



National Drug Policy 2007

Department of Medical Services
Ministry of Health
Royal Government of Bhutan

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PREFACE

Drugs constitute one of the essential components of health care delivery system in promoting health, preventing and managing diseases. Inappropriate use of drugs can be harmful and has medical, social and financial implications. Inadequate supply of essential drugs leads to treatment failure and loss of confidence in the health care system.

On this basis, the National Drug Policy was developed in 1987 to guide the pharmaceutical sector including traditional medicines, in the areas of quality assurance and regulation, supply management, manufacture, monitoring, evaluation and matter related therewith. Since then, there have been many developments both in the national and global pharmaceutical arena in terms of need to combat emergence of new diseases and pharmaceutical trade such as IPR, TRIPS, etc.

Therefore, the revision of the National Drug Policy 1987 was felt necessary to address the recent developments. While keeping the essence of the old edition intact, some structural changes have been made to incorporate additional information.

In order to ensure a coherent and a multi-sectoral platform to achieve the objectives of the national drug policy, several consultations were held with all the stakeholders. The main task was entrusted to a Technical Working Group comprised of the following:

1. Dr. B.R Giri, Sr. Medical Specialist, JDWNRH.
2. Sonam Dorji, Program Director, Quality Assurance & Standardization Division
3. Dorji Thinlay, Drug Controller, Drug Regulatory Authority
4. Kinga Jamphel, Head, Pharmaceutical and Research Unit
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The World Health Organization provided valuable technical and financial support for this undertaking.

PREAMBLE

Concerned with the health and well being of the people of Bhutan, which is one of the important elements of Gross National Happiness, The Royal Government shall, as enshrined in various documents such as the draft constitution, Article 9, section 21, endeavor to provide free access to basic public health services in both modern and traditional medicines. Do hereby adopt this policy to ensure accessibility, availability and affordability of safe, good quality and efficacious essential drugs to all the citizens of Bhutan through promoting rational use of drugs at all levels of health care system.

INTRODUCTION

Health is a fundamental human right. Access to healthcare includes access to essential drugs as a pre-requisite for realizing that right. The declaration of the Alma-Ata, identified “provision of essential drugs” as one of the eight elements of the primary health care, which resulted in improvement in the access to essential medicines worldwide.

Until 1986, problems existed in Bhutan in the drug supply system leading to poor drug availability, questionable quality, irrational prescribing and high drug costs. The Government felt the need to improve the drug supply system and, with the assistance of WHO, the Essential Drugs Program (EDP) was instituted. One of its first tasks was to develop a comprehensive National Drug Policy and Legislation that was approved by the Government in 1987. The public drug supply system is the most important source of drugs for the Bhutanese population. In line with “Vision 2020”, which aims at achieving Gross National Happiness, the primary objective of the National Drug Policy is ‘to ensure that primary health care services are extended to those living in the most remote part of the nation’ ‘to reach the un reached’.

The success of the National Drug policy will depend on the active participation of the main stakeholders in the pharmaceutical sector. The existence of this document is a sign of government's awareness of the problems Bhutan is faced with in the pharmaceutical sector. It forms a basis for planning, implementing, monitoring and evaluation of interventions in the pharmaceutical sector. In its efforts to achieve these, the Ministry of Health and other related Ministries have taken the following steps:

1. Institution of Advisory Technical Committees at various levels.
2. The publication and distribution of National Essential Drugs list (EDL), Standard Treatment Guideline, Bhutan National Formulary, etc.
3. The promulgation of the Medicines Act of Bhutan 2003.
4. Human Resource Development and deployment of pharmacy professionals.

In keeping with the emerging needs, revision of this policy document is crucial to address to the changes. The policy document covers both the modern and traditional medicines.

OBJECTIVES

The policy is aimed at achieving the various broad objectives as listed below:

1. To ensure the accessibility, availability and affordability of essential drugs to all citizens.
2. To ensure the safety, efficacy and quality of drugs
3. To promote good dispensing practices, prescribing practices and rational use of drugs.
4. To promote efficient supply management system.
5. To promote the development of local pharmaceutical industry and local production of essential drugs.

