5 Prescribing of medicines shall be guided by STGs and EML.

Dispensing

5.1.6 All medicines shall be dispensed and labeled using generic names or INN, and the brand name where applicable in parenthesis

5.1.7 The minimum information to appear on the label should include:

- Name of the patient
- Name of medicine dispensed
- 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
- Expiry date
- Batch number
- Duration of use

5.1.8 Medicines shall be dispensed only by persons authorized by the appropriate authority to do so.

5.1.9 Authorized inspecting officers, appointed under the Health Professions Regulatory Act 2013 (Act 857), Traditional Medicines Practice Act 2000 (Act 575) and all applicable laws shall make regular inspections of premises including public and private clinics, hospitals, maternity homes, where dispensing operations are performed.

5.1.10 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.

5.1.11 The MOH shall ensure that prescribers do not dispense and dispensers do not prescribe medicines except in emergency conditions.

Education and training

5.1.12 There shall be continuous education of the general public on responsible use of medicines.

5.1.13 There shall be continuous education of health providers and pre service health personnel on the responsible use of medicines including herbal medicines

Drug Information

5.1.14 The Ministry of Health shall support the establishment of drug information units at all teaching and regional hospitals.

5.1.15 The NDIRC shall collate all documents related to pharmaceutical sector at a designated center (library).

5.1.16 Government shall resource the National Drug Information Resource Centre (NDIRC) with collaborative efforts of all stakeholders including Herbal Medicine Practitioners to facilitate the collection, compilation, processing, presentation and dissemination of information regarding appropriate medicine use. The NDIRC shall generate funds internally to support its activities.

Health Security

5.1.17 The MOH and other relevant ministries, department and agencies shall develop and implement a national policy on antimicrobial use and resistance.

Drugs and Therapeutic Committees

5.1.18 The Ministry of Health shall continue to provide technical support for the establishment of Drug and Therapeutics Committees (DTCs) in health facilities (public, quasi-government, faith based and private) in the country in order to ensure correct, efficient, and cost-effective management of medicines. The establishment and functionality shall be as detailed in the Standards for Pharmaceutical Care (SPC) of the MoH.

Patient compliance and self-medication

5.1.19 Public information and education on medicines shall 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.

5.1.20 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.

5.1.21 Counseling on the use of medicines shall be instituted as part of the prescribing and dispensing process. Training curricula and continuous education programmes for all health professionals shall be revised where necessary to include a component on patient counseling on medicine use.

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

Pharmacovigilance

5.1.23 The Ministry of Health shall continue to maintain the National Centre for Pharmacovigilance (NCPv)

5.1.24 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.

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

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

5.1.27 Health care practitioners and the general public shall be

encouraged to report all adverse drug reactions to the NCPv.

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

5.2 PATIENT SAFETY

Preamble

The Ministry of Health has identified that patient safety remains an important pillar for the quality of care and health outcomes. Patient safety practices include initiatives designed to reduce medication errors thus making health care safer for both clients and healthcare providers.

Medication safety refers to freedom from accidental injury during the course of medication use. It includes activities to avoid, prevent or correct adverse drug events which may result from medication errors. Ensuring medication safety is related to professional practice, health care products, procedures and practices including prescribing, communication, product labelling, packaging, dispensing, distribution, sale, administration and education.

Situation analysis

Medication error and adverse drug reactions occur frequently leading to patient harm in the hospital setting. An earlier hospital study determined the rate of adverse drug events (medication errors or adverse drug reactions resulting in patient harm) to be 6.5 per 100 admissions of which 28% were preventable. A recent estimate also reveals that, on average, a hospital inpatient is subjected to at least one medication error per day.

Substandard, spurious, falsified, falsely labelled, counterfeit medicines (SSFFCs) also have negative implications for patient safety. An estimated 25% of medicines consumed in resource limited countries are said to be counterfeit. Developing countries alone account for about 77% of all reported cases of SSFFCs. Access to quality medicines in Africa remains a challenge. A survey by WHO on quality antimalarial medicines in seven African countries also revealed that, between 20% and 90% of the products failed quality testing.

Irrational use, non-adherence and non-compliance to treatments are also unsafe for patients. The overuse, underuse and misuse of medicines result in wastage of scarce resources and widespread health hazards. The most frequent cause of injuries due to medical care in hospitals is as a result of medication use.

Policy objective

The objective of this policy is to assure quality healthcare services through patient safety practices that protect people from undue harm.

Policy statement

5.2.1 The Ministry of Health (MOH) shall ensure that patient safety practices are developed and maintained at all levels within the health sector. Patient safety practices shall be emphasized and integrated into all standing protocols, policies and guidelines operational in the health sector.

5.2.2 The MOH Quality Assurance and Patient Safety Policy shall be implemented to assure good health outcomes for patients.

5.3 DISPOSAL OF MEDICINES

Preamble

The disposal of expired and unused medical products needs careful management and supervision in order to protect the health worker, the population and the environment.

Situation analysis

The Public Health Act, 2012 (Act 851) has specific provisions that mandate the FDA to ensure safe disposal of medicines [section 132 (2) (3) (4)]. FDA consequently has guidelines for safe disposal of medicines in line with international best practices.

Policy objectives

To ensure the safe disposal of medical waste including expired and unused

medical products.

Policy statements

5.3.1 The disposal of medicines shall be undertaken in a manner that protects and preserves the environment and ensures that medicines due for disposal do not return into the population for use.

5.3.2 The FDA shall ensure in collaboration with other agencies where appropriate, that suitable measures are instituted for the regular identification, collection and safe disposal of expired medicines and medicine waste.

CHAPTER 6

GLOBAL TRADE, RESEARCH AND DEVELOPMENT

6.1 GLOBAL TRADE IN PHARMACEUTICALS AND HEALTH TECHNOLOGIES

Preamble

Globalization and numerous international and bilateral trade agreements have a profound effect on pharmaceutical markets and prices. The effect is especially felt with newly-developed medicines which are still under patent and can be extremely expensive. Careful government policies are needed to strike the right balance between promoting innovation through protected intellectual property, and achieving universal access to newly developed essential medicines.

Situational analysis

The Government has issued administrative guidelines for taking advantage of Trade-related Intellectual Property Rights (TRIPS) flexibilities. Proof of concept has been given, as one compulsory license has been issued for parallel importation of an antiretroviral medicine. No TRIPS-plus provisions are enacted. Legal provisions for early development of generic medicines are in place.

Policy objectives

To maintain the balance between the minimum standard of intellectual property protection and public health good.

Policy statements

6.1.1 In implementing regulations related to intellectual property rights, Government shall take advantage of all the safeguards

within the TRIPS Agreement to meet public health needs and promote access to pharmaceuticals and other health technologies.

6.1.2 Government shall not enact legislation, regulations or policies more stringent than the minimum requirements of the TRIPS Agreement.

6.1.3 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 medicines and health technologies.

6.1.4 Parallel importation shall be promoted for pharmaceuticals and health technologies when the protection of the health of the public is concerned.

6.1.5 The government shall grant compulsory licensing to promote competition and access to medicines and health technologies of public health interest.

6.1.6 Regarding the exploitation of the rights conferred by patents on pharmaceuticals and health technologies, the government shall enact the appropriate 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.

6.1.7 The limited period in section 6.1.6 above 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.

6.1.8 Protection of test data shall not hinder application for generic medicines.

6.2 RESEARCH AND DEVELOPMENT

Preamble

Although significant knowledge about the pharmaceutical sector has accrued over the years, numerous questions still remain unanswered. Research capacity is needed to provide sound, scientific and reliable information to guide policy management and the practice of medicine use.

The abundance of medicinal plants in Ghana requires a well coordinated and intensified research programme to identify, classify and document their uses and potency in the management of disease conditions in the country.

Situation analysis

Several promising clinical research projects are ongoing, but there is little oversight and coordination of the various efforts and no systematic approach to analyze and make use of the research findings.

Policy objectives

To promote and coordinate pharmaceutical research in all sectors to inform policies and practices in the pharmaceutical sector.

Policy statements

6.2.1 There shall be a Pharmaceutical Research Platform to turn out information for updating pharmaceutical standards to international levels and speeding up production of medicines to meet access needs.

6.2.3 The Government shall support the development of high-level multidisciplinary research in disciplines such as medicine, pharmacy, pharmacology, medicinal chemistry, social science and the training of research personnel into the relevant areas of interest.

6.2.4 Exploratory and developmental research into local raw materials as sources for active ingredients and excipients shall be actively supported in order to achieve the objective of increased national

self-sufficiency in essential medicines requirements.

6.2.5 The MOH shall make use of research findings in making necessary adjustments in its strategies to ensure achievement of the objectives of the national medicines policy.

6.2.6 Government shall establish a coordinating center to collaborate with recognized research institutions for medicine research for the purpose of the appropriate use of their findings.

6.2.7 Research institutions shall be strengthened and supported to generate and disseminate knowledge to ensure the achievements of the objectives of the pharmaceutical sector.

6.2.8 Government, through its tertiary institutions and other research centers shall encourage and support collaboration between local pharmaceutical manufacturers and herbal industries in medicines research and development.

