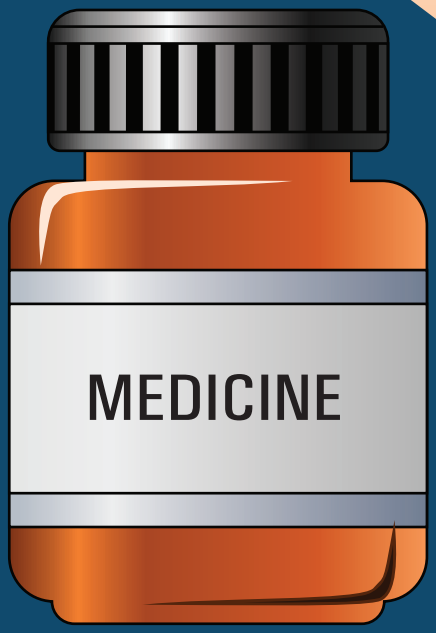
Republic of Botswana

BOTSWANA NATIONAL DRUGS (MEDICINE) POLICY



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BOTSWANA NATIONAL DRUG (MEDICINE) POLICY

Ministry of Health

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1. FOREWORD

The Botswana National Drug Policy (BNDP) shall act as a crucial tool in the attainment of the goals of Vision 2016. Founded on the principles of the Botswana National Health Policy, it aims at ensuring access to good quality, essential health-care by all citizens of Botswana, as well as assuring equitable distribution and utilisation of resources and services.

Drugs play an indispensable role in the delivery of quality preventive and curative health services. The BNDP aims at ensuring that drugs of internationally acceptable safety, efficacy and quality meeting WHO standards are available and affordable to all those who need them, and to promoting their rational use by prescribers, dispensers and consumers.

The BNDP provides a framework for the incorporation of the objectives of the pharmaceutical sector into the national health service structure and operations in order to ensure quality service, system efficiency and cost-containment.

The BNDP recognises the role played by all health workers in the pharmaceutical sector but identifies pharmacists and pharmacy technicians as pivotal in its successful implementation.

The BNDP requires the commitment of all stakeholders (Ministry of Health, Ministry of Local Government, private sector, other government ministries and departments, non-governmental organisations, members of the public, etc.) if it is to succeed in its aims.

This policy belongs to all of us. If used well, it will strengthen our health services and enhance our potential for being a prosperous productive and innovative nation because prosperity for all can only be attained with a healthy nation.

JOY PHUMAPHI, (MP)

MINISTER OF HEALTH

Date: 26/11/02

2. ABBREVIATIONS

BEDAP:	Botswana Essential Drugs Action Programme
BEDL:	Botswana Essential Drug List
BNDP:	Botswana National Drug Policy
BNF:	Botswana National Formulary
BTG:	Botswana Treatment Guide
CMS:	Central Medical Stores
DAB:	Drugs Advisory Board
DaTIS:	Drugs and Toxicology Information Services
DRU:	Drugs Regulatory Unit
DRA:	Drugs Regulatory Authority
IHS:	Institute of Health Sciences
MOH:	Ministry of Health
NASCOD:	National Standing Committee on Drugs
NDP:	National Development Plan
NDQCL:	National Drug Quality Control Laboratory
PSD:	Pharmaceutical Services Division
SADC:	Southern African Development Community
WHO:	World Health Organisation

3. GLOSSARY

Adverse reaction

A response to a drug that is noxious and unintended and which occurs at doses normally used or tested in human beings for prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.

Drug

Any substance or mixture of substances used or purporting to be suitable for use, or manufactured or sold for use in the diagnosis, treatment, alleviation, modification or prevention of disease, illness, abnormal physical or organic condition or the symptoms thereof, or restoring, correcting, or modifying any somatic or psychic or organic condition, and shall include a related substance and, to the extent that it complies with the above definition, a habit-forming drug. In the context of this document and unless otherwise specified the word medicine may be substituted for drug.

Essential drugs

Drugs that satisfy the health care needs of the majority of the population and are declared to be essential drugs by the National Standing Committee on Drugs.

Generic drug

A drug that is usually intended to be interchangeable with the innovator drug. It is usually manufactured without a licence from the innovator company and marketed after the expiry of patent or some other exclusivity rights. A generic drug may be marketed under a non-proprietary approved name or a brand name.

Generic name

A generic name means a non-proprietary approved name of a drug. Usually it is a non-proprietary name given by the WHO.

4. ACKNOWLEDGEMENTS

This document is a result of collective efforts from government institutions, international organisations, non-governmental organisations, professional organisations, academic institutions and individual professionals whose contributions are greatly appreciated.

The Ministry of Health Department of Technical Support Services through the Pharmaceutical Services Division appointed a Task Force to undertake the process of formulating and drafting a National Drug Policy. The formulation process covered: conducting a situation analysis and identification of stakeholders, seeking written submission from stakeholders, producing a working draft, circulating a working draft among stakeholders, conducting a stakeholder consensus workshop, approval of the policy by Cabinet and noting by the National Assembly for adoption.

The formulation and adoption process is itself an indication of high political and other forms of commitment from the Government of Botswana and other stakeholders.

