Request for Comments / Suggestions

DRAFT GUIDELINES OF NATIONAL RAW DRUG REPOSITORY AND REGIONAL RAW DRUG REPOSITORIES

National Medicinal Plant Board (NMPB), Ministry of AYUSH has initiated a process for the development of a National Raw Drug Repository (NRDR) and region based Regional Raw Drug Repositories (RRDR) in respect of raw drugs being used in the ASU&H systems of medicine.

The key objectives of establishing these repositories are to:

1. Act as accredited reference library for authentication of raw drugs.
2. Establish standard protocols and keys for authentication of raw drug used in the herbal industry.
3. Act as educational centre for creating general awareness about the raw drugs.

The Draft guideline covering above mentioned objective has been prepared by NMPB. NMPB is seeking any comments / suggestions from stakeholders to further update the draft guideline.

Any Comments / Suggestions on Draft Guideline from stakeholders will be highly welcomed.

DRAFT
Guideline for National Raw Drug Repository (NRDR) and Regional Raw Drug Repository (RRDR)

INTRODUCTION

National Medicinal Plant Board (NMPB), Ministry of AYUSH has initiated a process for the development of a National Raw Drug Repository (NRDR) and region based Regional Raw Drug Repositories (RRDR) in respect of raw drugs being used in the ASU&H systems of medicine.

The key objectives of establishing these repositories are to:

1. Act as accredited reference library for authentication of raw drugs.
2. Establish standard protocols and keys for authentication of raw drug used in the herbal industry.
3. Act as educational centre for creating general awareness about the raw drugs.

The activities in the repository shall be focused on the following:

1. Collection compilation, cataloging and documentation (including digitization) of information on raw drugs that are used in the traditional systems of medicine (ASU&H) and preparation of comprehensive monographs thereof.
2. Collection of plants and raw drug samples and preserving them with label for future reference and display in museum.
3. Digital Data Base: Plants and their parts are identified, named interrelate, and in detailed studies of particular groups of plants how they differ from each other
4. Providing authenticated reference samples of raw drug to the users.
5. Development of manuals with identification keys for identifications of raw drugs.
6. Testing of raw drugs for pesticide residue, aflatoxins, heavy metals, and microbial loads, etc.

NEED FOR NRDR & RRDR

The increased awareness about the uses and benefits of herbal medicines has led to high demand of quality medicinal plant resources. The trade of raw drugs is also poised for further increase due to the global growth of the herbal sector and due to that more plant species that are likely to enter commercial trade in the coming years.

The trade in medicinal plants, botanical drug products and raw materials is growing at an annual growth rate between 5 and 15% as per the World Bank reports. In India itself, there are nearly 9,500 registered herbal industries and a number of unregistered cottage-level herbal units which depend upon the continuous supply of medicinal plants for manufacture of herbal medical formulations. Large quantities of medicinal plant resources are also consumed by traditional healers, by practitioners of Indian Systems of Medicine and by the households as part of their traditional health care practices.

In India, the use of around 2400 plant species has been recorded in codified system of medicines. Out of these, 1587 species are used in Ayurveda, 1128 in Siddha, 503 in Unani, 253 in Sowa-Rigpa, 468 in Homoeopathy and 192 in Western System of medicine.

A nation-wide study on demand and supply of medicinal plants in India, commissioned by NMPB to FRLHT in 2006, has enlisted 960 medicinal plant species, belonging to 575 genera spread across 169 families, in trade. Out of these 960 species, 688 are part of the classical Materia Medica of 'Ayurveda', 501 species of 'Siddha' and 328 of the 'Unani' system, with many species overlapping across these systems. 41% of these 960 species are herbs, 26% are trees, 18% are shrubs and the remaining 15% are climbers. 81% (780) of these species in trade are sourced entirely or largely from the wild, the remaining traded species being obtained from either cultivation or imports.