6.2.9 Research priorities shall be determined on the basis of major health problems encountered in the country.

6.2.10 Government shall support areas of health research that have bearing on the National Drug Policy.

6.2.11 Research shall be aimed at supporting essential medicines programme and rational medicines use.

6.3 TRADITIONAL MEDICINAL PRODUCTS

Preamble

There is an increasing public expectation that the potential medical and economic benefits of traditional medicine be recognized by health authorities, and that patients be offered a choice between treatments with allopathic and traditional medicine. However, this can only be achieved if traditional medicines and practitioners are better regulated.

Situational analysis

Although widely believed to be effective and potentially accessible to many Ghanaians, documentation of the constituent herbs as well as the active ingredients of the local herbal medicines remain poor. Traditional medicine practice in the country is at present largely unregulated, although efforts are being made to improve this situation.

Policy objectives

To promote the sustainable use of safe and effective herbal medicines of approved quality.

Policy statements

6.3.1 The Ministry of Health and its agencies would maintain and upscale the pilot herbal medicine services units in selected hospitals into a multi-center, multi-disciplinary observation scheme for clinical trial and use of approved natural and herbal medicines that have passed the necessary quality assurance schemes.

6.3.2 The Ministry of Health and its relevant Agencies are to establish desk offices for health innovations and research with special reference to development and research of herbal and natural medicines.

6.3.3 The Herbal Medicine Industry shall promote sustainable cultivation of medicinal plant resources including plant tissue culture.

CHAPTER 7

GOVERNANCE

7.1 GOOD GOVERNANCE, TRANSPARENCY AND ACCOUNTABILITY

Preamble

Challenges in the pharmaceutical sector often result, at least in part, from a lack of standard operational procedures and a lack of transparency. Such practices can waste resources, which reduce the availability of essential medicines and undermines the reputation of the health system. Good governance and transparency in government operations are increasingly expected and demanded by the public.

Situation analysis

There is a general lack of transparency in the pharmaceutical sector. For example, the list of products registered by the FDA is not readily available, there is limited transparency in the tender processes and publication of results. Procurement prices of most medicines in the public sector, as well as results of medicine quality tests are not published. Also, there are no regular surveys of medicine prices and availability in facilities, and no regular statistics on medicine use. For some functions in the pharmaceutical sector, no standard operating procedures are available. The Medicines Transparency Alliance Ghana (MeTA-Ghana) Council focuses on improving transparency of data and includes key stakeholders and development partners. It also engages the general public and media through its multi-stakeholder engagement processes. It is not driven by the MOH.

Policy objectives

To promote cost-effective use of public resources through good governance, transparency and accountability in the pharmaceutical sector.

Policy statements

7.1.1 The Ministry of Health shall create and support an enabling environment for transparent processes and procedures within the pharmaceutical sector.

7.1.2 There shall be a central Management Information Systems (MIS) to enhance access to information on health technologies including pharmaceuticals.

7.1.3 There shall be adequate sharing of information to strengthen the capacity of consumers to demand accountability from providers with commensurate responsibility from consumers.

7.1.4 The Ministry of Health shall support the establishment of a multi-stakeholder platform to share information on the pharmaceutical sector.

7.2 RISK MANAGEMENT

Preamble

Risk management can be described as the culture, process and structures that are instituted to mitigate the consequences that will result from adverse effects of natural causes, human interferences, malfunctioning of equipment, appliances and other health system issues. Risk management in health systems is gaining prominence due to increasing awareness of the consequences of loss of critical health products and finances.

Situation analysis

Assessment of the sector has shown that there are risks throughout the supply chain. Key areas include lack of risk management policies and systems, weak risk assessment and mitigation measures, lack of fire detection system and firefighting equipment, among others.

The intent of risk management policy is to ensure that risk management is approached in a holistic and comprehensive manner and embedded

in routine activities. Institutionalization of the risk management process as enunciated in the policy will provide opportunity for greater risk management success, reduce the probability of failure and ensure sustainable systems are maintained.

Policy objective

The overall objective of this policy is to embed risk management into the culture and operations of the health system so that risks to medical products, personnel and facilities are constantly identified, analyzed, managed and reduced to acceptable levels.

Policy statements

7.2.1 The Ministry of Health shall be committed to protecting health products, facilities and personnel from the hazards of fire, explosions, theft, vandalism, natural catastrophes and environmental damage with the aim of achieving its goal of ensuring availability of medical products.

7.2.2 The risk management policy shall be implemented at all levels of the supply chain to anticipate and mitigate potential losses as well as implement preventive and corrective measures to reduce risks to acceptable levels.

7.3 HUMAN RESOURCE DEVELOPMENT FOR MEDICINES MANAGEMENT

Preamble

The presence and maintenance of dedicated professionally trained staff constitutes an essential component of the pharmaceutical system. While the ultimate goal is to have trained pharmacists in every health facility and medicines outlet, in the interim a good system of task-shifting and auxiliary personnel will be necessary to maintain a minimum level of service delivered through the right mix of skills.

Situational analysis

Several programmes of continuous professional education are ongoing. Scholarships have been given and there are many training opportunities in

drug management. Individual requests for study leave and opportunities are usually approved; but there is no systematic programme for career development. There are inadequate numbers and specialties of pharmacists in the public sector (MOH Staffing Norms, 2009). There were only 625 pharmacists in public service in 2016. There is no structural in-service training programme in place for auxiliary staff.

Policy objectives

To ensure that adequate, appropriately trained and well-motivated personnel equitably distributed are available in the health sector to provide effective and efficient pharmaceutical services.

Policy statements

7.3.1 Government shall ensure the establishment of staffing norms for the recruitment and deployment of the pharmacy workforce.

7.3.2 Government shall promote pharmacy workforce training institutions, geared towards meeting the requirements of the staffing norms.

7.3.3 Recruitment shall be based on the staffing needs of healthcare institutions, subject to transparent processes and national needs.

7.3.4 Distribution of the pharmacy workforce shall be equitable in line with the established staffing needs of all healthcare institutions.

7.3.5 Government shall ensure the retention of the pharmacy workforce by providing an enabling environment to minimize staff attrition.

CHAPTER 8

IMPLEMENTATION

8.1 NATIONAL MEDICINE POLICY IMPLEMENTATION

Preamble

The national medicine policy needs a detailed policy implementation plan, in which all components of the policy are translated into concrete activities, preferably listed with baseline data, concrete targets, a time frame, cost estimate and responsible person or organization. The implementation of the policy needs to be coordinated and monitored by the Minister of Health.

Situation analysis

In the early years of the previous national medicine policy (2004-2006) there were ad-hoc coordination meetings, but there was no formal NMP coordination system in place. The MeTA Council focuses on improving transparency and good governance in the policy implementation process. Many activities have taken place, but coordination between the various stakeholders has been weak and no mid-term evaluation has taken place.

Policy objectives

To ensure effective planning, coordination and monitoring of the implementation of the national medicines policy by the Minister of Health.

Policy statements

8.1.1 Based on the national medicines policy, a 5-year Ghana National Medicines Policy Implementation Plan shall be developed by the MOH Ghana National Drug Programme, which includes activities, responsibilities, timelines, indicators, baseline data,

communication strategy and targets for monitoring and evaluation.

8.1.2 This implementation plan and these indicators will serve as the basis for an annual review to be done by the Ghana National Drug Program. An independent mid-term evaluation shall be done.

8.1.3 A national medicine policy steering committee shall be established and will meet every six (6) months under co-chairship from public and private sector representations and report to the Minister of Health. The membership of the steering committee shall include representation from public and private sectors.

8.1.4 A national stakeholders meeting shall be convened by the Minister of Health once a year to present and discuss progress in policy implementation, based on a set of agreed indicators and targets.

ANNEX 1 IMPLEMENTATION PLAN, ACTIVITIES

1.1 IMPLEMENTATION PLAN FOR POLICY ON SELECTION OF MEDICINES AND OTHER HEALTH TECHNOLOGIES

1.1.1 Selection of essential medicines and health technologies

Policy Objective 3: To ensure that medicines selected for incorporation in the Essential Medicines List are suitable for the appropriate treatment of prevailing diseases, and that people's medicines needs at different levels of the health care system are met in the most scientifically sound and cost-effective manner.