During this elaborate process many parties played significant roles and their inputs were recognised and appreciated. In making the final document available the contributions of the following are here recognised:

- BNDP Formulation Task Force Members[1];
- World Health Organisation for technical support including a consultant and reviews of the document;
- Head of Department of Technical Support Services, Mr L. R. G. Manthe;
- Health Sectoral High Level Consultative Committee.

[1] Task Force members: Ishmael Joseph (Chairman), Botsang John, Segolame L. Ramotlhwa, Stanley S. Mapiki (Secretary), and Gaobotse S. Rampa.

5. INTRODUCTION

5.1. Background

Health services have grown tremendously in the past few years in terms of numbers and size resulting in the proportional increase in the need for pharmaceutical services. However, accountability, security and responsibility for drugs and pharmaceutical services in the majority of health facilities have been overtaken by the need to provide vital service with less consideration to cost-containment, system efficiency and quality of service.

Drugs are key to the success of any Primary Health Care strategy. However, in the majority of health facilities in Botswana, drugs are under the management of non-pharmaceutical health personnel. The responsibility for drugs falls under the Pharmaceutical Services Division, which is one of the three divisions under the Department of Technical Support Services of the Ministry of Health.

Although the NDP 7 (1991 - 1995) focused on manpower development this did not improve the staffing situation in the Pharmaceutical Division. This situation has been evident in the units like the Drugs Regulatory Unit (DRU), established to enforce the Drugs and Related Substances Act, and the drug quality control laboratory under Central Medical Stores, both established during this plan period. As the situation analysis has shown, the performance of these new units is not satisfactory.

During the same period (NDP 7) a new computerised Central Medical Stores was constructed. However, the situation analysis has revealed that even the new CMS will not solve problems due to poor drug management in those facilities without qualified pharmaceutical personnel.

Government encourages an increased role of the private sector in the economy, and health is not spared. This has seen an increase in private health establishments such as the private hospital, private clinics, and private pharmacies. These are largely controlled by self-regulation and market forces and at most recognition for partnership from the Ministry of Health. It is evident that the legislation to govern the standards of practice is still wanting. In addition certain public health policies (e.g. malaria and tuberculosis) applicable to the public sector hardly ever filter to the private sector.

Ad-hoc arrangements of the past when certain services (like pharmaceutical services) were not available in the country have become an accepted practice in Botswana with little or no consideration to the need for professional standards as such services become well represented. Consequently, pharmaceutical services in most government health facilities and private clinics are not under the continuous supervision of professional pharmaceutical personnel.

The National Health Policy emphasises financial sustainability, system sustainability, productivity, customer satisfaction and appropriateness of technology. These dictate an immediate analysis of the pharmaceutical sector in view of recommending an appropriate drug policy direction.

During NDP 8 (1997 - 2002) the Ministry of Health continues to embark upon human resource development. In the process the situation within the pharmaceutical sector should be addressed according to the needs of the sector. Furthermore the Ministry will focus on health sector reforms, strengthening of health policy making, introduction of innovative management systems and strengthening of health services and support to different levels of

the health service. For the pharmaceutical sector to benefit from this intended plan the needs should be determined to establish direction of the sector.

The Botswana National Drug Policy (BNDP) will address the objectives of the pharmaceutical sector in a futuristic manner in order to facilitate the incorporation of the development of the sector into existing and future plans of the Ministry of Health in order to ensure quality service, system efficiency and cost-containment.

The BNDP is formulated at a stage where several components of an essential drug programme are already in place even though they are not fully developed. In view of this, the BNDP aims at establishing Botswana Essential Drug Action Programme (BEDAP) to specifically address, among others areas of rational drug use, drug selection process and monitoring the implementation of the BNDP, a semi-autonomous Drugs Regulatory Authority, National Drugs and Toxicology Information Centres and a National Drug Quality Control Laboratory.

5.2. Aims and objectives

5.2.1 General aim of the BNDP

In accordance with the philosophy of the National Health Policy to attain health for all, the Botswana National Drug Policy (BNDP) is established with an aim to make the drugs of acceptable safety, efficacy and quality, available and affordable to all those who need them, and to promote their rational use by prescribers, dispensers and consumers.

5.2.2 Objectives

Upon successful implementation, the BNDP is expected to meet the following objectives:

5.2.2.1 Health Objectives

- To ensure the availability and accessibility of essential drugs to all citizens;
- To ensure the use of safe, efficacious and quality drugs;
- To ensure good dispensing and prescribing practices;
- To promote the rational use of drugs by prescribers, dispensers and patients;
- To provide the necessary training, education and information;
- To promote preventive care, informed decision making and overall individual responsibility for health;
- To contribute to the control of drug use and prevention of drug misuse and abuse.

5.2.2.2 Economic and Developmental Objectives

- To promote the lowering of drug costs in both the private and public sectors;
- To promote the cost effective use of drugs;
- To create a conducive environment for partnership between governmental and non-governmental providers in the pharmaceutical sector by means of an appropriate regulatory and administrative framework;

- To optimise the use of scarce resources and facilitate cross fertilisation of ideas through co-operation with international and regional agencies;
- To promote, support and encourage the development of local pharmaceutical industry and the production and distribution of essential drugs and raw materials;
- To promote knowledge, efficiency, management skills and productivity in the pharmaceutical sector.

