

Development of Sowa Rigpa in Bhutan through Research

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MENJONG SORIG
PHARMACEUTICALS

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Historical Background

- Bhutan hosts two categories of traditional medical systems:
 - The local healing system based on oral tradition and includes shamanism, herbalist and the pre-Buddhists (Bons) practitioners.
 - Sowa Rigpa based codified/formalized medical system.
- Sowa Rigpa was taught by Lord Buddha in the form of Medicine Buddha 2500 years ago.
- In the 8th century, Guru Rinpoche brought this teaching to Bhutan.
- Became prominent since 1616 during Zhabdrung Ngawang Namgyal.

Development Milestone

- 1967 Formally recognized by the Royal Government on the command of His Majesty the Third King of Bhutan.
- 1968 Indigenous Medicine Dispensary was established in Dechencholing, Thimphu.
- 1971 Three year Diploma Training program for Menpa started as on-the-job training.
- 1978 Five years Bachelors degree program for Drungtsho started as per the Royal command of His Majesty the Fourth King of Bhutan.
- 1979 Dispensary upgraded as National Indigenous Medicine Hospital.
- 1982 Mechanized Traditional medicine production started with WHO support.
- 1988 National Indigenous Hospital was upgraded as National Institute of Traditional Medicine (NITM).
- 1998 NITM upgraded as Institute of Traditional Medicine Services with three functional Units – NITM, National Traditional Medicine Hospital and Pharmaceutical and Research Unit.

Development Milestone

- 2013 Royal Government of Bhutan approved the status of Department of Traditional Medicine Services (DTMS) .
- 2016 Designation of NTMH as Teaching Hospital.
- 2017 Master Degree program in Sowa Rigpa science through research mode
- 2017 Menjong Sorig Pharmaceuticals (MSP) corporatized as wholly owned State Enterprise.
- 2017 Faculty of Traditional Medicine received Certificate of Accreditation from Bhutan Accreditation Council.

Mandates of TM Sector

- Design and develop policies, and ethical and professional standards for safety and efficacy of traditional health care services.
- Strengthen R&D for evidence-based traditional medicine services.
- Enrich TM through research on local, spiritual healing and ethno-medical practices.
- Develop and build leadership in research.
- Promote the development of infrastructure and environment for research on traditional medicines/medical practices/new product development through training of researchers and traditional practitioners on appropriate research methodologies.

TM Education System

- The Faculty of Traditional Medicine (FoTM) under the Khesar Gyalpo University of Medical Sciences of Bhutan is responsible for the development of human resources required for the delivery of traditional medicine services in the country.
- Faculty offers following university validated & Bhutan Medical and Health Council recognized programs:
 - 5 years Bachelor degree program in Traditional Medicine.
 - 3 years Diploma programs in Traditional Medicine and Integrated Sorig Pharmacy.
 - 2 years Master (Research) degree program in Traditional medicine.

TM in Bhutan's health system

- The BTM is considered as one of the most sustainable methods of health care delivery as both the medicines and human resources are developed within the country.
- The BTM not only adds dimension to the nation's health care system but also provides an alternative choice of service.
- TM sector caters to about 23.4% of the population from 66 TM Units/Hospital (Annual Health Bulletin 2017).

Special features of TM in Bhutan

- TM is fully integrated with the national health care delivery system.
- Traditional medicine services follow the same health plans and policy of the Ministry of Health.
- Traditional Physicians are at par with modern doctors in terms of civil service grades & entitlements.
- Mutual understanding of both the systems by different practitioners.
- District TM Units are directly under the administrative control of district health sector.
- Cross referral of patients between the 2 systems.
- Alternative choice of treatment to people.
- All Traditional Medicine are regulated & registered with Drug Regulatory Authority.
- Role is culturally and socially significant.

Reach of TM Services

National Traditional Medicine Hospital	1
No. of TM units at Regional Hospital	2
No. of TM units at district level	17
Number of TM units at sub-district level	10
Number of TM Units at Basic Health Unit level	36
Total	66

Range of Services

- Out Patient Department
- Therapies
 - Steam bath
 - Herbal Bath
 - Affusion / hydrotherapy
 - Gold & silver needle
 - Cupping
 - Moxibustion
 - Localized steam
 - Massage
 - Hot compression
 - Blood letting
- Five alimental therapy or Lay-nga OPD & In-patient services

Policy Framework

- The Medicines Act of the Kingdom of Bhutan 2003
- National Drug Policy 2007
- The Constitution of the Kingdom of Bhutan, 2008
- National Health Policy, 2011
- Economic Development Policy of the Kingdom of Bhutan, 2010 & 2016.
- National Strategic Plan for Traditional Medicine (2017 - 2023).

Why Research is important?

- Find answer to questions on efficacy, quality and safety posed by regulatory bodies.
- Evidence-based documentation.
- Preserve traditional knowledge.
- Ensure sustainability and continuity.
- Reap potential economic benefits.
- Discover new remedies for emerging diseases.

Enabling Conditions

- Established Research & R&D laboratory.
- Traditional Medicine Research Advisory Committee.
- Capacity building in GCP, Operational research, etc.
- Master degree program in Research
- Bhutan Health Journal
- Menjog Sorig Journal

Resource base for Research

- 2990 different types of raw materials are known for use in the manufacture of Sowa Rigpa Medicine.
- About 600 medicinal plant species have been identified in Bhutan.
- Currently only 250-300 ingredients are in use
 - 15 - 20 MT annually
- The main resource base around 90% is medicinal plant.
- About 85% of raw materials requirements are sourced within the country.