In order to achieve the objectives of the National Drug Policy, the following components have been identified and the policy statements mentioned under each component as below:

1.0 SELECTION

Selection of drugs is a crucial step in ensuring access to essential drugs and in promoting RDU. Selection of drugs shall be in accordance with the Essential Drugs Concept.

1.1 The Ministry of Health shall appoint an Expert Committee, known as the National Drug Committee responsible for selection of drugs for the public sector.

1.2 The committee will be composed of medical doctors and pharmacists and other relevant health professionals.

1.3 The selection of essential drugs will be based on the following criteria:

- 1.3.1 Therapeutic need
- 1.3.2 Relevance to national morbidity and mortality pattern
- 1.3.3 Safety, quality and efficacy
- 1.3.4 Cost effectiveness
- 1.3.5 Ease & safety in administration and dispensing
- 1.3.6 Usefulness in more than one condition
- 1.3.7 Likelihood of patient compliance
- 1.3.8 Training and experience of the prescribers
- 1.3.9 Treatment facilities in the country

1.4 In addition to statement 1.3 above, the following other criteria shall also apply:

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

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

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

- The clinical condition justifies the use of more than one drug;
- The therapeutic effects of the combination are 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.

1.4.4 In case of selection of traditional medicines, besides all the criteria that are relevant, other conditions such as availability of raw material, use of endangered species and legally prohibited materials should be considered.

2.0 QUANTIFICATION

Quantification of drugs shall be done consciously with sense of responsibility and accountability based on reliable quantification methods taking into consideration consumption, morbidity pattern and existing guidelines.

2.1 Quantification shall be done taking into consideration all the parameters such as demand, lead time, and transportation constraints, emergency needs and should include buffer stock.

2.2 Appropriate inventory management software shall be used and revised (if necessary) to ensure accurate quantification.

3.0 PROCUREMENT

Essential drugs shall be procured to ensure cost effectiveness and sustainability with consideration to the economy of the country and conforming to the principles of transparency, accountability and efficiency.

3.1 Only drugs registered in the country shall be procured.

3.2 Drugs for public sector shall be centrally procured and shall be in accordance with the prevailing financial rules and regulations. However, the objective shall be to procure acceptable quality drugs at reasonable price.

3.3 In general, drug donation is not encouraged. However, such matters shall be dealt on case-by-case basis. In case of acceptance, the regulatory requirements must be fulfilled.

4.0 STORAGE

All drugs shall be stored under appropriate storage conditions to maintain the quality and efficacy.

4.1 For the public drug distribution system, the Government shall establish appropriately equipped storage facilities at every level of health facility.

4.2 All the storage facilities must be managed by appropriate number of skilled and qualified personnel in line with the principles of good store management.

4.3 Expired, deteriorated and other drugs with quality-related problems shall be disposed-off in accordance with the prevailing guidelines.

5.0 DISTRIBUTION

Drugs being the life-line of the healthcare system, distribution to the health centers in the country shall be done in a prompt, efficient, timely and equitable manner.

5.1 Drugs shall be distributed under proper shipment conditions and ensure safety and proper delivery.

5.2 Distribution shall be done in an appropriate and timely manner in order to maintain equity and availability throughout the country.

5.3 A good inventory control system for medical supplies will be introduced at all levels of the supply system and all store keepers shall be trained on good store keeping.

6.0 FINANCING

The Government shall allocate adequate financial provisions to ensure procurement and supply of drugs, reduce dependency on donors and ensure sustainability.

6.1 The Government shall continue to finance the procurement and management of essential drugs in the public sector.

6.2 The Government shall also allocate adequate fund to procure pediatric dosage forms and develop appropriate guidelines.

6.3 The Ministry of Health shall explore alternate financing sources and develop innovative means and mechanisms to sustain the drug supply system.