5.3. Role of Pharmacists and Pharmacy Technicians[2]

5.3.1 Pharmacists

Pharmacists as health care providers shall play a leading role in the following areas:

a) manufacturing of drugs;

b) quality assurance/quality control;

c) formulation and enforcement of drug legislation and policies;

d) drug selection;

e) rational use of drugs;

f) drug distribution;

g) drug and toxicology information;

h) health promotion through public education;

i) drug utilisation studies and the formulation and implementation of associated intervention strategies;

j) Development of pharmacy and practice standards.

Pharmacists shall be involved as members of a multi-disciplinary team in drug selection, rational drug use, drug treatment policies, public health education and research. The role of the pharmacist as an important member of the health care team, and as adopted by the WHO, shall be enforced and promoted.

The pharmacist shall take the overall responsibility and professional accountability for all aspects of drug supply management in all drug outlets. In each health district, there shall be a district pharmaceutical officer who shall be responsible for the pharmaceutical services within that catchment area.

Pharmacists shall take responsibility for the provision of accurate drug information through the use of available scientific sources of reference and through established Drug and Toxicology Information Centres.

5.3.2 Pharmacy Technicians

Pharmacy technicians will continue to provide essential pharmaceutical services in the country either under the supervision of pharmacists or under the professional guidance of

2 Pharmacist refers to an individual with at least a Bachelor of Science in Pharmacy or Bachelor of Pharmacy or equivalent and is registered as a pharmacist in Botswana. Pharmacy technician refers to an individual with a diploma in pharmaceutical sciences and is registered as a pharmacy technician in Botswana.

the head of the pharmaceutical services. Each drug outlet shall/will be staffed with a pharmacy technician. Professional guidance, at least in the form of continuing education, guidelines and procedures, shall be provided.

6. NATIONAL PHARMACEUTICAL SERVICES ADMINISTRATION

Objective: *To establish a National Pharmaceutical Services Administration that will direct and co-ordinate the implementation, monitoring and evaluation of the National Drug Policy.*

In order to achieve this aim the Ministry of Health shall establish a National Pharmaceutical Services Administration that is adequately staffed and appropriately equipped to supervise the implementation, monitoring and evaluation of the Botswana National Drug Policy.

The implementation of the National Drug Policy shall require the following new functions:

a) Drug information and toxicology services;

b) Essential drugs selection and rational drug use;

c) Regional or district pharmaceutical services;

d) National Drug Quality Control Laboratory;

e) Support for the semi-autonomous Drugs Regulatory Authority.

7. LEGISLATION AND REGULATIONS

Objective: *To develop, regularly review and amend the drugs legislation with a purpose to ensure that drugs reaching consumers are safe, effective and meet approved standards and specifications of quality. The drug legislation shall form a legal basis for the enforcement of the BNDP.*

1) In order to achieve the above aim the MOH shall rapidly and fully implement the Drugs and Related Substances Act of 1992, in particular, carrying out the following activities in line with National Development Plans and National Health Policy objectives:
   a) Strengthening and empowering of the drugs regulatory authority;
   b) Improving drug registration system;
   c) Ensuring the licensing of premises;
   d) Strengthening and empowering the inspectorate and drug control functions;
   e) Promoting quality assurance and control measures.
2) The MOH shall from time to time review the drug legislation and regulations and establish procedures in order to support the aims of the BNDP. Special consideration will be given to the needs of the primary health care strategy where certain drugs may be re-scheduled to allow for prescribing and dispensing by a wider range of health workers.
3) The MOH shall promulgate a law to govern the practice of pharmacy to ensure the maintenance of high standards of professional pharmacy practice in all sectors and all areas where drugs are handled and enhance the implementation of the BNDP.

8. DRUGS REGULATORY AUTHORITY

***Objective:** To establish a semi-autonomous DRA with a purpose to ensure efficiency and credibility in the execution of drug regulatory functions to meet the needs of the Botswana National Drug Policy.*

1) MOH shall review the Drugs and Related Substances Act to provide for the appropriate autonomy of the regulatory authority, while remaining accountable to the Minister of Health. Such semi-autonomy shall provide for the generation and retention of revenues in order to use the accrued funds towards the development, improvement and strengthening of the regulatory authority.
2) The MOH shall ensure that the DRA is adequately staffed and appropriately equipped to effectively and efficiently render all the necessary drug regulatory services, including:
   a) Drug registration;
   b) Drug control and inspectorate functions;
   c) Adverse drug reaction monitoring;
   d) Post-marketing surveillance and other functions expected from the drugs regulatory authority.
3) The DRA will be fully computerised to meet the needs of the regulatory process.
4) The DRA will establish a comprehensive fee structure in order to ensure cost-effective operation.
5) The DRA will collaborate with authorities in other countries to facilitate harmonisation of drug regulation and control within the region and internationally and enhance information sharing.