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/comments	Budget notes
1	Establish national stakeholder forum for selection and use of medicines												link to the national consultations re: NMP implementation	

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/comments	Budget notes
		convene stake-holder forum as part of STG and EML review		x		x		meeting expenses, printing	stakeholders meeting record with commitments	MOH, GNDP	PS, CS, DP, MTI, Justice, Academia, Prof. Associ-ations, NHIA, FDA, GHS, GHAQI, CHAG, Psychiatry, Public Health Programmes, PPME-MOH, OCP, NMSC	20000	partners cover their own costs; MOH funds the meeting venue, printing materials	Budget is for two of such meetings for two reviews of STG and EML
2	Establish National Medicines Selection Committee (NMSC) to develop STGs and EMLs													
		Define TORs & appoint members		x		x		TA	NMSC in place	GNDP, MoH	PC, Medical Council, GHS, OCP, DP	1600	NMSC exists, but membership is up-dated prior to each review of the STG and EML to meet the requirements of the revision	2 day local TA, meeting expense
		Conduct train-ing of NMSC members on guideline development		x		x		TA, training workshops, training materials	training record	GNDP, MoH, HR	WHO, Universi-ties	66500	training needs identified	10 days local TA, 2 training workshops, 3 days, >35 people,

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/comments	Budget notes
		provide secretariat support to the NMSC	x	x	x	x	x	research, staff, printing	meeting minutes	GNDP, MoH	WHO, universities	6000	GNDP has technical staff to provide technical support to the NMSC	
		launch national NMSC		x				national consultation	NMSC launched	GNDP, MoH	Partners	1000	link to the national consultations re: NMP implementation	
3	Educate public and professionals on reimbursement modalities under SHI								IEC materials available and workshops conducted					
		Develop & disseminate IEC materials (for public education on SHI)		x	x	x	x	TA, printing, editing	IEC material available	GNDP, MoH, NHIA	CS, Media, PC, GMA, GRNA, PSGh	8400		local TA - 10 days,
4	Facilitate development and review of new/existing treatment guidelines and EMLs													

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/comments	Budget notes
		Establish information systems support for National Medicines Selection Process / development of STGs and of EMLs.	x		x			TA, database	Decision support tool with Readily available Data on pharmaceuticals in the sector e.g. EML status, NHIML status, FDA registration status, use in guidelines, Clinical evidence summaries, cost/price computation etc.	MOH, GNDP, NMSC	Public Health Programmes, NHIA, FDA, PSGh, DP	7200		TA, local 10 days
		Peer review workshops to Review and revise STGs & EMLs every two years		x		x		NMSC meeting expenses, research, TA	two revisions of STGs and EML	GNDP-MOH, NMSC	Public Health Programmes, NHIA, FDA, PSGh, DP, OCP, GHS	26400		TA, local, 10days; 2 day NMSC meetings

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/comments	Budget notes
		Technical retreats for evidence summaries deevlopment		x		x		meeting venue, transport, per diems, 3 days	retreat reports, evidence summaries, recommendations on EML applications	GNDP-MOH, NMSC (Evidence summary sub-group)	Public Health Programmes, NHIA, FDA, PSGh, DP, OCP, GHS	21920		2 retreats of 3 days each, TA - international
		Disseminate evidence summaries for medicines and health technologies		x	x	x	x	editing services, layout, printing	evidence-based summaries available	GNDP-MOH, NMSC (Evidence Summaries Sub group)	WHO, Programmes, HTA Committee	4200		
		Undertake study tour			x			travel, per diems	report	GNDP-MOH, NMSC	WHO, DP	5000		international study tour for NMSC members
		print & distribute approved STGS		x		x		editing services, layout, printing	revised editions of STGs and EMLs printed and distributed	MOH, GNDP	WHO, DP	10000		
		update website with revised and/or new STGs & evidence-summaries		x	x	x	x	website hosting/ server and maintenance fees, web designer	updated website	MOH, GNDP	WHO, DP, GHS	6750		for 5 years

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/comments	Budget notes
5	Implement STGs													
		Produce campaign material (IEC) to support implementation nationally		x	x	x		TA, printing, editing	IEC materials	MOH, GNDP	WHO, DP, GHS	4200		TA local, 10 days
		establish plaform for feedback on STGs, EML and evidence-summaries				x	x	website developer,	accessible platform for the public and health providers to submit feedback	MOH, GNDP		3000		
		convene stakeholder workshops		x	x	x			meeting reports	MOH, GNDP	GHS, DPs	2000		link to annual NMP implementation workshop
		Undertake training and information workshops (for health care professionals)		x		x		workshops, printing	advocacy workshops undertaken	GNDP-MOH	NHIA, PC, GMA, GRNA, PSGh	55000		annual workshops for HCPs and public, 1 day/year, 100 people/event, DSAs for 50?

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/comments	Budget notes
6	Assess adherence to treatment guidelines and rational use of medicines													
		Design methodology for rapid assessment of adherence to guidelines		x				TA, meeting expenses	standard methodology for drug use in adherence to guidelines	MOH, GNDP, NMSC	GNDP-MOH, NMSC	7510		international TA, 10 days
		convene annual stakeholder forum for use of medicines (using standard country-context drug utilization methodologies)	x	x	x	x	x	meeting costs, printing	stakeholder meeting records with commitments on rational use of medicines	MOH, GNDP	GNDP, MOH	6500		
		Facilitate implementation of recommendations to improve adherence to guidelines		x	x	x		consulations, travel	Guideline being implemented	GNDP, GHS, NHI	GNDP, GHS, NHI	10500		
6	Monitoring and evaluation													
		track implementation of STGs and EML		x	x	x	x	workshops	M&E report	MOH, GNDP, PTC	Programme, GHS, NHI	1000	linked to M&E plan	

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/comments	Budget notes
		monitor availability of essential medicines		x	x	x	x	monitorin	M&E report	MOH, GNDP, PTC	Programme, GHS, NHI	1000	link to PPA & reimbursements with EML	
7	Miscellaneous (procurement, etc)											3000		
	Total											278680		

1.1.2 Health Technology Assessments

Policy Objective 4: To strengthen the science and practice of HTA in support of evidence-based reimbursement decisions for the government and the NHIS

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/ comments	Budget notes
1	Establish National Committee for HTAs													
		Draft TORs & nominate of members	x					TA, meetings	HTA committee in place	GNDP-MOH	Ministry of Trade & Industry, WHO, PS	500		same as for selection
		Convene meetings	x	x	x	x	x	meeting expenses	meeting reports	GNDP-MOH	Ministry of Trade & Industry, WHO, PS	32900		same as for selection
2	Set up secretariat to support HTA													

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/ comments	Budget notes
		draft job descriptions	x					TA, meetings	job descriptions			500		
		recruit staff	x					advertising, interviews	staff appointed	GNDP-MOH, HR	Ministry of Finance, MOH	500		
		provide financial and technical support + accommodation and ICT	x	x	x	x	x	staff, accommodation, IT	staff has adequate resources	GNDP-MOH	WHO, Ministry of Finance, DP, GHS, Academia	54000		
3	Draft HTA Strategy with guidelines													
		Baseline assessment: undertake review of HTA		x				TA, ,meetings	HTA review report	GNDP-MOH, HTASC	WHO, DP, Academia, GMS, Programmes	7850		TA, international - 10 days
		draft HTA Strategy		x				TA, TWG, meeting expenses	HTA Strategy	HTASC, GNDP-MOH	WHO, DP, Programmes, GMS, PS, CS	9310		TA, international, 5 days; 10 member TWG - 4 meetings
		draft relevant guidelines for the use of HT		x				TA, TWG, meeting expenses	Guidelines for use of HT	HTASC, GNDP-MOH	WHO, Academia, Programmes, GHS, DP	12400		TA, international, 10 days; TWG 10 members, 4 meetings
		undertake stakeholder consultations re: HTA		x	x	x	x	meeting expenses, printing	HTA strategy approved	GNDP-MOH	Academia, PS, CS	5000		

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/ comments	Budget notes
		disseminate HTA guidelines		x	x	x	x	editing, printing, implementation workshops	editing, layout, printing	GNDP-MOH	PS, CS, Academia, DP,	10000		similar inputs as for selection
4	Develop the HTA assessment repository													
		develop the repository to host and share HTA information		x				TA, website	respository established	GNDP-MOH	WHO, PS, DP	6200		local TA, 10 days
		develop & implement SOPs for access and use of the repository		x	x	x	x	TA, meetings, printing	SOPs available	GNDP-MOH	WHO, PS	9200		local TA, 10 days
		Market respository and promote its use		x	x	x	x	IEC materials, printing, workshops	Respository used	GNDP-MOH	WHO, PS, GHS	2000		
5	Regional and Global collaborations for HTA													
		participate in regional and global workshops/meetings on HTA		x	x	x	x	travel, per diems	Number of regional and global workshops participated in	GNDP-MOH	HTA SC, WHO	21120		1 regional and 1 international meeting/year

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	notes/ comments	Budget notes
	Total											171480		

1.1.3 Emerging Diseases and Pharmaceuticals

Emerging Diseases and Pharmaceuticals

Policy Objective 13: To ensure the rapid registration, procurement and distribution of any new vaccine or medicine needed for the treatment and containment of an emerging disease

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
1	Strengthen disease surveillance and response system													
		undertake review of disease surveillance and response system		x				TA, meetings	report	MOH	GHS, Programmes, DPs, Defence, WHO	16100	learn from the Ebola experience.	TA, international 20 days

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		develop & implement a plan of action to strengthen the surveillance and response system		x	x	x	x	TA, meetings	plan of action	MOH	GHS, Programmes, DPs, Defence, WHO, FDA, Ambulance services, NADMO, Ministry of Information, Disease control, Procurement and Supply, Immigration	11710	Include in the plan a standing committee to respond to emergencies	TA, international 10 days
2	Mobilise resources for emerging diseases												Personnel available but equipments and funds needed for this activity. Build an emergency response fund for emerging diseases	
		identify resource needs		x				TA, meetings	needs identified	MOH	GHS, Programmes, DPs, WHO	5950		TA, international 5 days
		draft resource mobilisation plan		x				TA, meetings	resource plan	MOH	GHS, Programmes, DPs, WHO	5950		TA, international days