6.4 The Government shall exempt all drugs (including raw materials used for local manufacturing) from all taxes.

6.5 The Ministry of Health shall be responsible for projecting cost of drugs from time to time and develop appropriate models for costing.

7.0 QUALITY ASSURANCE AND REGULATION

The Drug Regulatory Authority (DRA) shall be the agency that develops and implements most of the legislation and regulations on pharmaceuticals to ensure the quality, safety and efficacy of drugs and the accuracy of product information.

7.1 An appropriate quality assurance system shall be instituted at all the levels of drug supplies management including local manufacture and shall include all plans, processes, and procedures that conform to all regulatory requirements.

7.2 The Government shall have built in mechanisms in the public health laboratory to carryout quality testing of drugs in the country for both private and public sector.

7. 3 The Government shall allocate at least 2-3% of annual drug budget to cover the cost of quality assurance and drug testing.

7.4 All drugs used in both public and private sectors shall be registered with the National Drug Regulatory Authority

7.5 Regular inspections shall be carried out to prevent and control sales of counterfeit and sub-standard drugs in the country.

7.6 The list of registered products shall be published in the public domain by the Drug Regulatory Authority and a National formulary containing the list of all the registered drugs shall also be published.

7.7 Appropriate Drug information shall be provided and made available both to the patients and the health professionals.

8.0 ADVERTISEMENTS AND PROMOTION

In order to prevent risks of misuse and creation of brand royalty, the Government shall as far as possible, restrict commercial Advertisement and marketing of drugs unless otherwise required.

8.1 Any advertisements and promotion of drugs when necessary shall be as per the prevailing rules and regulations.

9.0 LOCAL MANUFACTURE OF PHARMACEUTICALS

In order to promote self-sufficiency, the Government shall encourage, promote and support research and development and local manufacture of pharmaceuticals including traditional medicines.

9.1 The regulatory agency shall develop and enforce guidelines on manufacture such as but not limited to Good Manufacturing Practices (GMP), Good Clinical Practice (GCP), and Good Storage Practice (GSP).

9.2 To ensure safety, quality and efficacy of products, the regulatory agency shall regulate manufacture of medicinal products and cause periodic inspection of the manufacturing premises both within and outside the country.

9.3 The Government shall, to the extent feasible encourage manufacture of bulk essential drugs within the country to reduce dependency.

9.4 Extemporaneous preparations, when undertaken, shall comply with the basic requirements of safety and quality.

10.0 RATIONAL DRUG USE

In order to minimize wastage and ensure effective treatment, rational prescribing, dispensing and use of drugs by health professionals/ health workers shall be instituted and right information shall be provided to the prescribers as well as the patient.

10.1 The concepts of essential drugs and the principles of rational use of drugs shall be incorporated in the curricula of health training institutions.

10.2 A drug information center shall be established in collaboration with all stakeholders to provide appropriate drug information.

10.3 Standard guidelines such as Standard Treatment Guideline (STG) both for adult and pediatrics, guidelines for Rational Drug Use, etc shall be developed and revised from time to time and made accessible to health workers/ health professionals at all levels as and when necessary.

10.4 The Essential Drug List (EDL) shall be updated at regular intervals and distributed to all health institutions and health care providers.

10.5 Based on the existing EDL, a National Formulary (BNF) shall be developed and revised periodically to provide guidance on the use of these drugs.

10.6 All drugs shall be prescribed and dispensed by their generic name or International Non-proprietary Name (INN) only.

10.7 Prescribing and dispensing practices shall be monitored at appropriate interval to assess the extent of RDU.

10.7 Hospital Therapeutic Committees (HTC) shall be established in all functional hospitals to review drug utilization and to promote RDU.

11.0 DISPOSAL OF DRUGS

Improper disposal of unwanted and expired drugs can cause health and environment hazards and therefore must be disposed off safely.

11.1 Expired and all those drugs which need to be disposed off shall be done in line with the prevailing regulations and procedures.

12.0 PHARMACOVIGILANCE

Although medicines are useful to alleviate human illness, all medicines are not completely safe. Therefore, pharmacovigilance is necessary to safeguard the public from possible adverse drug reactions (ADR) and prevent the cause of false public alarm and misinterpretation.