8.1. Registration of drugs and related substances

***Objective:** To ensure that all drugs and related substances imported, manufactured, exported, distributed, sold and used in Botswana are registered on the basis of safety, quality and efficacy.*

1) The DRA shall develop, review and disseminate drug registration procedures and guidelines.
2) Registration certificates will be issued only when all registration and good manufacturing practice requirements are met.
3) Drug registration status will be reviewed periodically.
4) The MOH shall review the Act to ensure that all registration exemptions are carried out in consultation with the DRA.
5) Prioritisation of drug registration will be based on the needs of the health care system and whether the drug is locally produced.

8.2. Licensing of practitioners and premises

***Objective:** To ensure that all drug importers, exporters, wholesalers, manufacturers, retailers and their premises are licensed.*

1) The MOH will review the Drugs and Related Substances Act and mandate the DRA to enable it to license drug importers, exporters, ware-houses, agents, manufacturers, representatives, distributors, dispensers and dispensing practitioners.

2) The MOH shall review the Drugs and Related Substances Act and Regulations to provide for immediate suspension of any licence issued by the DRA where there is violation of the law.

3) The licensing of premises shall take into account the size, socio-economic status and demographics of the target market and the distance between similar businesses.

8.3. Inspection

Objective: *To ensure that all premises in Botswana in which drugs are manufactured, stored, distributed, dispensed, or sold are subjected to periodic inspection and audit.*

1) The DRA shall carry out routine inspections and spot checks on all drug premises in the country.

8.3.1 Post-marketing Surveillance

Objective: *To ensure drugs on the market meet the appropriate standards of safety, efficacy and quality.*

1) The DRA, in consultation with the NASCOD and other bodies shall review the efficacy of drugs used in the country.

2) The DRA shall periodically sample drugs on the market for testing.

3) The DRA shall be responsible for adverse drug reaction monitoring.

4) All drug outlets shall report adverse drug reactions to the DRA.

5) The MOH shall review the Drugs and Related Substances Act to ensure that all drug importers and exporters provide quarterly reports of all drug imports or exports in order to ensure that only registered drugs are imported into Botswana or exported out of Botswana.

8.3.2 Regulation of Prescription and Dispensing

Objective: *To ensure that only qualified persons are allowed to prescribe or dispense drugs.*

1) The MOH will review, develop and enforce regulations and guidelines to ensure that only qualified persons are allowed to prescribe or dispense drugs.

2) Private medical or dental practitioners will only be permitted to dispense emergency drugs. Where there are no pharmacies within a specified regulatory distance medical or dental practitioners will employ pharmaceutical personnel to carry out the dispensing.

3) In order to ensure the provision of a comprehensive pharmaceutical care, a pharmacy shall be under the full-time continuous physical supervision of a registered pharmacist.

4) All drug prescriptions will be completed in multiple copies in order to allow the DRA to continuously monitor drug use patterns in Botswana.

8.3.3 Advertising and marketing

Objective: *To ensure that the promotion, marketing and advertisement of drugs comply with the requirements of the Drugs and Related Substances Act and the WHO Ethical Criteria for Medicinal Drug Promotion.*

1) The MOH through the Pharmaceutical Services Division (PSD) will adapt the WHO Ethical Criteria for Medicinal Drug Promotion and Guidelines for the Sale and Marketing of Drugs through the Internet into regulations to control promotion and advertising of drugs through all media.

8.4. Control of drugs of abuse and related substances

Objective: *To control drugs and related substances of abuse, to ensure the availability of treatment and rehabilitation services for substance abusers, and to assist in combating illicit drug trafficking.*

1) The MOH working with other Ministries and Departments like Education, Labour and Home Affairs, Police, Attorney General Chambers, and Customs and Excise will continue to assist in enforcing the SADC Protocol on Combating Illicit Drug Trafficking and relevant United Nations Conventions to combat illicit drug trafficking.
2) The MOH will play a prominent role towards the establishment of a multi-sectoral national drug control co-ordinating committee involving all the interested parties to be responsible for the formulation, monitoring and evaluation of strategies against substance abuse, illicit drug trafficking and related activities.
3) The MOH shall work with the multi-sectoral National Drug Control Co-ordinating Council to develop strategies towards illicit drug demand reduction and contribute towards combating illicit drug production, supply and trafficking, and related activities.
4) All enforcement agencies and departments such as the Botswana Police and Customs and Excise will submit data on drug seizures and destruction and other activities against illicit drug trafficking to the DRA.
5) The MOH will strengthen the DRA to enable it to compile statistics, information and reports on the drug and other substance abuse and illicit drug trafficking activities for dissemination to the International Narcotics Control Board and other interested parties.
6) The DRA will compile data on the use of Habit Forming Drugs as drugs and will also review and update consumption requirements for the health sector.
7) The MOH will review appropriate legislation in view of incorporating regulation of the sale and supply of volatile solvents and substances containing such solvents with potential for abuse.

9. QUALITY ASSURANCE

Objective: *To ensure that high quality standards are maintained throughout the implementation of the BNDP and drugs of good quality, efficacy and safety are produced, imported, exported, distributed and used in Botswana.*

1) The MOH shall ensure that adequate legal, regulatory, technical and managerial elements of the pharmaceutical quality assurance system are put in place.