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		implement plan		x	x	x	x	workshops, travel, per diems	resources mobilised	MOH	GHS, Programmes, DPs, WHO	10000		
	Total											49710		

1.2 IMPLEMENTATION PLAN FOR POLICY ON STRATEGIC PURCHASING

1.2.1 Financing

Policy Objective 5: To ensure the joint responsibility between government and consumers for a fair system of medicine financing, which will ensure universal access to essential medicines, including the vulnerable section of the population

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
1	Establish procurement and supply system													
		develop procurement strategy	x					TA, meetings	procurement strategy developed	MOH and PPA	MOH-P&S, GHS -P&S ,PSCH, MoF, NHIA	21900		TA, international, 20 days, 4X 2day meetings

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		Disseminate and implement the strategy		x	x	x	x	workshops, printing	strategy implemented	MOH, Parliamentary Select Committee on Health & GNDP	MOH-P&S, GHS-P&S,MoF,NHIA,GHAG,SPMDP,PSGH	30000		workshops, M&E, training, advocacy
2	Monitor and evaluate financing of medicines and prices													
		develop and implement a pricing policy	x					TA, workshops	Pricing policy developed	NHIA and MOH	MOH-P&S, GHS -P&S ,GHAG,SPMDP,PSG and MoF	41900		TA, international, 30 days, 4X 2day meetings, + implementation workshops
3	Ensure rational selection and pricing of medicines									NHIA, GNDP, MOH-P&S	NMSC, MOF		linked to the PTC selection guidelines and procurement strategy.	
		monitor availability of medicines		x	x	x	x	Tool for monitoring	Monitoring conducted	GNDP, NHIA, MOH, Pharmacy Council	MOH- P&S, NMSC, PS	2000	linked to M&E	reports, data collection
		monitor affordability of medicines		x	x	x	x	Tool for monitoring	Monitoring conducted	GNDP, NHIA, MOH	MOH-P&S, PTC, PS	2000	Limked to M&E	reports, data collection

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
4	Monitor prescribing practices									NHIA, MOH, GNCDP	GHS		linked to Policy objectives 3 (Selection) and objective 11 (rational use)	
		Monitor impact of the medicine pricing on NHIA			x		x	Development of monitoring tool,resource person	Impact on NHIA establishment	NHIA, MOH, GNCDP	MoF,CHAG,Farmer council,SPMDP and community pharma.	4000		
		Develop rational use of medicines guidelines								NHIA, MOH	GHS, Programme, PS, CS, WHO	1000	linked to selection	
		train on use of guidelines								NHIA, MOH, GNDP	GHS, Programmes	1000	linked to selection	
	Total											103800		

1.2.2 Pricing

Policy Objective 6: To improve the medicines governance mechanisms and promote affordability of medicines in Ghana

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	comments/notes	Budget notes
1	Establish the NMPC								NMPC in place	Minister of Health	PS, CS, GHS, DP			

		Draft TORs & members nominated	x					TA, meetings	NMPC established	Minister of Health	PS, CS, GHS, MOH, DP	500		same as for selection
		provide secretariat support to the NMPC		x	x	x	x	admini, printing, meetings				6000		same as for selection
2	Develop Medicines Pricing Strategy/Policy													
		review medicines pricing policies		x				TA, meetings	review report with recommendations for Ghana	MOH, NHIA and GNDP	WHO, PS,-Pharma council ,MoF,NHIA,-CHAG	10000		TA, 10 days, international, meetings
		draft pricing strategy		x				TA, meetings	pricing strategy	MOH, NHIA,GNDP	WHO, PS, CS, Academia, GHS,MoF	10000		TA, 5 days, international, meetings
		develop pricing guidelines: reference pricing, reimbursements, mark-ups, VAT						TA, meetings	pricing guidelines	MOH, NHIA, MoF,GNDP and PPME	WHO, PS, CS, PMAG, DP	17540		TA, 10 days, international, meetings
		facilitate implementation of guidelines			x	x	x	workshops, advocacy materials	Policy implemented	MOH, NHIA, MoF	WHO, PS, CS, PMAG, DP,GNDPand PPME	10000		link to annual NMP progress workshops
	Total											54040		

1.2.3 Procurement of medicines and medicine-related health technologies

Policy Objective 7: To ensure that national resources to procure and distribute medicines for the patients are used in the most cost-effective way, that the best possible prices are obtained for good quality products, and that wastages and losses are restricted as much as possible.

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	comments/notes	Budget notes
1	Establish national medicines procurement committee								PC in place	MOH				
		nominate and appoint committee members	x					TA, meetings	PC in place	MOH	GHS, RMS, TH, PS, NHIA	1000		same as selection
		provide secretariat support to the PC	x	x	x	x	x	admin staff, accommodation, office supplies, telephone, computer	PC operational	MOH, P&S	GNDP	6000	GNDP must have technical staff to support	same as selection
		technical meetings of PC	x	x	x	x	x	quarterly meetings @ MOH, 1 day, 10 people, transport refund, printing	meeting records	MOH-P&S, GNDP	GHS, RMS, PS	26000		4 meetings/ year, honoraria

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	comments/notes	Budget notes
2	Develop national procurement strategy												strategy will be all encompass-ing - address decentralsied procedures, reimbursements, mark-ups, rate contracting etc.	
		approve draft strategy	x					stakeholder meeting (1 day), confer-ence venue, printing	approved national strategy	PC, P&S, MOH	GHS, Pro-grammes, DP, PS, NHIA	2000	link to existing procurement strategy under discussion	
		develop and im-plement 10 year plan for upgrade of facilities		x	x	x	x	TA (30 days), stakeholder meeting, meeting ven-ue, printing, transport	costed Up-grade plan	MOH, P&S	GHS, GNDP, RMS, TH, DH, CMS	25900		international TA, stakeholder meetings
3	Faciliate merger of procurement functions of MOH and GHS													
		develop plan for the merger of the two bodies	x					consultant	merger plan	MOH, P&S, GHS-P&S	DP, GNDP,	2000		TA, 1 day, meetings

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	comments/notes	Budget notes
		implement merger plan		x				meetings, workshops, transport, printing	one merged body overseeing procurement	Minister of Health, Select Committee on Health	MOH-P&S, GHS P&S	6000		meetings, workshops
4	Implement procurement MIS													
		develop MIS		x				TA, meetings	costed MIS plan	P&S	MOH, GHS P&S	8950		TA, 10 days, meetings
		procure & maintain resources for MIS		x	x	x	x	meetings, transport, printing, computers, software for resources	MIS in place	P&S	MOH, GHS	40000		
		train staff on use of MIS		x	x	x	x	workshops, transport, printing	trained staff using MIS	P&S	MOH, GHS	2800		2 trainings/year; 5 people per session
5	Develop and update procurement guidelines, including quantification guidelines			x	x	x	x	TA, meetings, printing	updated guidelines	P&S	MOH, GHS	15950	linked to existing procurement strategy	TA, international, 20 days
7	Develop and implement database of approved suppliers								updated database of approve suppliers.					
		identify approved suppliers	x	x				meetings, transport, printing	list of approved suppliers	P&S	FDA, MOH, GHS, NHIA, PS	2100		TA, local, 5 days,

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	comments/notes	Budget notes
		database of suppliers established and maintained	x	x	x	x	x	database, staff,	database in place	P&S	FDA, MOH, GHS, NHIA, PS	5000		software, data analyst
8	Monitor implementation of procurement guidelines													
		Devolop M&E procurement indicators .	x					TA, meeting, transport, printing	approved procurement indicators	P&S, PC	MOH, GNDP, GHS, FDA, NHIS	2000	linked to M&E plan	
		Indicators collected and analysed		x	x	x	x	training workshops, collection & analysis of indicators, printing	up-to-date analysis of the availability, affordability and quality of essential medicines	P&S, PC	MOH, GNDP, GHS, FDA, NHIA	12000	part of regular monitoring	
	Total											157700		budget will increase by the facilities upgrade and maintenance costs

1.3 IMPLEMENTATION PLAN FOR POLICY ON QUALITY ASSURANCE

1.3.1 Quality assurance of pharmaceuticals

Policy Objective 8: To ensure that all medicines available for use in Ghana are safe, effective and meet approved specifications and standards

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
1	Develop and review guidelines for key areas of medicines regulation													
		strengthen & support scientific/ technical committee for advertising of medicines	x	x	x	x	x	meetings, transport, per diems, sitting fees, printing	reviewed and updated guidelines on advertising of medicines	FDA	MOH, GHS, NHIA, PS, PMAG	11500		10 members, 5 meetings, sitting fees
		establish & support scientific/technical committee for registration of medicines and premises	x	x	x	x	x	meetings, tarnsport, per diems, sitting fees, printing	reviewed and updated guidelines on registration of medicines and premises	FDA	MOH, GHS, NHIA, PS, PMAG	23000		10 meetings
		establish & support scientific/technical committee for conduct of clinical trials	x	x	x	x	x	meetings, tarnsport, per diems, sitting fees, printing	reviewed and updated guidelines for conduct of clinical trials	FDA	MOH, GHS, NHIA, PS, PMAG	11500		5 meetings