12.1 Pharmacovigilance centres shall be established to monitor adverse drugs reactions and events.

12.2 Pharmacovigilance centres shall monitor patient safety by collecting Adverse Drug Reactions and events and other drug related problems like substandard drugs, counterfeit drugs, inappropriate use, medication error, etc. from various health professionals/ health workers.

12.2 All ADR reports and other drug related problems shall be properly compiled, reviewed and necessary preventive measures shall be taken.

13.0 INTELLECTUAL PROPERTY RIGHTS, GLOBAL TRADE AND PHARMACEUTICALS

In the modern era of globalization, there are a number of international treaties and conventions related to trade. It is important to understand and study the risks and benefits of such treaties so as to safeguard the national interest concerning public health and ensure access to pharmaceuticals. Therefore, the Government must keep the health of the public and access to pharmaceuticals in the forefront while undertaking and signing any bilateral or international treaties related to trade in health.

13.1 The Government shall take advantage of all the flexibilities and safeguards within the TRIPS Agreement for the promotion of public health and ensuring access to pharmaceuticals.

13.2 The Ministry of Health shall collaborate with the Ministry of Trade and Industry and other relevant agencies in the area of Intellectual Property Rights in developing legal framework that enhances access to essential drugs including grant of compulsory licensing and parallel importation.

14.0 EMERGING DISEASES AND PHARMACEUTICALS

New diseases are emerging while existing diseases may pose new challenges. Such diseases usually become issues of concern when treatment is very expensive and out of reach of most of the people, or the treatment or control is simply difficult or not available at all. In order to address such challenges, appropriate intervention policy must be conceived and put in place.

14.1 The Government shall allocate adequate resources and establish a system where both the public and private sectors shall be involved to provide drugs needed to adequately treat and control emerging diseases.

14.2 When new emerging diseases with no previously known treatment are identified, the Government shall support and fund the research, development and manufacture of the drugs needed to treat such diseases.

14.3 In case of such emerging diseases, if treatment is available elsewhere, the Government shall make arrangements to procure such drugs and expertise and maintain adequate stocks of drugs till such time such diseases are no more a public health concern.

15.0 HUMAN RESOURCES

To support the successful implementation of the policy and to promote the concepts of essential drugs and rational drug use while ensuring proper management of the limited resources to promote long-term sustainability, it is necessary to develop expertise and human resources in the pharmaceutical field.

15.1 Drug management systems at all levels shall be managed by appropriately trained and skilled personnel.

15.2 Adequate number of Pharmacy professionals shall be trained by the Government to manage the Hospital Pharmacies and drug supply system in the country.

15.3 Appropriate in-service training programs shall be designed and implemented at different levels to enhance the skills and meet the emerging challenges and legal requirements.

16.0 RESEARCH AND DEVELOPMENT

Research is an important component of healthcare system. Research capacity should be built to provide a sound, scientific and reliable information that will influence and guide policy management and practice of drug use. The abundance of medicinal plants in Bhutan requires a well coordinated and intensified research program to identify and document their uses and potency in the management of disease conditions in the country.

16.1 The Government shall support areas of health research that have bearing on the National Drug Policy as well as identify and support scientific and operational research activities in the pharmaceutical sector and in traditional medicines. Operational research shall focus particularly on the following areas:

- The impact of the National Drug Policy and its core principles on the health service systems and delivery
- Problems related to prescribing and dispensing practices at different levels of the healthcare system
- The economics of drug supply, management and use
- Socio-cultural aspects of drug use, including self medication, acceptability and use of supply systems, and knowledge. Attitudes and practices of users of drugs.

16.2 The Government shall encourage the development of multidisciplinary research in areas such as medicine, pharmacy, pharmacology, medicinal chemistry and the training of research personnel in the relevant areas.

16.3 The Government shall promote collaborative research with recognized research institutions within and outside country for drug research.