2) All drug manufacturers shall extend good clinical, laboratory and manufacturing practices to all drug development, formulation and manufacturing.

3) All distributors shall ensure that drugs are obtained from reputable sources, inspected for quality defects at the time of receipt, stored properly and distributed according to the provisions of the law.

4) All suspected or confirmed drug quality defects shall be reported to the DRA.

5) The MOH through the DRA shall ensure compliance with good laboratory, clinical, manufacturing and distribution practices through inspection, registration evaluation, post-marketing surveillance and implementation of the WHO Certification Scheme on the Quality of Products Moving in International Commerce.

10. NATIONAL DRUG QUALITY CONTROL LABORATORY

Objective: *To establish an independent NDQCL with a purpose to ensure that drugs produced, distributed, exported and used in Botswana are tested for conformity to the standards of quality recognised internationally.*

1) The MOH shall establish and ensure the efficient operation of an independent National Drug Quality Control Laboratory (NDQCL).

2) The NDQCL shall conduct routine tests of samples from the Public and Private Sectors and will function as a reference laboratory for the local drug manufacturers and distributors.

3) The NDQCL shall collaborate with the Botswana Bureau of Standards, University of Botswana and other local, regional and international quality control laboratories, in the harmonisation of drug testing procedures, staff development and the promotion of good laboratory practices.

11. BOTSWANA ESSENTIAL DRUGS ACTION PROGRAMME

Objective: *To establish a Botswana Essential Drugs Action Programme with a purpose to implement some of the key components of the BNDP and monitoring the implementation of the BNDP.*

1) The MOH shall establish the Botswana Essential Drugs Action Programme (BEDAP) to specifically address areas identified as either completely lacking or experiencing significant deficiencies.

2) The head of the BEDAP unit shall be a pharmacist or medical practitioner with a background on essential drugs concept. The unit shall function as a co-ordinating centre for all matters pertaining to drug treatment policies.

3) The main areas of focus of BEDAP shall be:

   a) Drug selection;

   b) Rational use of drugs;

   c) Monitoring the implementation of the BNDP.

11.1. Selection

11.1.1 National Standing Committee on Drugs (NASCOD)

Objective: *To ensure that the drug selection process is conducted in a credible manner to result in a list(s) of essential drugs applicable to all health care levels in both the public and private sectors.*

1) The MOH shall establish and appoint the NASCOD, which shall be composed of experts in the relevant medical, pharmaceutical and allied health sciences in both the public and private sectors with the following functions:
   a) Select drugs and related substances for the BEDL;
   b) Produce the Botswana Treatment Guide (BTG) and ultimately produce a Botswana National Formulary (BNF);
   c) Revise BEDL and BTG or BNF regularly;
   d) Continuously monitor the use of drugs in the country and effect the necessary drug treatment policy and protocol changes.
   e) Consider special order items.

11.1.2 Drug selection process

Objective: *To ensure that, only the registered drugs of proven efficacy, safety and quality are selected to satisfy the health needs of the majority of the population of Botswana.*

1) The selection of drugs for the Botswana Essential Drugs List (BEDL) shall be in accordance with the essential drugs list concept as defined by the World Health Organisation (WHO). In particular, the selection of drugs shall be based on the following criteria:
   a) Disease pattern/prevalence in Botswana;
   b) Registration status according to Drugs and Related Substances Act and DRA requirements;
   c) Well documented efficacy and safety of the drug;
   d) The quality (including stability) of the product;
   e) Single pharmacologically active ingredient except in very special circumstances;
   f) Cost.
2) The BEDL shall be produced in generic names.

11.2. Rational Use of Drugs

Objective: *To ensure rational drug prescription, dispensing and informed use by medical, pharmaceutical, allied health personnel, medical aid schemes and the community in order to maximise therapeutic benefit, safety and minimise costs.*

1) This will be achieved through:
   a) Training and education;
   b) Provision of scientific drug information for professionals and the community;

c) Establishment of good prescribing, dispensing, advertising and marketing practices;

d) Relevant research and development.

11.2.1 Education and Training

Objective: *To ensure that appropriate education and training is provided to health personnel and the general public on importance of rational drug use.*

1) The MOH shall involve the following key groups to develop complementary policies and practice, such that health personnel shall receive both theoretical and practical training in the area of rational drug use:

   a) Drugs and Therapeutics Committees to develop and maintain standard treatment guidelines;

   b) Professional associations to establish standards of professional practice, conduct and comprehensive continuing education;

   c) Academic institutions to update curricula of all health programmes offered locally to ensure that students are sufficiently exposed to the basic concepts of primary health care, essential drugs, and rational use of drugs;

   d) Research institutions and individuals to study drug use and recommend appropriate interventions;

   e) Ministry of Education and the relevant organisations to incorporate into the curriculum basic education components that will promote better understanding and appreciation of the role of drugs in health care;

   f) Industry and consumer groups to promote the policy on rational drug use.

2) The BEDAP unit will play a leading role in conducting drug utilisation studies and organising courses or workshops on Promoting Rational Use of Drugs including public education through the media.

