# National Drug Policy -1995

## 1. Introduction

### 1.1 Preamble

In accordance with the objectives of the National Health Policy 1991, to fulfill the commitment of Government of Nepal (GoN), to provide "health for all" and to improve and manage by establishing co-ordination among the governmental , non- governmental and private organizations involved in the activities related to drug production, import, export, storage, supply, sales, distribution, quality assessment, regulatory control, rational use and information flow, the National Drug Policy 1995 has been promulgated for implementation.

### 1.2 Definition

For the purpose of this policy, a "drug" means any substance which is intended to be used in human beings or animals for diagnosis, treatment, cure, mitigation and prevention of diseases or for promotion of health or for the destruction of micro-organisms which have caused disease or to affect the physical structure or function of a body.

## 2. Main Policy

To maintain, safeguard and promote the health of people by making the country self-reliant in drug production; ensuring the availability of safe, effective, standard, and quality drugs at affordable price in quantities sufficient to cover the need of every corner of the country; and to manage effectively all the drugs-related activities including production, import, export, storage, sale, supply and distribution.

## 3. Objectives

a) To evolve a suitable mechanism to ensure the availability of safe, effective and quality medicines at reasonable price throughout the country.
b) To adopt a well-defined and effective mechanism for procurement, transportation, sale-distribution, storage and dispensing of drugs at various levels of governmental and non governmental health institutions.
c) To supply adequate quantity of essential drugs at each level of government health institutions.
d) To include drug industries as priority sector by all concerned ministries of GoN in order to make the nation self-reliant in production of essential drugs.
e) To develop pharmacy manpower for the effective implementation of the drug policy.
f) To promote rational use of drugs and to establish a drug information system.
g) To set up a well equipped quality control laboratory with trained staff under the Ministry of Health and Population to carry out the testing, analysis and standardization of drugs.

h) To develop an appropriate system to administer and monitor uniformity in drug prices.
i) To define, promote, and regulate the quality and standards of Ayurvedic, Homeopathic, Traditional and other systems of medicine by adopting scientific approach.
j) To improve the existing infrastructure of the Department of Drug Administration (DDA) and provide sufficient qualified and trained personnel for strengthening the drug administration mechanism and effective enforcement of the Drug Act.
k) To consolidate and amend the existing Drugs Act, Rules and Regulations to facilitate effective implementation of the Drug Policy.

# 4. Policy Strategies

## 4.1 Drug Management

### 4.1.1 Selection of Essential Drugs.

The Policy aims at preparing National Lists of Essential Drugs for use in central, regional, primary health centers, and referral hospitals as well as other lists for district hospitals, health posts, sub-health posts and primary health care in accordance with WHO`s concept of essential drugs.

### 4.1.2 Procurement, storage and distributions of drugs at different health institutions.

a) The policy aims at procuring necessary drugs by accepting tenders from a list of standard manufacturers or their authorized agents and identified by GoN using a pre-qualifying process
b) Procurement of essential drugs by GoN will be made under generic names.
c) Drug related activities such as procurement, distribution, storage and dispensing at governmental as well as non-governmental institutions will be carried out by qualified pharmacy personnel.
d) In order to ensure sufficient volume of the required drugs at different health institutions, the schemes related to partial or full cost-sharing will be implemented phase-wise.
e) To apply scientific methods for maintaining quality and minimizing all possible changes of deterioration of drugs during transport and storage.
f) The mechanism of procurement and distribution of drug will be modernized to assure timely supply of drug to all health institutions.
g) The regional offices of the DDA will be established phase-wise at all five regions in the country.

## 4.2 Quality assurance and regulatory control measures

a) National Medicines Laboratory will be developed as an independent National Quality Control Laboratory and under this organizational structure Regional Drug Testing Laboratory will be set up in a phase-wise manner.

b) Drug registration will be based on scientific facts. The manufacture, import, sale and distribution of ineffective, harmful, toxic as well as irrationally combined formulations will be banned.
c) Submission of a certificate of "Good Manufacturing Practices (GMP)" issued as per WHO guideline will be made compulsory for registration of manufacturers of imported drugs.
d) The quality and standard of locally manufactured drugs will meet the standards prescribed in National Code of Drug Manufacturing Conduct similar to WHO specifications.
e) The mechanism of registration and evaluation of drug will be updated to ensure the quality of marketed products.
f) A definite custom point will be identified for entrance of imported pharmaceuticals into the country.