16.4 Research on use of drugs shall be promoted to provide information on attitudes and beliefs that contribute to inappropriate drug use or non-use.

17.0 POLICY IMPLEMENTATION

In order to achieve the objectives of the policy it is important to confer the responsibilities to respective agencies and individuals within the Ministry of Health. The policy shall be implemented

by establishing mechanisms for coordination and collaboration. In order to measure the effectiveness of the policy, appropriate monitoring and evaluation of systems shall be instituted to identify possible problems and initiate corrective measures.

17.1 The Ministry of Health shall confer the responsibility to the Essential Drugs Program (EDP) and the Drugs, Vaccines and Equipment Division (DVED) to take the lead role in implementing this policy.

17.2 The Department of Medical Services, Ministry of Health shall be the Focal Agency for the promotion of inter and intra-sectoral collaboration and co-operation.

17.3 All pharmaceutical legislation shall be regularly reviewed to verify conformity to this policy.

17.4 The Essential Drugs Program in collaboration with Policy and Planning Division, Ministry of Health shall define and develop indicators for monitoring and evaluation of the implementation of this policy.

17.5 The indicators of National Drug Policy shall be incorporated in the Health Information Management System

17.6 Monitoring and evaluation shall take place at regular intervals but a complete external evaluation shall take place every five years.

17.7 Monitoring systems for private sector shall also be developed and implemented by the regulatory agency.

18.0 AMENDMENTS

This policy document shall be reviewed and revised at appropriate interval based on the need but at least once in every five years.

ANNEXURE A: DEFINITIONS

1. Pharmacovigilance: is the science of detection, assessment and prevention of adverse drug reactions (ADR) and drug related problems. It is concerned with the early detection of unknown Adverse Drug Reactions, and the frequency of known ADRs, and would be a major resource for ensuring the safe and rational use of medicines in Bhutan.

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

3. Rational Drug Use means that patients receive medicines appropriate for their clinical needs, in doses that meet their individual requirements for adequate period of time, and at the; lowest cost to them and their community.

4. Drug, Medicine, Medicinal product, Pharmaceutical products are terms used inter-changeably in this document and include herbal medicines and any substance included in any publication, or any substance or mixture of substances prepared, sold or represented for use in the diagnosis, treatment, mitigation or prevention of disease, disorder or abnormal physical state, or symptoms thereof, or restoring, correcting or modifying organic functions in man.

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

6. Essential Drugs are those that satisfy the health needs of the majority of the population. They should therefore be available at all times and in appropriate dosage forms. It also includes vaccines.

7. Supply Management: It would consist of selection, quantification, procurement, distribution and use of the drugs.

8. Government means the Royal Government of Bhutan.

9. Essential Drugs Concept is that use of limited number of carefully selected drugs based on agreed clinical guidelines leads to a better supply of drugs, to more rational prescribing and to lower costs.

14. Adequate financial provisions-means allocation of adequate fund to procure essential drugs both for adult and pediatrics.

15. Appropriate storage conditions- means suitable storage conditions that will keep the efficacy of the drug intact till its expiry.

ANNEXURE B: ACRONYMS

ADR	Adverse Drug Reaction
ADRM	Adverse Drug Reaction Monitoring
GMP	Good Manufacturing Practice
GCP	Good Clinical Practice
GSP	Good Storage Practice
EDP	Essential Drugs Program
HTC	Hospital Therapeutic Committee
IEC	Information, Education and Communication
INN	International Non-Proprietary Name
MoH	Ministry of Health
BNCA	Bhutan Narcotic Control Agency
NPC	National Pharmacovigilance Centre
NDC	National Drugs Committee
NDIC	National Drugs Information Centre
NDP	National Drug Policy
EDL	National Essential Drugs List
DTL	Drug Testing Laboratory
TM	Traditional Medicines
RDU	Rational Drug Use
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
DRA	Drug Regulatory Authority
QC	Quality Control
R&D	Research and Development
ITMS	Institute of Traditional Medicines and Services
HTC	Hospital therapeutic Committee