The raw material sourced from the forest and other wild sources always remains a subject of questioning as to their proper identity. Therefore, a comprehensive mechanism is required for proper authentication of these raw materials used by the manufacturers for preparing the ASU&H drugs. Sometime raw drugs derived from even cultivated sources are also rejected either for their poor active constituents or for lack of authenticity.

There are several issues in the present scenario that emphasize the need for the establishment of repositories both at the National and Regional level.

a. **Resource Availability:** There are approximately 960 medicinal plant species, which form the source of botanical raw drugs that are commercially traded in the country. These plants are sourced from forests, roadsides, wastelands and a small proportion is cultivated or imported. It is estimated that a jus about 20% of the total supply of medicinal plants comes from cultivation with the remaining 80% being collected from forests and roadsides, usually in an unsustainable manner. The rising industrial demand and uncontrolled exploitation has caused wild populations of many of these species to come under the Red List categories.

b. **Poor Quality of Raw Materials**: Most of the adverse drug reactions to phyto- medicines and toxicity could be attributed mainly due to contamination or substitution of the plant material, contaminants most likely to be found in medicinal herbs are heavy metals, microorganisms, pesticides, herbicides and radioactive isotopes. These contaminants cannot be excluded completely but may be significantly reduced by proper cultivation and harvesting. Any one of the factors - collection, preparation, dispensing, packaging and dosage can be the cause of toxicity. This leads to low credibility and reliability in the minds of the users.

c. **Traceability:** Lack of traceability of raw materials is a great inhabitant for exports of raw material, value added raw material and drugs. Most companies like to understand the chain of procurement of raw materials since it gives a better idea whether the crop is organic, grown in conducive environment, etc. In the present scenario, traceability is miserably lacking and is of paramount importance.

d. Inadequate Information among collectors, traders, users and regulating agencies about the proper identity of the specific plant entitles resulting in improper use of plant materials for preparation of ASU&H formulations.

e. Lack of harmonization in use for same raw drug entity across different regions of the country with multiple trade names.

f. Lack of properly identified raw materials in use and the absence of credible database of macroscopic, microscopic & phyto-chemical profiles to serve as a reference for authentication and verification of such materials.

CONCEPT

The raw drug repositories would be developed in a phased manner and would be based on the principles of (a) work specificity to avoid duplication, and (b) strong networking. The national level National Raw Drug Repository (NRDR) would network with Regional Raw Drug Repositories (RRDR) and would be primarily engaged in developing and maintaining the central data-base of raw drugs used in the country and in undertaking focused research on the raw drugs. The Regional Raw Drug Repositories (RRDRs) would, on the other hand, play a stellar role in collection, documentation, and authentication of raw drugs collected largely from the respective agro-climatic region. The RRDRs would share and deposit one sample of each species with NRDR, and would also provide necessary samples to NRDR for research purposes.

The focus of these repositories would be on the traded raw drugs used in the ASU&H System of Medicine. The National and the Regional Raw Drug Repositories shall house 4 different sections dedicated to (a) herbarium, (b) raw drugs, (c) original references/ extracts and literature, and (d) macroscopic, microscopic, chemical and DNA profile data base along with digital herbarium on each raw drug assigned to the repository.

In the first phase, the NRDR and the RRDRs shall collect authentic and market samples and develop a database of traded medicinal plants, as enlisted in the NMPB sponsored national studies on demand and supply of medicinal plants.

TASKS OF THE NATIONAL RAW DRUG REPOSITORY (NRDR) & THE REGIONAL RAW DRUG REPOSITORIES (RRDRs)

Tasks of the NRDR & the RRDRs would include development of comprehensive database of raw materials used in ASU&H:

1. Raw drug repository
2. Herbarium- digital herbarium.
3. Reference extracts, samples of raw drugs for validation.
4. Development of profile for identification of raw drugs - macroscopic & microscopic, Chemical and DNA profiling to be developed.

DEVELOPMENT OF ONE NATIONAL REPOSITORY AND NETWORKING WITH REGIONAL REPOSITORIES

A network of one NRDR and upto 8 agro-climate region specific RRDRs shall be developed in the country. The RDRDs shall be digitally interlinked with other RDRDs and the NRDR.