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		establish & support scientific/technical committee for pharmacovigilance	x	x	x	x	x	meetings, tarnsport, per diems, sitting fees, printing	reviewed and updated guidelines for pharmacovigilance	FDA	MOH, GHS, NHIA, PS, PMAG, WHO Collaborating Centre for Pharmacovigilance	11500		5 meetings
		establish & support scientific/technical committee for importantion, transport, storage and distribution of medicines	x	x	x	x	x	meetings, tarnsport, per diems, sitting fees, printing	reviewed and updated guidelines for importtaion, transport, storage and distribution of medicines	FDA	MOH, GHS, NHIA, PS, PMAG	17200		8 meetings
		establish & support scientific/technical committee for registration of tobacco and tobacco products	x	x	x	x	x	meetings, tarnsport, per diems, sitting fees, printing	reviewed and updated guidelines for registration of tobacco and tobacco products.	FDA	MOH, GHS, NHIA, PS	11500		5 meetings
2	Ensure adequate legislation for the regulation and supply of quality and affordable medicines and health technologies													

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		review and update national medicines legislation and regulations in keeping with updated guidelines	x	x				TA, meetings	update legislation and guidelines	FDA	Ministry of Justice, MOH	26350		international TA, 20 days, 6 meetings
3	Strengthen capacity of NQCL									FDA	MOH, GHS, Treasury, PS, PMAG			
		facilitate and maintain ISO accreditation		x	x	x	x	TA, equipment, staff, maitenance, reference standards, reference texts,	ISO accredited NQCL	FDA	WHO, PMAG, MOH	70000		look at current operational costs+ international TA, 20 days.
		facilitate and maintain WHO prequalification		x	x	x	x	TA, equipment, staff, maitenance, reference standards, reference texts,	WHO pre-qualified NQCL	FDA	WHO, PMAG, MOH ministry of Trade and Industry (MOTI) should be included here due to the work they are already doing with PMAG in this regard.	100000		look at current operational costs+ international TA, 20 days.

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
4	IEC campaigns on qaulity and safety of medicines									FDA	MOH, GHS, NHIA, PS, PMAG, CS			
		develop & implement IEC materials for the public and health care providers		x	x	x	x	TA, editing, prints, meetings, workshops	IEC campaigns undertaken	FDA	MOH, GHS, NHIA, PS, PMAG, CS	51400		TA, local, 20 days, public broadcasts, newspaper adverts
5	Maintain the FDA website		x	x	x	x	x	webmaster, designer, website, software	updated FDA website	FDA	MOH, GHS, PS, PMAG	20000		look at existing operational costs
6	Enforce regulations													
		undertake GMP inspections of manufacturing plants	x	x	x	x	x	transport, per diems, printing	no. of GMP inspections undertaken	FDA	PMAG	100000		use existing operational costs
		inspect pharmacies, wholesalers, distributors and importers	x	x	x	x	x	transport, per diems, printing	no of importers, wholesalers, retailers and distributors inspected	FDA	Prof. Associations, Importers, wholesalers	50000		use existing operational costs
		inspect ports of entry	x	x	x	x	x	transport, per diems, printing	no of ports of entry inspected	FDA	Customs	20000		use existing operational costs

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		sample and test quality of medicines circulating in the market	x	x	x	x	x	transport, laboratory tests, storage,	no of medicines tested	FDA	NQCL, PMAG, PS	50000		use existing operational costs
		provide relevant sanctions for non-conforming manufacturers, suppliers, distributors and retailers of medicines	x	x	x	x	x	meetings, printing	no of offenders sanctioned	FDA	Ministry of Justice, Police, Customs	20000		use existing operational costs
	Total											593950		draft costs probably an underestimate. Use actual operational costs of FDA.

1.3.2 Local Manufacture

Policy Objective 9: As part of an industrial policy, to strengthen the domestic pharmaceutical industry with a focus on the cost-effective production of good quality essential medicines and health products

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
1	Advocacy for financial stimulus for local manufacturers									PMAG	MOH, Ministry of Finance (MOF) and MOTI			
		undertake cost-benefit study for providing incentives to local manufacturers	x					TA, study, transport, meetings	study report	PMAG	MOH, MOF and MOTI	14950		TA, international, 20 days, meetings
		draft advocacy plan/ strategy	x					consultant, meetings, printing	Advocacy plan for local manufacturers	PMAG	MOH, MOF and MOTI	4000		
		implement advocacy plan		x	x	x	x	workshops, meetings, printing, editing	number of advocacy outreach programmes undertaken	PMAG	MOH, MOF and MOTI	20000	link to annual progress meetings	
2	GMP Roadmap developed and implemented													
		Implement GMP Roadmap			x	x	x	meetings, inspections, trainings	number of local manufacturers with approved GMP status	FDA, PMAG	MOH, Ministry of Trade and Industry, DP	80000		workshops with manufacturers

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
3	Increase financial and technical investment in the manufacturing sector													
		promote local manufacturers through regional and national tradeshows			x	x	x	advocacy materials, meetings with DPs, tradeshows	number of tradeshows held	PMAG	MOH, PMAG, Ministry of Trade and Industry, DP	30000		
		develop an investment strategy for local manufacturers		x				TA, meetings	investment strategy	PMAG	MOH, Ministry of Trade and Industry, DPs	8760		TA, international, 10 days
		Develop regular briefs for MTI and Foreign Affairs Offcials + President		x	x	x	x	TA, printing, meetings	briefing papers	PMAG, MOH	FDA	6400		TA, local, 20 days
		Disseminate information on local manufacturing sector to economic advisers in embassies		x	x	x	x	TA, printing, meetings	briefing documents	PMAG, MOH	DPs, MTI, Foreign Affairs	6400		TA, local 20 days
		promote south-south cooperation and tech ransfer		x	x	x	x	TA, workshops, study tours	number of south-south agreements	PMAG, MOH, MOTI	UNDP, DP	50 000		TA, international - 10 days

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
3	Finalize and implement the Domestic Pharmaceutical Manufacturing Industry Policy													
		Finalize the DPMI Policy		x				TA, workshops	DPMI Policy	PMAG, MOH, MOTI	UNDP, DP	8200	link to the situational analysis	TA, international 10 days
4	Promote R&D for local manufacturing													
		establish platform for engagements between research institutions and manufacturers		x				meetings, transport	engagement platform for researchers and manufacturers	PMAG, MOH	Academia, UNDP, DP	2000		
		convene regular meetings of stakeholders		x	x	x	x	meetings, printing	research proposals	PMAG, MOH	Academia, UNDP, DP	10 000		
5	Strengthen HR for local manufacturing													
		HR needs identification	x					TA, meetings	report	PMAG, MOH	training institutions, UNDP, PS, Education	15150		TA, international (10 days) and local (20 days)

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		situational analysis of training institutions	x					TA, meetings	report	PMAG, MOH	PS, Education, MTI, UNDP, DP	21150		TA, international (20 days) and local (20 days)
		HR training plan developed and implemented		x	x	x	x	TA, meeting, printing	plan	PMAG, MOH	training institutions, UNDP, PS, Education	10000	developed as part of the situational analysis	does not include staff recruitment and appointment
6	Facilitate regional collaboration													
		participate in AU meetings on local production	x	x	x	x	x	travel, per diems	meeting record	PMAG, MOH, FDA, MOTI	GNDP	16000		4 staff members attended 2 day AU annual meetings
		participate in regional meetings on regional medicines harmonisation	x	x	x	x	x	travel, per diems	meeting record	PMAG, MOH, FDA, MOTI	GNDP	20000		4 staff members attended 3 day regional harmonisation meetings, annually
	Miscellaneous (Licences, procurement, etc)		x	x	x	x	x			MOH, FDA, PMAG		20000		

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
	Total											283010		

1.4 IMPLEMENTATION PLAN FOR POLICY ON USE OF MEDICINES

1.4.1 Rational use of medicine

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
1	Develop and implement GPP guidelines													
		Develop GPP guidelines, including an M&E Plan	x					TA, meetings, printing	GPP guidelines with an M&E plan	GHS, GNDP, MOH	CHAG, Quasi Government Institutions, SPMDP, Private Hospital Group, WHO	6400	GPP embraces WHO concept of essential medicines; promotes prescribing using INN,	TA, local 20 days
		update regulations to ensure GPP		x				TA, meetings, printing	updated regulations	MOH, GHS, GNDP	Regulatory Councils	4200		TA, local 10 days

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		train HCP on GPP		x	x	x	x	workshops, travel, printing	training undertaken	MOH, GHS, GNDP	Health facilities, NHIA	35600		2 day workshosp, 2/per year, 20 participants/ workshop; I held in a conference venue/year; 1 in HCFs/ year
		faciliate inclusion of GPP guidelines in undergraduate medical, nursing and pharmacy curricula		x	x	x	x	meetings	GPP included in undergraduate curricula	MOH, Universities, Ministry of Education	GHS, GNDP, Regulatory Councils, National Accreditation Board	5000		
		monitor & provide feedback on prescribing practices		x	x	x	x	meetings, transport	GPP indicators monitored	MOH, GHS, GNDP	NHIA	5000	linked to M&E plan	
		NHIA reimbursements based on generic prescribing	x	x	x	x	x	meetings, printing	number of NHIA reimbursements based on generic prescribing	NHIA, GHS, GNDP	MOH, PS	63000	already being done by NHIA	

