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.

Draft

National Medicines Policy – 2007

1. Introduction

National Drug Policy 1995 was promulgated by the Government of Nepal to complement National Health Policy 1991. This Policy has positive impact on development of pharmaceutical industries and gradual improvement in the pharmaceutical sectors of the country, which are evident from the following progress made in the various strategies:

- National List of Essential Drugs published in 1986 and revised in 1992, was revised in 1997 and 2002 and list was further classified for district, primary health care centre, health post, sub-health post and primary treatment level.
- In order to ensure availability of required essential medicines at different health institutions, community drug programme (cost sharing schemes) was implemented in 47 districts Health post / Sub health posts.
- Brach offices of Department of Drug Administration established in three regions of the country.
- National Medicines Laboratory was developed as National Quality Control Laboratory.
- Good Manufacturing Practices as per WHO guidelines was made compulsory for registration of medicine.
- Eight custom points were identified for the importation of drugs.
- Standard treatment schedule for Health Post and Sub Health Post was revised in 1999.
- Training on Good Manufacturing Practices was conducted.
- Drug Information Network of Nepal was established and made functional.
- Nepalese National Formulary was published in 1997.
- A Pharmaceutical Affairs Unit (named as Pharmaceutical / Quality Standard Section) established at the Ministry of Health & Population.
- Bachelor level Pharmacy education started at four Universities and Diploma (Certificate) level education started at twenty one institutes under Council for Technical Education and Vocational training (CTEVT)
- Nepal Pharmacy Council Act promulgated in 2000 and registration of pharmacy personnel started.
- The number of domestic modern medicines industries increased to 40 and are producing 215 essential drug items out of 493.
- Three quality control laboratories were established in private sector.
- Number of industries for the production of traditional medicines increased to 33.
- Evaluation of new formulations of traditional medicines on scientific basis carried out by Department of Ayurved.
- National Guidelines for Use of Pharmaceuticals for clinical trial developed by Nepal Health Research Council.
- One industry established in joint venture and another has technical collaboration with a foreign company.

- Monitoring and evaluation of progress made in implementation National Drug Policy done twice.

Since the introduction of the National Drug Policy 1995, there have been remarkable achievements in the area of pharmaceutical manufacturing, access and use of medicines. There are changes in the socio-economic sectors. Nepal has become the member of WTO. It is of utmost importance to modernize and expand Nepalese pharmaceutical sector aiming at export markets and attract the foreign investment. To keep pace with the changed circumstances it is inevitable to update the present National Drug Policy.

Thus in order to properly deal with the changes and developments taken place in the pharmaceutical sector the National Medicines Policy 2007 has been promulgated to meet the current needs of the country. The National Medicines Policy 2007 is the revision of National Drug Policy 1995 including its all the relevant and useful elements and incorporating necessary changes and developments. It addresses the aims and objectives of Nepal Health Sector Reform Programme.

The updated National Medicines Policy 2007 has been promulgated for implementation to ensure that the common people have access to the safe, effective and quality medicines at affordable price for proper healthcare with the principle of social equity by establishing coordination among governmental, non-governmental, private organization and consumer representatives involved in pharmaceutical sectors for better health outcomes.

1.1 Definition:

For the purpose of this policy a "medicine" means any substances which is intended to be used in human beings or animals and birds for diagnosis, treatment, care, mitigation and prevention of diseases or for promotion of health of the destruction of micro-organisms which have caused diseases or to affect the physical structure or function of the body. The term "medicine" includes prescription and non-prescription medicines, including complimentary health care products.

2. Main Policy:

To maintain, safeguard and promote the health of people by ensuring access to essential and other medicines at affordable prices to all irrespective of their socio-economic status or place of living; by making the country self-reliant in pharmaceutical manufacturing for human and veterinary use and to mange effectively all the pharmaceutical related activities including production, import, export, storage, supply, sales, distribution, quality assessment, regulatory control, rational use and information flow.

3. Objectives:

Among the afore-mentioned achievements there are still ample scopes and needs for further improvement in many of them. The present National Medicines Policy 2007 has been thus formulated to achieve the following objectives:

a. To evolve a suitable mechanism to ensure access to essential and other medicines at reasonable price throughout the country.
b. To strengthen system of procurement, storage, transportation and dispensing of medicines at various levels of government and non-government institutions.
c. To ensure adequate supply of essential medicines at each level of government health institutions at a price individuals and the community can afford.
d. To provide required services and facilities by including pharmaceutical industry as priority sector by all concerned ministries of the Government of Nepal.
e. To make the nation self-reliant in the production of essential medicines.
f. To regulate the importation and production of human and veterinary medicine by effective implementation of Good Manufacturing Practices norms.
g. To develop adequately trained pharmacy human resource in various areas of pharmaceutical sector for the effective implementation of the policy.
h. To ensure rational use of medicines both at prescribers and consumers level.
i. To strengthen the system of quality assurance to make quality as an essential attribute in national production and importation.
j. To develop an appropriate mechanism to monitor the price of medicine.
k. To promote Ayurvedic, Homeopathic, traditional and alternative system of medicines by adopting scientific approach.
l. To strengthen Department of Drug Administration as National Medicine Regulatory Authority (NMRA) and National Medicines Laboratory as National Control Laboratory (NCL) for the effective enforcement of the Drug Act
m. To ensure proper monitoring and reporting of Adverse Drug Reactions (ADR) for implementation of Pharmacovigilance programme.
n. To encourage collaboration among universities, research institutes and manufactures for promoting research & development activities.
o. To encourage transfer of technology by allowing contract manufacturing by foreign manufacturers with the national companies.
p. To review and reform the existing Drug related Act, Rules and Regulation to facilitate effective implementation of the medicine policy.

4. Policy Strategies:

Medicines Management:

Review of National List of Essential Medicines:

The National List of Essential Medicines will be periodically reviewed and revised for different level of healthcare facilities in accordance with the revised WHO concept of essential medicines.

Procurement, storage and distribution of medicines by public and private health institutions:

a. Procurement of medicines for all government and semi-government health institution will be made in accordance with the National List of Essential Medicines.
b. The bulk procurement of necessary medicines for government and semi-government health institution will be made by accepting tenders from list of standard manufacturers or their authorized agents identified by Government of Nepal using a prequalification process.
c. The availability of essential medicines, which could be in short supply, will be ensured by providing incentives to the local industry to manufacture these medicines.
d. Medicines supply system will be modernized and strengthened and will be managed to ensure correct orders, efficient procurement, proper packaging, storage, distribution and inventory control.
e. A system will be developed for monitoring supplier performance.
f. All the medicines procured for the government health institutions shall be monitored for quality. Companies supplying substandard medicines shall not only be required to compensate for the loss but also shall be debarred for future supplies.
g. Procurement of essential medicines by the Government of Nepal will be made under generic names.
h. Medicines related activities such as procurement, distribution, storage and dispensing at government as well as non-government institutions will be carried out by qualified pharmacy personnel.
i. Good Pharmacy Practice Guidelines will be developed and implemented in the retail pharmacy in phased (gradual) manner.
j. Further policy for issuance of pharmacy services (retail pharmacy) will be developed viewing the size of community population to be served in the catchment area or on the basis of area instead of concentration on one place.
k. Refresher courses on modern concept of Good Pharmacy Practices will be conducted in collaboration with public private concept.
l. Cost sharing schemes emphasizing community drug programme will be implemented at different health institution to ensure availability of essential medicines.
m. Efforts will be made to promote rational prescribing and use of essential medicines.
n. Substitution of Pharmaceutical products will be controlled through proper regulation and monitoring.

Quality assurance and regulatory control measures:

a. National Medicines Laboratory (NML) will be developed as an independent National Control Laboratory (NCL) and its capability for analysis of medicine shall be improved with the provision of modern equipment and trained staffs. NML will be strengthened to carry out the testing of vaccines and biological products.
b. Department of Drug Administration (DDA) will be strengthened by addition of human resources and infrastructure development to make it more efficient National Medicine Regulatory Authority (NMRA) to regulate modern, traditional and complimentary medicines for human and veterinary use, as well as allied products like nutritional supplements, cosmetics, medical devices, diagnostic agents and other health promotion products.
c. The branch offices of the Department of Drug Administration will be established to cover various parts of the country as required.
d. Registration of medicine will be based on scientific evidence. The manufacture, import, sale and distribution of ineffective, harmful, toxic as well as irrational combination formulation will be banned.
e. The mechanism of registration and evaluation of medicine will be updated to ensure the availability of quality products.
f. Advertisement of medicine will be regulated.
g. System of registration will be introduced for medicines received as donation by government or non-government organizations, taking special consideration for fast track procedure in emergency situation.
h. DDA will progressively benchmark the regulatory standards for Good Manufacturing Practices, Good Laboratory Practices and Good Pharmacy Practices with respect to international standards.
i. DDA in coordination with Nepal Health Research Council will monitor the implementation of Good Clinical Practices for clinical trial to ensure patients safety and will progressively harmonize standards for clinical testing with international practice.
j. A Pharmacovigilance programme for effective post-marketing surveillance and Adverse Drug Reaction reporting will be implemented to ensure ongoing assessment of the medicine.
k. Adequate storage and sampling facilities will be developed at the custom point to comply GMP requirements.