Proposed regions for setting up RRDRs:

1. Himalayan Region (Uttarakhand, Himanchal Pradesh, Jammu-Kashmir)
2. Western Region (Punjab, Haryana, Delhi, Rajasthan, Gujrat)
3. Northern Region (Uttar Pradesh, Bihar, Jharkhand)
4. Central Region (Madhya Pradesh, Maharashtra, Chhattisgarh)
5. Eastern Region (West Bengal, Orissa, Sikkim)
6. North Eastern Region (Assam, Arunachal Pradesh, Meghalaya, Mizoram, Nagaland, Tripura, Manipur)
7. Southern (A) Region (Karnataka, Goa, Andhra Pradesh, Telangana)
8. Southern (B) & Island Region (Tamil Nadu, Kerala, Pondicherry, Andaman & Nicobar

The above 8 regions have been proposed mainly based on agro-climatic similarity and logistic considerations. There is, however, possibility of merging these under four larger zones by merging 1&2, 3&4, 5&6 and 7&8 proposed regions.

PROPOSED ACTIVITIES FOR NRDR

The NRDR shall carry out the following core tasks:

- Maintain raw drug samples and herbarium of traded medicinal plants sourced from the Regional Raw Drug Repositories
- Development of national museum of raw drug samples
- Processing, cataloguing and profiling of raw drugs
- Development and maintenance of a web-based image library and virtual repository
- Setting standard manuals for testing of raw materials
- Maintenance of database of macroscopic, microscopic, and chemical profiles of raw drugs & developing DNA profiles of important raw drugs
- Services like authentication, testing, training, etc.
- Keeping reference samples of extracts
- Guide and steer the activities of RRDRs
- Any other services related to raw drug

PROPOSED ACTIVITY FOR RRDR

The region-specific RRDRs shall carry out the following core tasks:

- Collection of assigned raw drug samples of traded medicinal plants with accompanying passport data; cataloguing of raw drugs and storage for easy retrieval.
- Development of herbarium of samples of traded medicinal plant species of the region
- Cataloguing and educational display of raw drugs in museum of raw drugs for creating general awareness
- Development of image library and virtual repository
- Development of identification keys based on macroscopic, microscopic, and chemical profile of raw drugs
- Providing services like authentication, testing, training etc.
- Quality certification of raw drug including testing for pesticide residue, aflatoxins, heavy metals, and microbial loads, etc.

- Act as regional raw drug reference library for research on medicinal plants
- Any other services related to raw drug

COLLECTION OF RAW MATERIALS

RRDRs shall do survey, inventorise and collect authentic raw drugs in trade, along with their substitutes and adulterants, from the critically identified plants in the field (wild and/ or cultivation). Raw drugs in trade would also be collected from market. Similarly, the RRDRs would make herbarium collection of the plant species forming source of the assigned raw drugs of the region. Each RRDR shall deposit one set of the raw drug samples and the herbarium sheets and share database with the NRDR.

PROCESSING, CATALOGUING AND PROFILING

Processing and cataloguing of data shall include all kinds of raw materials which are traded under codified ASU&H systems. Development of database of all the raw materials collected includes categorization, details of protocols for processing, accession, cataloguing and bar-coding. Custom designed software is necessary to key-in and maintain data related to different accessions for easy retrieval and reference. A brief profiling along with monograph with botanical and chemical parameters viz. taxonomical, morphological, macroscopic, microscopic, powder analysis, HPTLC shall also be developed. DNA profiling has to done ultimately over the second phase at later stages.

DEVELOPMENT OF IMAGE LIBRARY AND VIRTUAL REPOSITORY

The prime focus under this activity is to establish a virtual repository which contains all information regarding the raw materials with botanical and chemical profiling. The information created shall be uploaded on a website portal, to be specially developed and maintained by the NRDR, which could be accessed by various user groups by registering for annual or life-time membership fee. The information on the web-portal shall also possess image library of all raw materials that are traded, codified and used in folk medicine for easy identification.

