

Regulatory Aspects of Herbal Medicines in Nepal

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National Drug Policy

Relating to Herbal & Traditional Medicines

Objective:

To define, promote and regulate the standards of Ayurvedic, Homeopathic, Traditional and other system of medicines by adopting scientific approach.

Policy Strategies:

- ▶ In order to promote the drugs under Ayurvedic, Homeopathic, Traditional and other system of medicines, the production of drugs for which the formula is well documented under their recognized literatures will be facilitated both at governmental and private sectors.

The drugs based on these formulas as well as other ingredients will be modernized into dosage forms and be subjected to scientific evaluation for their safety, efficacy and quality.

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▶ Activities related to drugs under Ayurvedic, Homeopathic, Traditional and other system of medicines will be developed suitably involving qualified personnel and related technologist.

▶ The Ayurvedic department will conduct and co-ordinate all technical activities related to Ayurvedic drugs.

Regulations:

▶ **Governing Act:** Drug Act 1978

▶ **National Authority for Drug Control:** Department of Drug Administration (DDA), Government of Nepal, Ministry of Health and Population is National Regulatory Authority (NRA)

▶ **National Reference Laboratory:** National Medicines Laboratory (NML) is the principal body of Government of Nepal for scientific research, testing and analysis of drug.

Relevant Drug Regulations:

- ▶ Drug Registration Regulation (1989) – Production, Export/Import
- ▶ Drug Consultative Council and Drug Advisory Committee Regulation (1980)
- ▶ Drug Enquiry and Inspection Regulation 1980
- ▶ Drug Standard Regulation 1983
- ▶ Drug Manufacturing Code (1986)

Drug Registration Requirements:

Domestic Products

- ▶ Obtaining the letter of recommendation for the establishment of drug industries
- ▶ Obtaining the product license
- ▶ Registration for sale/distribution of products (National Guidelines for GMP)

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Imported Products

- ▶ Registration of imported product for sale and distribution of product
- ▶ Obtaining the letter of recommendation for export-import of drugs (WHO GMP Guidelines)

Documents Required for Registration of Foreign Manufacturing Company:

- An application by the company for the company registration in prescribed form
- Letter of authority to the importer (Registered with DDA) issued by the responsible person of the company
- Site Master File (as per PICS guidelines or guidelines provided by Department of Drug Administration, Nepal)
- Up-to-date manufacturing license issued by National Regulatory Authority (NRA)

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- List of products intended to be registered
- Letter of warranty (in format provided by Department of Drug Administration, Nepal)
- Latest GMP internal audit report
- Photocopy of Registration of Nepalese Importer (Wholesaler)
- A complete set of documents for at least one product needed for product registration as prescribed.

Documents Required for Registration of Medical Products:

- ▶ Application for product registration in prescribed form.
- ▶ Application for product import recommendation letter in the prescribed form.
- ▶ Attested copy of Valid Certificate of Pharmaceutical Products (CPP) as recommended by WHO (Attested by National Regulatory Authority or Notary Public).
- ▶ Detail formulation including recipients, color, flavor etc.

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- ▶ Product specification
- ▶ Methods of analysis
- ▶ Samples of the product (2-unit packs), labels and cartoon
- ▶ Analytical report from own lab and from any of the laboratories for the same batch
- ▶ Government laboratory of the exporting country or Nepal (Nepalese laboratories)
(approved by Government of Nepal.

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Note:

- ▶ Listed for the inspection of manufacturing site
- ▶ If satisfied with manufacturer about GMP implementation status -
 - ▶ Registration of the manufacturer
 - ▶ Process for the product registration of each medicine.

Registration Fees:

SITE INSPECTION:

SAARC Countries:	USD 1500
Other than SAARC Countries	USD 2500

REGISTRATION OF MANUFACTURER:

SAARC Countries	NRs. 50000
Other than SAARC Countries	NRs. 80000

PRODUCT:

Import Registration	NRs. 2400
Import Recommendation	NRs. 300

Some Statistics:

Number of Registered Pharmacy Outlets

Wholesalers:

Allopathy 855

Veterinary 166

Homeopathy 22

Ayurvedic/unani 82

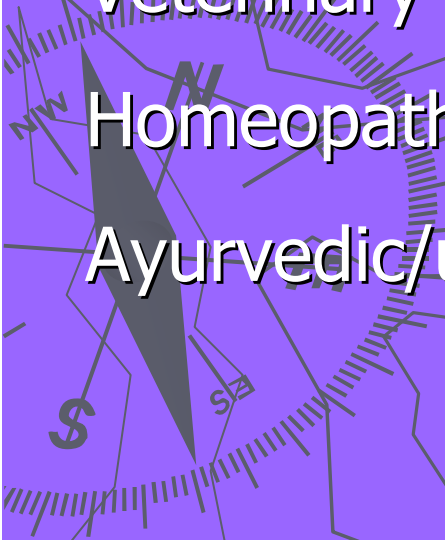
Retailers:

Allopathy 4957

Veterinary 997

Homeopathy 76

Ayurvedic/unani 273



Number of Registered Industries

Domestic Industry:

Allopathy	40
Veterinary	7
Ayurvedic/unani	32

Foreign Industry:

Allopathy	217
Veterinary	24
Ayurvedic/unani	29

Commitments for the promotion of Herbal Medicines:

- ▶ Restriction on use of unnecessary, irrational and harmful medicines
- ▶ Registration on Scientific Basis for Quality Assurance
- ▶ Amendment of Act and Regulation for export promotion in the context of WTO
- ▶ Implementation of National Guidelines on GMP (2007) for manufacturing Herbal Medicines

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- ▶ Rationalize use of Multi Ingredients in Herbal Medicines
- ▶ Developing Clinical Trial Protocol for Curing Specific Diseases by Herbal Medicines
- ▶ Establishing Centre for Ayurvedic Drug Research

Opportunities:

➤ SAARC Region Rich in Plant Resources

➤ Many examples on use of Herbal Medicines since it's Part of Cultural Heritage in the Region

➤ Many old testaments and literatures available on herbal medicines in the region.

➤ Globally more & more people getting attracted towards use of herbal medicines

Challenges:

- ▶ Developing the herbal medicaments on scientific basis.
- ▶ Quality Control and Quality Assurance techniques
- ▶ Counterfeit & substandard TM medicines in the market
- ▶ Many commercial TM formulations in the market.



Constraints:

- ▶ Resource constraints for the research activities
- ▶ More Research centers required
- ▶ More Expertise required
- ▶ Inadequate techniques for QC monitoring

Actions to be taken:

- ▶ Regional coordination / co-operations/
Networking for the research activities
- ▶ Developing joint monographs
- ▶ Developing quality control techniques
- ▶ Regional/Domestic market surveillance
for counterfeit & substandard TM
medicines and ADRs.

The background of the slide is a purple topographic map with white contour lines. In the bottom-left corner, there is a compass rose with a dark grey arrow pointing towards the top-left. The cardinal directions are labeled: 'N' for North, 'NE' for Northeast, 'E' for East, and 'S' for South. The text 'Thank You' is centered in the upper half of the map.

Thank You

For more information:
www.dda.gov.np