Rational Use of Medicine and information system:
Education and Training:

a. Public health and health education programme and other programmes relating to Rational Use of Medicine will be coordinated between government and non-government organization.
b. Issues relating to proper use of medicines will be reported accurately and responsibly by the media.
c. Rational use of medicine will be promoted through the government by coordinating and funding efforts with other agencies.

d. Rational use of medicine will be promoted by constituting Drugs and Therapeutics Committee, involving the pharmacists in the pharmacy services at all level of hospitals.
e. Different interventions including pre-service and in service training to healthcare provider and improved supervision in the healthcare system will be implemented.
f. Training modules on production technologies, quality assurance, good manufacturing practices, good pharmacy practices, good laboratory practices, good distribution practices will be developed and conducted for quality use of medicines.
g. Consumer education and awareness programme will be conducted for seeking proper healthcare.

Medicine Information

a. Medicine Information system will be strengthened to disseminate the relevant information about rational use of medicines, adverse reaction, toxicity, side effects etc to all concerned through different media. Revision of Nepalese National Formulary will be done on regular interval and Drug Bulletin of Nepal will be published regularly.
b. A more comprehensive medicine information system shall be established in each branch office of Department of Drug Administration in respect of registered drugs.
c. Code on Ethical Promotion of Medicine will be developed and implemented.
d. Nepalese Pharmacopoeia consisting of individual monographs, standards of drug material and accessory raw materials to be used in a formulation will be brought out.
e. Non-government organization will also be encouraged to participate in providing consumer medicine information for rational use of medicine to the public.
f. Media will be made responsible in delivering accurate information.

Prudent Use of Antibiotics:

a. Prevailing antibiotics use 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 record keeping system will be developed.
c. Treatment protocols for antibiotics use will be developed for different level of recognized health workers.
d. A sub committee comprising of experts from relevant sector to advice on prudent use of antibiotics will be constituted to advice the Drug Advisory Committee and Government of Nepal.

Human resource Development:

a. Academic institutions will be encouraged to conduct research and development activities and produce appropriate qualified pharmacy personnel required for the country.
b. Surveillance system of Nepal Pharmacy Council will be strengthened to ensure the production of quality human resource for pharmaceutical sector.

National Pharmaceutical Industry:

a. The domestic pharmaceutical industries will be accorded a status among national priority sectors with a view to meeting the requirements of medicine within the country and promoting their exports to other countries.
b. The national industry will be strengthened by reducing barriers to trade in pharmaceutical sector for cost effective quality production and exports of pharmaceuticals.
c. In order to promote new investment into the pharmaceutical industry and encourage the introduction of new technologies and new medicines an incentive frame works will be created.
d. Licensing for manufacture of medicine for export will be simplified to meet the regulatory requirement of importing country and facilitate the utilization of national capacity.
e. In order to encourage technology transfer and availability of newly developed drugs foreign companies will be allowed to manufacture drugs collaborating with the national industries.
f. Both local industries will be allowed to manufacture drugs under contract manufacturing arrangements at any other manufacturing plants of their choice.
g. National industries will be given incentives to produce essential medicines in order to achieve self-reliance in the production of essential medicines.
h. Production of active ingredients, excipients and packaging materials will be encouraged.
i. While purchasing medicines for the public sector, first priority will be given to national industries in accordance with the financial regulations.
j. Facilities in the private sector quality control laboratory will be strengthened to provide services and to follow the good laboratory practices.

Traditional Medicines:

a. In order to promote medicines under Ayurvedic, Homeopathic and system, the production of medicines for which the formula is well documented under the recognized literature will be encouraged both at governmental and private sectors. The medicines based on these formula as well as other ingredients will be modernized into dosage form and be subjected to scientific evaluation for their safety, efficacy and quality.
b. Activities related to medicines under Ayurvedic, Homeopathic and other system will be developed suitably by involving concerned qualified personnel and related technologies.

c. Quality control of herbal medicines will be strengthened by fixing appropriate institution and quality control services will be given to the herbal medicine manufacturer.
d. All the technical activities related to Ayurvedic medicines will be conducted through the co-ordination of Department of Ayurveda.

5. Research and Development:

a. Research and development in the pharmaceutical sector will be encouraged by creating conducive environment and giving incentives for research and development.
b. Clinical trials on drugs will be carried out through Nepal Health Research Council at the institutions recognized by Government of Nepal.

6. Technical Co-operation:

a. Government of Nepal will encourage involvement of national and international agencies for technical co-operation in areas of pharmaceutical manpower training and transfer of technology.
b. Government of Nepal will co-ordinate in technical co-operation for the export of medicines and harmonization of international standards.
c. Technology Transfer between national industries as well as Universities and Industries will be encouraged and facilitated.

7. Implementation Plan:

a. For implementation of this policy, implementation plan shall be prepared and revised every five years on the basis of current situation analysis.
b. The implementation plan shall identify the basic problems and measures to be taken; the targets to be achieved in quantitative terms in a specified time and prepare an estimate of the resources needed to implement the plan and identify the sources of funding and support.

8. Monitoring and Evaluation:

The committee constituted by Government of Nepal will be given full responsibility for monitoring and evaluation of implementation of this policy.