11.2.1.1 Health Workers

Objective: *To ensure that all health personnel involved in diagnosis, prescribing, dispensing or any other drug related programmes receive adequate and continuous (theoretical and practical) training on rational drug use.*

1) The MOH shall develop, assess and revise all drug related curricula of medical, pharmaceutical, paramedical and nursing programmes to cover:

   a) Primary health care and essential drugs concept;

   b) Stock management;

   c) Rational use of drugs;

   d) Patient counselling and communication;

   e) Analysis of sources for drug promotion and advertising.

2) The BEDAP unit will develop and implement a standard programme for continuing education.

3) The BEDAP unit shall develop and implement an orientation programme for all new health personnel on rational use of drugs.

11.2.1.2 Community

Objective: To ensure that the educational strategies and programmes on appropriate drug use directed to the public are developed, implemented and maintained.

1) The MOH in collaboration with key groups shall develop special emphasis programmes for such vulnerable groups as children, youth, pregnant and lactating mothers, the elderly, and people with chronic conditions.

2) The MOH, in collaboration with key groups, shall provide the general public with sufficient knowledge to be able to critique advertising and commercial information, practise safe, responsible and limited self-medication and to initiate effective communication with health personnel.

11.2.2 Prescribing Practices

Objective: To promote rational prescribing.

1) The MOH through NASCOD shall develop guidelines for the different levels of prescribers and prescribing facilities.

2) Drugs will only be prescribed in generic names unless where specific and acceptable or valid justification for preferring a particular brand is given. The prescribing and dispensing of drugs shall be in accordance with the relevant provisions of laws and regulations, acceptable standards of prescribing and dispensing, BEDL and the approved standard treatment protocols or national formulary.

3) The PSD through NASCOD will continuously monitor and evaluate prescribing practices in order to develop and introduce improvement strategies.

11.2.3 Dispensing

Objective: To ensure that all drugs are dispensed according to the provisions of the Drugs and Related Substances Act and good dispensing practice.

1) The MOH through the PSD shall develop dispensing guidelines to cover the different levels of drug dispensers and dispensing facilities.

2) The PSD shall continuously monitor and evaluate dispensing practices in view of developing strategies for improvement.

11.2.4 Drugs and Therapeutic Committees

Objective: To encourage both public and private health facilities to establish and maintain multidisciplinary drugs and therapeutics committees with a purpose to ensure rational, efficient and cost-effective use of drugs.

1) Key health personnel will be encouraged to participate in collaborative management of drugs in their institutions in order to promote the rational use of drugs.

   a) The core terms of reference shall include the following, among others:

   b) Produce a list of essential drugs, consistent with the BEDL;

   c) Monitor the use of the list in ordering and procurement of drugs;

   d) Promote and monitor, safe, cost-effective and rational drug use;

e) Promote adherence to standard treatment guidelines;

f) Function as a formal link to BEDAP and/or NASCOD.

11.2.5 Promotional and marketing activities

Objective: *To ensure that drug promotion and marketing activities are aimed at improving health care through rational use of drugs.*

1) All promotional and marketing information shall be reliable, accurate, truthful, balanced, up to date, substantiated, co-ordinated, and understandable to the target audience.

2) Promotional and advertising materials shall not contain misleading or unverifiable statements and omissions likely to result in unjustifiable drug use or undue risks.

11.2.6 Role of the health workers

Objective: *To ensure that all health workers recognise the importance of an integrated approach when addressing issues of rational drug use.*

1) This aim will be achieved through a co-ordination by BEDAP at national level and Drug and Therapeutic Committees at facility level.

2) Health workers, including health service managers, shall be made aware of rational drug use and other BNDP objectives in order to facilitate the implementation process.

11.2.7 Rational drug use research

Objective: *To promote research on rational use of drugs with a view to develop strategies to improve attitudes, beliefs and practices contributing to the inappropriate use of drugs.*

1) The BEDAP shall periodically carry out drug use studies using relevant drug use indicators and continuously monitor drug use in the country. BEDAP shall collaborate with NASCOD to come up with appropriate intervention strategies to correct any anomaly.

12. DRUG INFORMATION

Objective: *To establish an independent drug and toxicology information centre with a purpose to collect, compile and disseminate unbiased peer-reviewed and other drug information to all health workers in both the public and private sectors and members of the public.*

1) The MOH shall establish Drug and Toxicology Information Services (DaTIS) Centres at referral health facilities. These centres shall be run independently from the hospital pharmacies and shall establish links with more established WHO collaborating DaTIS Centres within the region and abroad.

2) The DATIS shall be managed under the PSD and shall be headed by a clinical pharmacist with the relevant postgraduate qualification.

3) The MOH shall provide funding for the centres to enable them to acquire or have access to the necessary drug literature publications and up-to-date systems of drug information.

13. DRUG SUPPLY

Objective: *To ensure that essential drugs of good quality are always available to all consumers in adequate quantities at the lowest possible cost.*

1) The MOH shall maintain a highly efficient, secure and reliable system of drug procurement, storage, management and inventory control, and distribution.