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
2	Promote use of STGs													
		disseminate STGS	x	x	x	x	x	printing, website	availability of STGs	GHS, GDNP	MOH, NHIA, PS, Health facilities	30000		
		train HCW on use of STGs	x	x	x	x	x	workshops, trainers, transport	trained HCW	GHS, GNDP	MOH, Health Facilites, PS	35600		
		Faciltate use of STGs in unveristy training programmes	x	x	x	x	x	meetings,	STGs used in university teaching	MOH, Universities	GHS, GNDP	5000		
3	Establish DTCs to monitor and support rational use of medicines													
		establish DTCs regionally and at TH	x	x	x	x	x	meetings	functional DTCs established	MOH, Universities	GHS, GNDP	32000		10 regional DTCs, meet 4X year, 10 members
		provide training for DTCs	x	x	x	x	x	workshops, printing	DTC members trained	MOH, GHS	GHS, GNDP, health facilities, WHO	63000	WHO training course on PTCs	
		provide resources for DTC	x	x	x	x	x	internet, references	DTCs adequately resourced	GHS, GNDP, MOH, health facilities	DPs, WHO	5000		

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		develop & implement standard prescription forms	x	x	x	x	x	meetings, printing	standard prescription form	GHS, MOH	GNDP, Medical & Dental Council, NHIA	5000	already being done	
4	Develop and implement GDP guidelines													
		Develop GDP guidelines	x					TA, meetings	GDP guidelines	MOH, GHS, GNDP	PS, PC, NHIA, FDA	4200	includes guidelines on generic substitution	local TA, 10 days
		update regulations to ensure GDP, including generic substitution		x				TA, meetings	updated regulations	MOH, GHS, GNDP	PC, PS, NHIA	4200		local TA, 10 days
		develop standard dispensing materials	x	x	x	x	x	printing, electronic equipment	standrad labels	MOH, GHS	GNDP, NHIA, PC, PS, P&S, PSGH	5000		
		train HCW on GDP		x	x	x	x	workshops, transport	number of HCW trained on GDP guidelines	MOH, GHS, GNDP	PC, NHIA	35600		
		monitor & provide feedback on dispensing practices		x	x	x	x	workshops, printing	GDP indicators monitored	GHS, GNDP	MOH, PC, NHIA	2000	link to M&E plan	

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		include GDP guidelines in undergraduate pharmacy curricula		x	x	x	x	meetings	GDP guidelines included in unversity curricula	MOH, Universities, Ministry of Education	PC, GHS, GNDP, NAB, Regulatory bodies	5000		
		provide & maintain equpment for electronic labelling		x	x	x	x	electronic equipment	electronic labels	MOH, GHS	GNDP, NHIA	20000		
5	Support NHIA accreditation of HCP												already being done by NHIA	
		draft accreditation criteria		x				meetings, printing	accreditation criteria	NHIA	MOH, GHS, GNDP, PS, PC	4200	based on GDP and GPP	local TA, 10 days
		accredit providers based on criteria		x	x	x	x	meetings, transport	accredited providers	NHIA	MOH, GHS, GNDP, PS, PC	5000		
		monitor accredited providers		x	x	x	x	transport, DSA	monitoring of providers	NHIA	MOH, GHS, GNDP, PS, PS	5000		
		database of accredited providers maintained		x	x	x	x	software, website	database	NHIA	MOH, GHA, GNDP, PS, PC	10000		
		reimburse providers based on criteria	x	x	x	x	x		reimbursements	NHIA	MOH, GHS, PS, PC	5000		

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
6	Public education on rational use of medicines													
		Develop IEC materials for RUM		x				TA, editing, printing, media	IEC materials developed	MOH	GHS, GNDP, CS, PS, Communications, NHIA	10000		local TA, 10 days
		disseminate IEC materials		x	x	x	x	workshops, media, printing	IEC materials disseminated	MOH, NHIA	GHS, GNDP, CS, PS, Communications	5000		
7	Establish and/or strengthen DICs													
		identify existing and new DICs	x					TA, sitautional analysis	list of DICs	MOH, GHS, NDIRC	GNDP, WHO, PMAG	4200		local TA, 10 days
		support establishment of DICs		x	x	x	x	meetings	number of DICs	MOH, GHS, NDIRC	GNDP, WHO, PMAG	200000	advocacy to new DICs	10 regions, support over 4 years: 5000*10*4

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		provide resources for DICs	x	x	x	x	x	references, licenses, internet, staff, electronic databases	Functioning DICs	MOH, GHS, NDIRC	GNDP, WHO, PMAG, DP	40000	serves also as a library hosting reference sources for medicines information	Increase the budget to 40,000; this activity covers subscription for 5 years (5000*5 years), References for 10 DICs, databases and mobile application for medicine information, journals, flyers as well as M&E
		establish national hotline service			x	x	x	staff, dedicated phone lines	hotline service available	MOH, GHS	GNDP, PMAG, PC, NDIRC, FDA	10000		
		train & retrain DIC staff	x	x	x	x	x	workshops, study tours	trained staff	MOH, GHS, NDIRC	WHO, GNDP, PS	20000		

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		collaborate with other agencies	x	x	x	x	x	meetings	collaboration between FDA, poisons centre, pharmacovigilance centre and national DIC	MOH, GHS, NDIRC	WHO, Pharmacovigilance centre, Poisons centres, FDA, PC, PMAG	5000		
8	Advocacy for RUM													
		develop advocacy campaigns for RUM	x					consultant, meetings	advocacy campaign	MOH, GHS	WHO, GNDP, PS, NHIA	4200		
		advocate for separation of prescribing and dispensing functions		x	x	x	x	meetings	advocacy	MOH, PC,	GNDP, GHS, PS	2000		
		support reporting of ADRs	x	x	x	x	x	workshops, printing	ADRs reported	MOH, GHS	WHO, GNDP, PC, PS	5000		
	Total											705400		

1.4.2 Patient Safety

1.4.3 Disposal of medicines

Disposal of medicines

Policy Objective 10: To ensure the safe disposal of medical waste, including expired and unused medical products

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	Notes	Budget notes
1	Draft regulations to ensure the safe disposal of expired and unwanted medicines		x					TA, meetings, printing	regulations for safe disposal of medicines	FDA	MOH, GNDP, Environmental services, PC, PSGH	9600		TA, local, 30 days
		develop & implement criteria and monitoring framework for pharmacies to be designated as collection points for unused medicines		x	x	x	x	TA, meetings, printing	framework for identification of pharmacies as collection points for unused medicines	PC, MOH	FDA, GNDP, PSGH	9400		TA, local, 20 days
		public education campaign for take-back of unwanted medicines		x	x	x	x	TA, media, printing	number of campaigns conducted	PC, MOH	FDA, GNDP, Prof Associations (PSGH, GMA), CS	20000		TA, local, 10 days
		collection of unused medicines		x	x	x	x	transport	unused medicines collected	PC, MOH	FDA, GNDP	5000		

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	Notes	Budget notes
		disposal of unwanted medicines		x	x	x	x	incinerators, landfills	record of disposal of medicines	MOH, Environmental services	PC, FDA, GNDP	10000		
	Total											54000		

1.5 IMPLEMENTATION PLAN FOR POLICY ON GLOBAL TRADE, RESEARCH AND DEVELOPMENT

1.5.1 Global trade in pharmaceuticals and health technologies

Global trade in pharmaceuticals and health technologies

Policy Objective 12: To maintain the balance between the minimum standard of intellectual property protection and public health good

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
1	Incorporate TRIPs flexibilities into all legislation													
		Facilitate collaboration between MTI, MOH, Justice and AGs office	x	x	x	x	x	printing, meeting expenses	increased collaboration between MOH, MTI, Fianance, Justice, AG's office	MOH	MTI, Justice, AG, Finance	2000		

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		Undertake review of national legislation wrt TRIPs flexibilities	x	x				TA, meetings	review of legislation with recommendations	MOH, Justice, AG	MTI, FDA, P&S, GNDP, WHO, UNDP, PMAG, Finance	8200		TA, international 10 days
		draft guidelines for BOLAR exemptions		x				TA, meetings	guidelines	MOH, Justice, AG	MTI, FDA, P&S, GNDP, WHO, UNDP, PMAG, Finance	8200		TA, international 10 days
		develop guidelines for data exclusivity		x				TA, meetings	guidelines	MOH, Justice, AG	MTI, FDA, P&S, GNDP, WHO, UNDP, PMAG, Finance	18000		TA, international 10 days
		review and revise guidelines for parallel importation		x				TA, meetings	updated guidelines	MOH, Justice, AG	MTI, FDA, P&S, GNDP, WHO, UNDP, PMAG, Finance	8200		TA, international 10 days
2	Implement revised and new guidelines				x	x	x							
		update national legislation to faciliate use of guidelines		x	x			meetings, TA	updated legislation	MOH, Justice, AG	MTI, FDA, P&S, GNDP, WHO, UNDP, PMAG, Finance, parliament	20000	link to sub-activity 2	include parliamentarians
3	Advocate for use of guidelines			x	x	x	x	meetings, printing	advocacy undertaken	MOH, MTI	FDA, P&S, GNDP, WHO, UNDP, PMAG	5000		