RESEARCH FUNCTION OF THE REPOSITORY

The prime research function is to address the concerns about the identity and quality of the raw material being used and its sustained supplies. The research activity shall also include:

1. Field character based identification keys for critical identification of plant species forming source of prioritized raw material
2. Key Distinguishing Characters (KDC) database on morphological and anatomical characters for prioritized raw materials and their known adulterants/ substitutes/ equivalent species using techniques such as:
   - Macroscopy (organoleptic characters like color, odor, taste, fracture, etc.)
   - Microscopy (anatomy and powder microscopy)

The RRDRs would be encouraged to take the project route to add on specific research activities to the assigned core activities.

SERVICE FUNCTION OF THE NRDR & RRDRs

The service function of the repositories would include the following:

1. To act as referral center for validation and to authenticate botanical raw drugs.
2. To periodically replenish the stocks in the repository through proper mechanisms.
3. To provide authentic raw material to educational and research institution, industries, farmers at specific cost.
4. To develop education materials, appropriate to the target group (students, rural communities, traders and commercial consumers, etc.) in the form of books, pamphlets, posters, audio-visuals like CDs, etc.
5. Capacity building and awareness creation for ASU practitioners, staff of Forest Departments, farmers, wild gatherers, traders, manufactures, etc.
6. Issue Quality Certification to tested raw material.

QUALITY ANALYSIS OF RAW MATERIALS

90% of the ASU&H industry is of micro and small level with turnover of a few lakhs of rupees with no laboratory facility for quality control as per GMP (Good Manufacturing Practices) requirements of Govt. of India (Schedule T, Drugs & Cosmetic Act, 2000). The NRDR & the RRDRs shall provide paid service to such manufacturers for identification and testing of raw material used by them.

The suggested parameters for such testing include the following:

- Macroscopic, Microscopic, Powder analysis
- Physicochemical analysis: Ash values, extractive values, moisture content, density, viscosity, surface tension, optical rotation, congealing point, etc.
- Microbial analysis: Total bio-load, pathogens, etc.
- Heavy metal analysis: By AAS
- Aflatoxins analysis: B1, B2, G1, G2
- DNA barcoding (if necessary)

BENEFITS OF REPOSITORY

The proposed raw drug repositories are poised to act as one-point node for information on raw drugs used in ASU&H sector and will be of immense use in:

- Helping standardization and quality certification of raw drugs used in ASU&H.
- Helping collation of information on the form in which the raw drugs are usually traded; time, season and maturity stage for collection; habitat; practices of post-harvest handling, and classical methods of harvesting and processing, etc.
- Acting as global referral library along with data base of information.
- Creating awareness and capacity building of various stakeholders in respect of good harvest and post-harvest handling practices for quality of end products and maximum returns to gatherers.
- Authentication of raw materials used by herbal industry and under export.
- Acting as an accredited educational center for creating awareness about India's medical traditions at various forums nationally and internationally
- Dissemination of information through print media and electronic media/ web to the practitioners, manufacturers, students, farmers, community at large.
- Development of passport data for easy export.

ELIGIBILITY CRITERIA FOR NRDR AND RRDRs

Research institutions, universities, and councils having (a) clear long-term mandate on research on raw drugs used in ASU&H, (b) necessary infrastructure, (c) a minimum of 5 year experience in operation and maintenance of similar nature of work, and (d) demonstrated capacity to manage the repository beyond the project period, would be eligible for applying for NRDR/ RRDRs. The EOI route would be followed for selecting the appropriate organizations for developing RRDRs.

TIME FRAME

The time frame for first phase of development of the NRDR and RRDRs will be five years from the date of sanction of the project.

SUSTAINABLITY

The selected organization would allocate necessary budget and manpower resources to the management of repository beyond project period. The repositories would also maintain a revolving fund created out of the revenue received from the services provided.

STEERING & MONITORING MECHANISM

A national level committee of experts on the subject would be set up to guide, steer and monitor the progress of establishment of raw drug repositories at the national and regional levels.