13.1. Procurement

Objective: *To procure good quality essential drugs in sufficient quantities and at the lowest possible prices to meet the needs of the health service.*

1) The public and private sectors shall purchase drugs registered in accordance with the Drugs and Related Substances Act.
2) CMS shall purchase all drugs for the public sector through a competitive tendering system adhering to Supplies Regulations and Central Tender Board Guidelines.
3) The MOH in conjunction with relevant ministries shall develop special procurement guidelines and regulations for drugs.
4) The MOH shall promote transparency in the administration of tenders.
5) All drugs in the public sector shall be procured by generic name only and the private sector shall be encouraged to do the same.
6) The MOH shall develop, monitor and maintain efficient national drug quantification and stock management systems.
7) All procurement procedures shall satisfy public health needs, the national legislation requirements and, to an extent that does not compromise public health, the requirements of relevant international trade agreements to which Botswana is signatory.

13.2. Donations

Objective: *To ensure that drug donations meet all requirements for safety, efficacy, quality and need.*

1) The MOH shall adapt the Inter-Agency Guidelines for Drug Donations, published by WHO, in order to ensure that all donated drugs meet the following criteria:
   a) All drug donations shall be based on Botswana's expressed need and must be relevant to the disease pattern in the country;
   b) All donated drugs shall be of good quality and have a shelf life of more than twelve months at the time of donation, i.e. when handed over to the recipient;
   c) All donated drugs shall be authorised for use in Botswana and must meet the labelling requirements as stipulated in the Drugs and Related Substances Act.
2) All donations will be tested by the NDQCL for conformity to specifications.

13.3. Drug Storage

Objective: *To ensure the safe and secure storage of drugs at all levels of health care and transit points to maintain quality and minimise wastage.*

1) The MOH and relevant partners shall provide and maintain appropriate, secure, adequate, well equipped and well managed storage in the public health facilities.
2) The DRA shall assess or inspect the drug storage in all health facilities in order to ascertain that drug storage is adequate and to ensure that drugs are stored according to prescribed conditions.
3) The MOH shall develop, review, distribute and monitor the use of appropriate standard operating procedures to ensure safe and secure drug storage.

13.4. Drug Distribution

Objective: *To ensure a safe, secure, cost-effective and efficient system of drug distribution with a purpose to ensure that drugs of good quality are available and accessible to all those who need them, at the right time and to the intended destination.*

1) The Central Medical Stores (CMS) shall be responsible for the distribution of drugs to all the public, mine and mission health facilities. Distribution in the private sector shall be through licensed distributors.
2) Only drugs registered according to the Drugs and Related Substances Act shall be distributed in Botswana.
3) All suppliers shall ensure that quality and security is maintained during transportation.
4) The MOH shall provide appropriate drug distribution equipment to all health facilities to ensure that security and accountability are maximised for each drug dispensed to both in and out patients.
5) The PSD will periodically review the drug distribution system with a view to improve its cost effectiveness.

13.5. Drug Management and Inventory Control

Objective: *To ensure the continued availability of essential drugs in sufficient quantities at all levels of health care by adopting good drug management practices and accountability.*

1) The MOH in conjunction with the Ministry of Local Government and other relevant partners shall review and improve the inventory control and drug supply management systems at all levels.
2) Disposal of expired drugs shall follow approved guidelines to minimise environmental pollution.

13.6. Local Drug Manufacturers

Objective: *To promote the growth of the local drug-manufacturing sector with a purpose to ensure that Botswana can be self-sufficient in producing affordable good quality essential drugs.*

1) The DRA shall regularly carry out inspections in order to ensure compliance with Good Manufacturing Practices by all drug manufacturers.

2) The MOH will purchase at least 30% of its drug requirements from local companies provided they meet the set CMS procurement criteria and any local procurement policy criteria.

3) The MOH shall implement all Government policies aimed at promoting local industry development.

13.7. Emergency Drug Supply

Objective: *To ensure that adequate drug supplies are available to meet the primary health care needs of displaced populations as a result of disasters.*

1) The MOH, the Red Cross and other emergency relief organisations will quantify, compile and review a list of drug items required to complete an emergency health kit. The following will be consulted: the Inter-Agency Guidelines for Drug Donations, the Composition of the New Emergency Health Kit 98, and Model Guidelines for the International Provision of Controlled Drugs for Emergency Medical Care.

2) The MOH through CMS will provide items required for the completion of the emergency health kit under emergency situations.

14. ECONOMIC STRATEGIES

Objective: *To ensure that drugs are affordable and available to all those who need them.*

14.1. Financing

Objective: *To ensure a sustainable drug supply system through an integration of different forms of financing mechanisms such as public financing, user fees and health insurance in order to improve equity and cost-effectiveness in the pharmaceutical sector.*

1) The MOH, in consultation with Ministry of Local Government, Ministry of Finance and Development Planning, non-governmental organisations and the private sector will plan, budget and secure sufficient funding for the implementation of the various components of the BNDP.

2) To facilitate this, the MOH will adopt an implementation plan detailing annual, medium- and long-term plans directed towards achieving the objectives of the BNDP.