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
4	Draft competition law			x				TA, meetings	competition law	MOH, Justice, AG's office	MTI, Finance, UNDP, PMAG	20000		TA, international 10 days
	Total											89600		

1.5.1 Research and development

Research and Development

Policy Objective 16: To promote and coordinate pharmaceutical research in all sectors to inform policies and practices in the pharmaceutical sector

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
1	Promote innovations in health technologies and pharmaceuticals													
		R&D mapping and needs assessment	x	x				TA, meetings	Plan for manufacture of APIs	MTI	MOH, PS, PMAG, UNDP	16000		TA, international 10 days, TA local, 20 days
		Promote generic formulations	x	x	x	x	x	TA, meetings	Advocacy	MOH	MTI, PMAG, GHS	5200		TA, local, 10 days

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		Strengthen FDA Laboratories for accreditation, bioequivalence and biopharmaceutical testing	x	x	x	x	x	travel, meetings, equipment, references	Accredited FDA labs	FDA	MOH, MTI, PMAG	10000	link to QA	
		Provide co-financing to manufacturers to achieve WHO pre-qualification	x	x	x	x	x	meetings, travel	pre-qualified manufacturers	Treasury	WHO, MOH, FDA	10000	link to GMP roadmap	
		Promote HR development	x	x	x	x	x	meetings, trainings, accreditation	HR	Ministry of Education, HR	MOH, PC, Medical Council, Health and Research Council	10000	link to HR	
		Develop R&D priorities based on medcine needs for Ghana	x	x	x	x	x	meetings, travel	R&D priorities	MOH, Science and Technology	Universities, DPs, WHO	3000		
	Total											54200		

1.5.3 Traditional Medicinal Products

Traditional medicinal products

Policy Objective 15: To promote the sustainable use of safe and effective herbal medicines

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget (US$)
1	Create awareness of traditional medicines													
		Develop and implement an IEC on traditional medicines		x	x	x	x	TA, meetings	IEC developed	MOH	Traditional Medicine Practitioners	4200		TA, local, 10 days
2	Promote quality of herbal products													
		Develop guidelines for clinical trials and registration of TM			x			TA, meetings	guidelines developed	FDA	TM suppliers, TM practitioners	4200		TA, local, 10 days,
		Promote testing of TM			x	x	x	travel, samples, QC	TMs tested	FDA	TM suppliers, TM practitioners	6000		
3	Include TMs in the NHIA Minimum Benefit Package													
		Develop & implement generic coding for TMs for reimbursements		x	x	x	x	TA, meetings	reimbursement codes for TM developed	NHIA	TM practitioners, TM suppliers, CS, PS, Treasury	5200		
4	Support HRD													

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget (US$)
		Establish and support clinical positions for practitioners in the MOH organogram		x	x	x	x	meetings	HR, MOH	GHS	Ministry of Finance, MOH, TM practitioners	2000	does not include salaries for posts	
		Develop & implement postgraduate specialisation training programmes for HCWs		x	x	x	x	TA, meetings, training curricula	post-grad training programmes	Universities, Education Ministry	TM practitioners, PC, Medical Council, MOH, GHS, NHIA	5400		TA, local 20 days
		Develop and implement specialist training programmes for medical herbalists		x	x	x	x	TA, meetings, training curricula	post-grad tarining for medical herbalists	Training Centres, Universities, Education Ministry	TM practitioners, MOH, GHS, NHIA	9400		TA, local 20 days
5	Develop a National Herbal Medicine Services													
		Develop tools to Improve supervision of of TM services across the health system		x	x	x	x	TA, meetings	supervision tools developed	GHS	MOH, TM practitioners	7400		TA, local, 10 days
		Transfer oversight mechanism from Steering committee to national services			x	x	x	meetings	TM services transferred	GHS	Steering Committee on Herbal Medicines and IPR, MOH, Ministry of Finance	3000		

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget (US$)
		Secure funding for GHS Medicine Centres			x	x	x	meetings, travel	funding mechanism for services	MOH	GHS, Treasury, NHIA	2000		
6	Support manufacturers of TM													
		Ensure manufacturers and their products are registered	x	x	x	x	x	database, meetings, training	registered products and manufacturers	FDA	MOH, GHS, TM Manufacturers, NHIA	5000		
		Develop & enter into Benefit Sharing partnerships with manufacturers		x	x	x	x	TA, meetings	benefit sharing partnership guidelines developed	MOH, AG	GHS, Manufacturers, NHIA	3100		legal TA, Local, 5 days
7	Strengthen collaboration for sustainable cultivation of medicinal herbs	Strengthen collaboration amongst TM stakeholders		x	x	x	x	workshops, meetings	agreements between stakeholders	TM practitioners, Steering Committee	Manufacturers, NHIA, DPs, MOH, Forest Services, Forestry commision Parks and Garden, Agro-Business Support Services	3000		
8	Protect IP of herbal and TM													

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget (US$)
		Establish IP Committee and Small Innovations Committee		x	x	x	x	workshop, meetings, accommodation	Committees established	Steering Committee, MOH	MTI, DPs, WTO, WIPO	1000		
		Develop draft legislation to protect traditional knowlegde in TM		*	*	*	*		Draft legislation developed	MOH	Attorney general ,MOT. FDA.TMP. and centre for research into plant medicine(mampong)	30000		TA local
		Develop IP strategy			x	x	x	TA, meetings	IP strategy	Steering Committee	MOH, DP, WTO, WIPO	9050		TA, international, 10 days
		Establish desk office	x	x				meetings	Desk office established	IP office	MTI, MOH, GHS, DPs, WTO	5000		
		Offer scholarships and fellowships for training of IP officers		x	x	x	x	workshops, funding	scholarships and fellowsships available	IP office, MOH, Ministry of Education	MTI, GHS, DPs, WTO, WHO	10000		
		Provide training opportunities			x	x	x	travel, training workshops, per diems	trained staff in IP	IP office, MOH	WIPO, WTO	5000		

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget (US$)
9	Promote safe and rational use of TM													
		Develop & implement use guidelines for TM		x	x	x	x	TA, contracts	guidelines	Traditional Medicine Council, MOH	GHS, DPs	9050	linked to IP strategy	TA, international 10 days
		monitoring and evaluation of TM use	x	x	x	x	x	meetings, training	M&E indicators	MOH, GHS	GNDP, NHIA, TM practitioners	2000	linked to M&E Plan	
	Total											131000		

1.6 IMPLEMENTATION PLAN FOR POLICY ON GOVERNANCE

1.6.1 Good governance, transparency and accountability

Good Governance, transparency and accountability
Policy Objective 2: TO promote cost-effective use of public resources through good governance, transparency and accountability in the pharmaceutical sector.

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
1														
2	Development of GGM framework												Political support for GG in the pharmaceutical sector; high level champion (Minister/President/Laureat?)	
		training of assessors and transparency assessment	x	x				TA, survey, per diems	assessment report + recommendations	MeTA Ghana	WHO, DPs	22880	Adapt WHO tool, contracting independent assessors	TA; 1 local, 1 international - 10 days, field work (5 days), report and feedback
		develop monitoring mechanism to detect improvements in GG	x	x	x	x	x	TA, survey	assessment report	MeTA Ghana	WHO, DPs	6000		1 day national consultantion, printing, expenses
		national consultation to discuss findings	x					printing, meeting expenses	national meeting held	MeTA Ghana	WHO, DPs, PMAG, PS, CS NMP SC, MoH, GNDP	5000		1 day national consultantion, printing, expenses

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		GG Framework with guidelines developed as well as development of information sharing platform	x	x				TA, TWG, printing, meeting expenses	GG Framework developed	MeTA Ghana	WHO, DPs, PMAG, PS, CS, NMP SC, MoH, GNDP	42350		TA, 5 days international, 3 TWG meetings with 10 people
2	Implement GGM framework				x					MeTA Ghana	PMAG, PS, CS, WHO, NMP SC, MoH, GNDP, FDA,			
		implementation of information sharing platforms	x	x	x	x	x	website, webdesign, outreach	platforms exist	MeTA Ghana	WHO, DPs, PMAG, PS, CS, NMP SC, MoH, GNDP	10000		
		implement recommendations/ principles of GG		x	x	x	x	TA, TWG, meeting ex-penses, GG recommend-ed activities	updated/ revised legislation	MeTA Ghana	WHO, DPs, PMAG, PS, CS, NMP SC, MoH, GNDP	35000		TA, local 10 days, 5 member TWG with three meetings

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		establish complaints mechanims, using innovative mechanisms		x	x	x	x	dedicated phone lines-toll free, website for complains, mobile phone app, staff, suggestion box	complaints desk functional	MeTA Ghana	GNDP, PMAG, WHO, GHS, NMP SC	30000		
3	Promote GG across the pharmaceutical sector													
		Develop GG advocacy tool			x			TA	GG advocacy tool	MeTA Ghana, MOH	GNDP, PMAG, WHO, GHS	2200		TA, local 10 days
		Mobilise resources			x	x	x	Operational costs: Transport and communica-tions				1000		
		Undertake advoca-cy and awareness on GG as well as GG instruments available			x	x	x	Printing costs, Media costs, Meeting costs		MeTA Ghana, MOH	GNDP, PMAG, WHO, GHS	30000		
4	Implement the patients' charter with a focus on medicines													