### 4.3 Rational drug use and its information

#### 4.3.1 Education and Training

a) To promote rational use of drugs, the health workers at all levels who are eligible to prescribe drugs, available at the health institutions will be trained regularly in "Standard Drug Treatment Schedule". The prescribers will have to adhere to the schedule allocated for the level of health care they are involved in.
b) Rational use of drugs will be promoted by involving the qualified pharmacists in the pharmacy services at all levels hospitals services and other relevant institutions.
c) Curricula for training on different aspects of drugs will be developed and training will be conducted for pharmacists and other health personnel.
d) Training modules on production technologists, quality assurance and good manufacturing practices will be developed for pharmacists involved in the production of drugs.

#### 4.3.2 Drug Information

a) GoN will effectively develop an efficient "Drug Information System" to disseminate the relevant information about proper use of drug, adverse reaction, pharmacology, toxicity, standard and efficacy etc. to all concerned through different media including publication of National Drug Formulary.
b) Nepalese Pharmacopoeia consisting of individual monographs, standards of drug materials and accessory raw materials to be used in a formulation will be brought out.
c) Non-governmental organizations will also be encouraged to participate in providing information about rational use of drugs to the public.

**4.3.3 Prudent Use of Antibiotics** (added by amendment in 2001)

a) Prevailing antibiotics used in food products, animal feeds and agriculture substances will be managed properly.
b) Supervision and monitoring on use of antibiotics will be carried out. Misuse will be controlled and proper recording system will be developed.
c) Antibiotic will be classified into different groups for prescribing purposes by medical Doctors, veterinary doctors and other health personnel.
d) GoN will constitute a national antibiotic control committee comprising of experts from human and animal health, agriculture and representation from professional organizations/councils and organizations involved in consumers right and other sectors for prudent use of antibiotic.
e) GoN will constitute a national antibiotics therapeutics advisory committee (NATAC) comprising of experts from relevant sectors to advice a prudent use of antibiotics.

## 4.4 Manpower Development

a) A Pharmaceutical Affairs Unit will be set up in the Ministry of Health and Population for effective coordination of activities pertaining to pharmaceutical development.
b) Academic institutions will be encouraged to develop pharmaceutical education both in governmental as well as in non-governmental sectors for the production of qualified pharmacy manpower required for the country.
c) Regulatory measures will be adopted to bring registration to pharmacy manpower involved in the various activities under the pharmaceutical profession.

## 4.5 National Drug Industry

a) The domestic pharmaceuticals industries will be accorded a status among national priority sectors.
b) In order to achieve self-reliance in the production of essential drugs the entrepreneurs will be encouraged to promote and establish pharmaceutical industries both in public and private sectors. The aim is to be able to produce 80% of the essential drug formulations in the coming 10 years.
c) Production of active ingredients, excipient and packaging materials will be encouraged.
d) While purchasing drugs for the public sector, first priority will be given to domestic products in accordance with the financial regulations.
e) The government will provide facilities in the importation of machineries, equipments, raw materials, excipients and packing materials required for the domestic pharmaceutical production.
f) Private sectors will also be encouraged to set up quality control laboratories for drugs to be used within the country.

### 4.6 Traditional Medicines

a) In order, to promote the drugs under Ayurvedic, Homeopathic and other systems, the production of drugs for which the formula is well documented under their recognized literature will be facilitated both at governmental and private sectors.
b) The drugs based on these formulas as well as other ingredients will be modernized into dosage form and be subjected to scientific evaluation for their safety, efficacy and quality.
c) Activities related to drugs under Ayurvedic, Homeopathic, and other systems will be developed suitably by involving qualified personnel and related technologies.
d) The Ayurvedic Department will conduct and coordinate all technical activities related to Ayurvedic drugs.

## 5. Research and Development

a) Research on the novel areas such as improved pharmaceutical technology for production of bulk drugs as well as development of the new drug delivery system will be encouraged.
b) Clinical trials of drugs will be carried out through Nepal Health Research Council at the institutions recognized by GoN.

## 6. Technical Cooperation

GoN will encourage involvement of national and international agencies for technical cooperation in areas of pharmaceutical manpower training and technology exchange.

## 7. Monitoring and Evaluation

a) GoN will constitute a committee responsible for successful and effective implementation of the Drug Policy as well as for monitoring and supervision of its implementation.
b) GoN will identify responsible sector for successful implementation of the national Drug Policy as well as develop criteria for its evaluation.