3) The MOH shall study ways to improve the cost-recovery and cost sharing systems to ensure that those who are able to pay for health services, including drugs, are required to do so. User fees will be reviewed periodically to reflect the increasing nature of drug costs. A free health service, including the supply of drugs, will be maintained for those who are unable to pay. A thorough economic assessment will be performed to ensure equitable provision of health services.

14.2. Pricing

Objective: *To ensure the affordability of essential drugs by all those who need them.*

1) The MOH shall introduce mechanisms intended to increase economic access to essential drugs by all members of the society. Some of these mechanisms include insurance coverage, price information and price competition through generic substitution.

2) The MOH shall introduce a pricing system of cost plus fixed handling fee or professional fee to regulate producer, wholesale, retail, and dispensing doctor drug prices.

15. DRUG RESEARCH AND DEVELOPMENT

Objective: *To identify, promote and support research activities such as operational research and drug development research with a purpose to facilitate the realisation of the aims of the BNDP.*

1) The MOH shall review the legislation to ensure that an appropriate regulatory framework is provided for the conduct of clinical trails.

2) The MOH shall establish a National Research and Ethics Committee to review clinical trial proposals in order to ensure that they conform to the requirements of the Drugs and Related Substances Act, other relevant pieces of legislation and comply with WHO Guidelines on Good Clinical Practice.

3) Institutional research and ethics committees shall be established to screen and monitor clinical research at facility level.

15.1. Operational Research

Objective: *To identify inadequacies in achieving the specific components of the BNDP and finding solutions to the problems identified.*

1) The Health Research Unit, the PSD, other Ministry of Health departments and interested parties will identify critical research areas and facilitate the carrying out of the studies. Results of these studies will be used to develop, introduce and support practical and cost-effective interventions.

2) The MOH shall fund and provide support for the development of protocols, carrying out of the studies, interpretation and use of the findings.

15.2. Drug Development Research

Objective: *To support drug research based on specific national health priorities and capacities.*

1) The MOH shall develop, review and maintain an appropriate regulatory and administrative structure to accommodate the specific drug research needs aimed at introducing more cost-effective drug treatment interventions for old and emerging health problems.

2) The MOH shall collaborate with reputable pharmaceutical, medical and scientific research bodies showing interests in drug research activities in Botswana.

3) The MOH through the PSD shall develop guidelines on drug research.

15.3. Traditional Drugs

Objective: *To investigate and promote the safe and effective use of traditional drugs in line with the provisions of the National Health Policy.*

1) The MOH shall encourage traditional practitioners through customary leaders and traditional practitioners associations to work more closely and openly with the formal health sector while still remaining independent.

2) The MOH shall work closely with traditional practitioners, non-governmental organisations, private sector and the University of Botswana to compile a national data base of indigenous medicinal plants, animal derivatives, mineral salts, their uses, dosage and methods of identification.

3) The MOH shall study the effectiveness and toxicity of the indigenous medicinal plants, animal derivatives and mineral salts.

4) The MOH shall work through existing structures to promote preservation and protection of medicinal plants.

16. HUMAN RESOURCE DEVELOPMENT

Objective: *To develop the human resources with the expertise necessary to support the successful implementation of the BNDP.*

1) The MOH shall develop and execute effective, comprehensive and appropriate short and long-term human resources recruitment and development plans to meet the needs of the BNDP.

2) The MOH in conjunction with the University of Botswana and its affiliated institutions and in collaboration with professional associations, medical and/or pharmaceutical research and academic institutions in the region shall develop and implement appropriate continuing education programmes to meet the needs of the BNDP.

3) The MOH shall put in place appropriate strategies aimed towards enhancing productivity, providing quality service and improving staff and consumer satisfaction.

17. TECHNICAL CO-OPERATION

Objective: *To promote inter-sectoral and international co-operation and collaboration to ensure the successful implementation of the BNDP.*

1) The MOH shall involve the Ministries of Finance, Commerce and Industry, Agriculture, Education and Local Government, the Botswana Police, Attorney General Chambers, Department of Customs and Excise and other departments in the implementation of the relevant components of the BNDP.

2) The MOH shall consult with all relevant health related professional associations, medical aid societies, academic institutions, civic organisations, international organisations and pharmaceutical industry on all issues relevant to the successful implementation of the BNDP.

3) The Government of Botswana through the Ministry of Health and Ministry of Foreign Affairs shall encourage and support technical co-operation and collaboration with all

countries in the Southern African Development Community (SADC), Commonwealth and Other United Nations Member States on drug related matters.

18. MONITORING AND EVALUATION

Objective: *To establish mechanisms for monitoring and evaluating the implementation of the BNDP.*

1) The Ministry of Health and other stakeholders shall adopt a national pharmaceutical master plan outlining and prioritising approaches, activities, the budget and responsible departments for the implementation of the BNDP.

2) The MOH through the PSD shall:

   a) Monitor the various components of the BNDP;

   b) Develop indicators for monitoring the BNDP using guidelines developed by the World Health Organisation;

   c) Monitor progress in BNDP implementation biannually;

   d) Review the implementation of the master plan and conduct a full evaluation of the BNDP every 5 years.

BOTSWANA NATIONAL DRUGS (MEDICINE) POLICY

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MINISTRY of HEALTH
REPUBLIC OF BOTSWANA

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