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		Undertake community outreach and awareness		x	x	x	x	TA, community outreach expenses, printing	Community awareness undertaken	MeTA Ghana-CSO-Coalition of NGOs in Health	NMP CS, PS, GNDP, MOH, GHS	41000	link to existing outreach programmes	TA, local, 10days, regional workshopsX10, campaign materials
	Total											225,430		

1.6.2 Risk management

				Priority	Timeline (In years)				
Ref.	Activity	Lead	Collaborators	1=high, 2=medium, 3=low	1	2	3	4	5
1	Setup of risk management committee to over see the implementation of the risk management policy. Terms of reference shall include reporting to the National Medicines policy Implementation Steering committee	MOH	CMS, Agencies of the MOH, RMS, OCP, GNDP, MOH-P&S, Development Partners in Supply Chain	1	X				
1	Development of risk assessment guidelines for all health facilities and warehouses. Training in risk assessment and mitigation at the health facility level as well as the RMS, CMS level.	MOH	CMS, RMS, Agencies of the MOH, GHS-HQ, OCP, GNDP, MOH-P&S, Development Partners in Supply Chain	1	X	X	X		
1	Sensitization meetings for senior management on risk transfer strategies and modalities	MOH	Agencies of the MOH, RMS, CMS, Health Facilities	1	X				

1	Operational manual for all medical stores including health facility stores, RMS and CMS, detailing best practices for risk minimization	MOH	GHS, Health Facilities Development Partners in Supply Chain	1	X				
1	Procurement and Installation of security apparatus: -CCTV systems, -Fire protection and alarm systems, -Physical protection systems -Personnel protection apparatus -Access control systems -Information security infrastructure and tools (including malware protection, controlled data access, information backup systems etc.)	MOH	CMS, Agencies of the MOH, RMS, OCP, GNDP, MOH-P&S, Development Partners in Supply Chain	2	X		X		X
1	Development of business continuity plans, contingency plan as well as crisis management plans at all levels of the supply chain. -Health facilities -RMSs -CMS	MOH	CMS, Agencies of the MOH, RMS, OCP, GNDP, MOH-P&S, Development Partners in Supply Chain	1		X	X		X
1	Development of security audit checklist and rating system, with security upgrade protocols This can include: -regular data quality, data security and data integrity audits -transport security audit checklist -vehicle tracking system -road worthiness checklist	MOH	All stakeholders	1		X			
1	Development of monthly health safety and environment (HSE) checklist including safety drills at all storage facilities for medicines	MOH	All stakeholders	1	X	X	X	X	
1	Development of SOPs for risk related (high risk) operations: -waste disposal -risk communication management -personal safety and security	MOH	CMS, Agencies of the MOH, RMS, OCP, GNDP, MOH-P&S, Development Partners in Supply Chain	1	X	X			

1	Development and implementation of risk communication standards	MOH	CMS, Agencies of the MOH, RMS, OCP, GNDP, MOH-P&S, Development Partners in Supply Chain	2	X	X				

1.6.3 Human Resource Development for Medicines Management

Human Resource development for medicines management

Policy Objective 14: To ensure that adequate, appropriately trained and well-motivated personnel equitably distributed are available in the health system/sector to provide effective and efficient pharmaceutical services

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
1	Develop HRD plan for the pharmaceutical sector													
		draft & develop methodology	x					TA, meetings	assessment methodolgy	MOH, GHS	WHO, HR, Universities, HCFs, PC	4500		TA, international, 5 days
		undertake assessment		x				TA, travel, meetings	assessment report	MOH, GHS	WHO, HR, Universities, HCFs, PC	8900		TA, international, 5 days, local TA 5 days
		draft HR plan		x				TA, meetings	HR plan	MOH, HR	GHS, HCFs, PC	6200		TA, international 5 days, local 5 days

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		mobilise resources & implement recommendations, undertake advocacy and dissemination		x	x	x	x	meetings, printing	resources mobilised	MOH, GHS	Ministry of Finance, Public Sector Commission, HCFs, PC	5000	includes identification of new grads and cadres to be trained	
2	Develop job profiles with job descriptions													
		review and revise job descriptions	x					HR consultant, meetings	revised job descriptions	HR	MOH, GHS	5400		TA, local, 20 days
		undertake regular job evaluations	x	x	x	x	x	staff	job evaluations	HR	MOH, GHS	6000	career pathways clearly described	
3	Develop relevant pre, in and post service training programmes													
		review existing pre, in and post service training programmes	x	x				TA, meetings	review reports	HR, MOH	Universities, PC, Nursing Council, Medical Council, GHS, WHO, PMAG	6400	link to HR plan	TA, local, 20 days

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
		revise training curricula		x	x			meetings, workshops	revised training curricula	HR, MOH	Universities, PC, (Nursing Council, Medical Council), GHS, (WHO, PMAG) FIP	6400		
		implement & evaluate training programmes			x	x	x	training materials, websites, reference texts, internships, training sites	trained graduates and HCWs	HR. MOH	Universities, PC, (Nursing Council, Medical Council, GHS, WHO,) PMAG	10000		
4	Provide incentives to attract and retain staff in deprived communities													
		identify incentives		x				meetings	incentives identified	HR, MOH	PC, GHS	2000		
		mobilise resources for incentives		x	x	x	x	meetings	resources mobilised	HR, MOH	Ministry of Finance, PC	5000		
		recruit staff		x	x	x	x	accommodation, salaries,	staff recruited	HR, MOH	GHS, Ministry of Finance	1000	advertisements etc, not actual salaries etc	

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Outputs	Responsible	Collaborators	Budget	notes/comments	Budget notes
5	Develop service policy for involvement of private sector in provision of services in deprived communities													
		undertake review and draft policy		x				meetings, TA	policy	HR, MOH	Ministry of Fianance, NHIA, GHS, PC	3200		TA,local,10 days
		mobilise resources for policy implementation			x	x	x	meetings, travel	resources mobilised	HR, MOH	Ministry of finance, NHIA, GHS, PC	5000		
6	Dissemination of HR policies and procedures													
		ensure HR policies and procedures are readily available	x	x	x	x	x	website, printing,	HR policies	HR, MOH	GHS	5000		
		create awareness of HR policies and procedures	x	x	x	x	x	workshops, printing	awareness workshops	HR, MOH	GHS	5000		
	Total											85000		

1.7 POLICY IMPLEMENTATION

1.7.1 National Medicine Policy implementation

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	comments/notes	
1	Constitute the National Medicine Steering Committee												NMP is approved	
		Draft TORs for the Steering Committee, request nominations from stakeholders.	x					TA (1 day), transport, meeting expenses, communication costs	TORs, Nominated members	GNDP, MoH	WHO, PS	640	local TA, meetings held in MOH offices	
		Convene meetings twice/year	x	x	x	x	x	meeting expenses, TA, honoraria	meeting report	GNDP	MOH, WHO	29800	2 day meetings conducted every six months; 1 annual meeting at MOH offices & 1 meeting/per year at a conference venue;10 members; 1000 dollars to cover unforseen costs	

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	comments/notes	
		Secretariat support to the SC	x	x	x	x	x	communica-tions, printing, research	meeting report	GNDP	MOH	2000	Secretariat sup-port includes ar-ranging meetings, doing reasearch, drafting agenda with the Chair	
2	Monitor NMP im-plementation using M&E framework												M&E plan approved and integrated into PPME monitoring system	
		M & E plan with indicators devel-oped		x				TA (internation-al, 10 days), printing, meet-ing expenses	M&E Plan	GNDP, PPME	MOH, GHS	9700	M & E plan and indicators	
		Baseline survey of NMP undertaken		x				TA; training, transport, allowances for data collection team, data analysis, report writing, dissemination	baseline report	SC, GNDP, MoH	WHO, PPME	37110	Local TA for 20 days, 3 day training workshop, 5 day field visits to 10 regions by 2 member teams, analysis, report-ing, dissemination of findings	
		Annual NMP assessments		x	x	x	x	training, transport, per deims, data analysis, reporting	annual prog-ress report	SC, PPME	GNDP, PPME, MOH, GHS	8200	local TA, data collection tool, training of officers, printing, dissemi-nation	

#	Activities	Sub-activities	Y1	Y2	Y3	Y4	Y5	Inputs	Output	Responsible	Collaborators	Budget	comments/notes	
3	Annual progress review of implementation with stakeholders		x	x	x	x	x	conference venue and conference costs, including meals/ coffees	5 annual progress meetings held	MOH	SC, GHS, PPME, PS	20200	1 day national stakeholder consultation; 30 people, TA - 3 days/year to draft progress report	
4	Facilitate and undertake mid term review of NMP				x				review report	SC, GNDP, MoH	Partners, WHO	16300	Consultant to be contracted for 20 days, 10 days in the field, printing	
5	Facilitate development of follow up programme as per mid-term review results					x		TA, per diems, meeting expenses, printing	revised implementation plan	SC, GNDP, MoH	Partners, WHO	3340	Consultant to revise implementation plan - 5days	
	Miscellaneous (procurement, etc)											5000		
												132290		