Sowa Rigpa Research in Bhutan

- Initiated in 1990 under DISVI (Italian NGO) Project.
- Further streamlined in 1998 under PRU.
- Initial activities focused in production.
- Basic facilities set up.
- Inadequate manpower with required skills and knowledge.
- Still in its infancy.

Major Role of MSPCL

- Research and development activities.
- Screen traditional medicines and medicinal plants ingredients for active therapeutic compounds – 11 HAMP.
- Resource mapping for alternate sources and cultivation trials – 11 areas and 30 species.

Dosage Forms development

- Medicine is produced using modern science and technology based on principles of GMP but not forgetting its roots (Sowa Rigpa) and sanctity of the past, a tested knowledge and medical system.
- Currently 134 products that constitute as National Essential Traditional Medicine and 19 additional health promoting herbal products produced in various dosage forms:

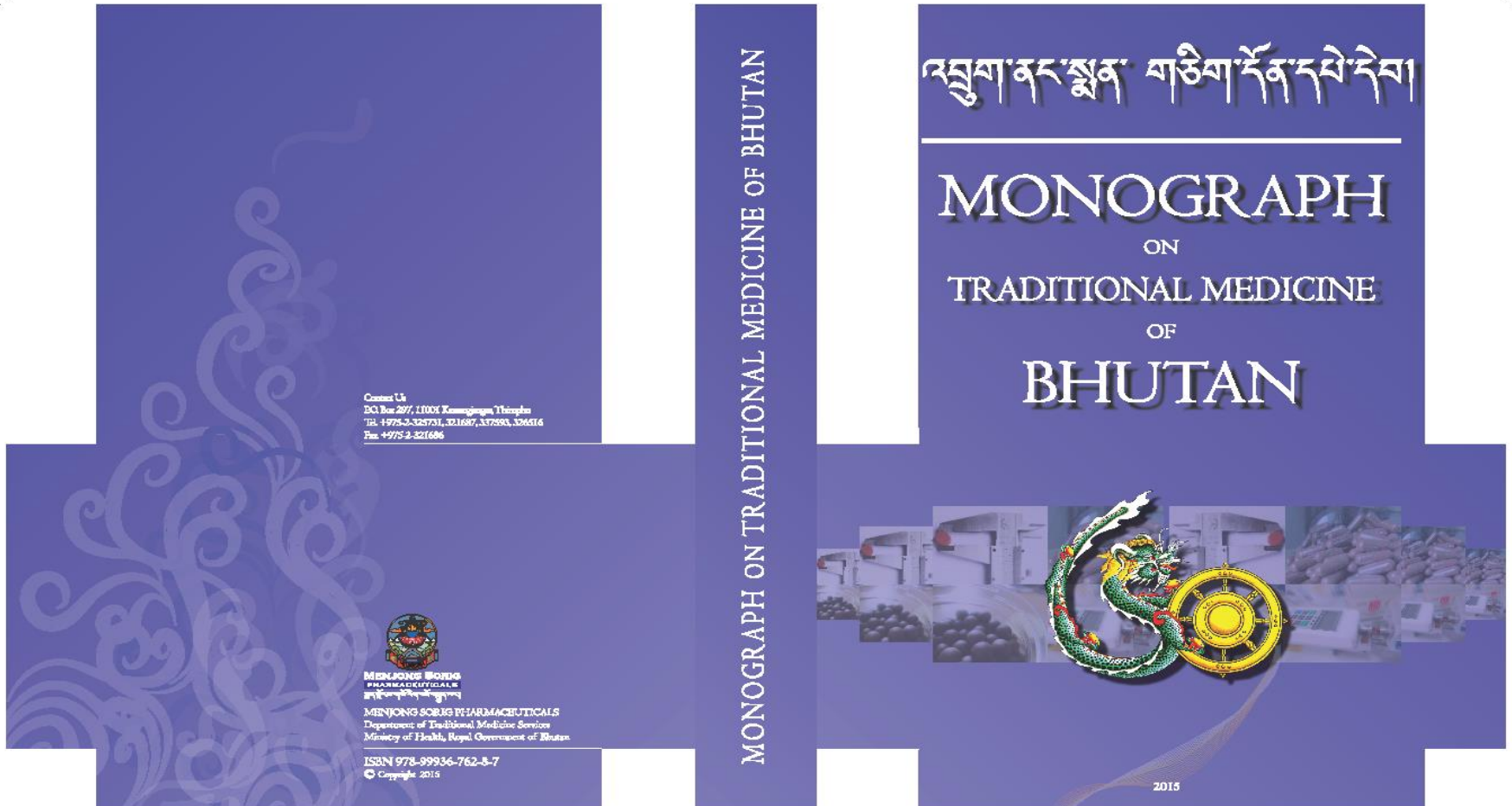
Capsule	32		Ointment	5
Pill	31		Drops	3
Tablet	28		Syrups	2
Powder	9		Bath Mixture	1
Teas/Thang	3		Paste	1

QA, Production & QC Systems

In order to standardize and strengthen production of safe and quality TM, following systems/guidelines are developed:

- Monograph on Traditional Medicine Formulations – 116 products.
- Pre-processing methods for raw materials – 33 ingredients.
- Test Methods for quality control of raw materials.
- Monograph on medicinal plants of Bhutan – 40 HAMP 2 volumes
- Monograph on Previous minerals and metals – 227
- Coding and Standardization of Sowa Rigpa and botanical nomenclature - 300 medicinal plants.
- Herbarium specimens – 116 HAMP & 101 LAMP.
- An Illustrated Guide books on High and Low Altitude Medicinal Plants of Bhutan.
- Materia Medica on Low Altitude Medicinal Plants of Bhutan.
- Sorig uses of individual medicinal raw ingredients – 123 raw materials.
- Guideline for Good Collection Practices of Medicinal Plants in Bhutan.

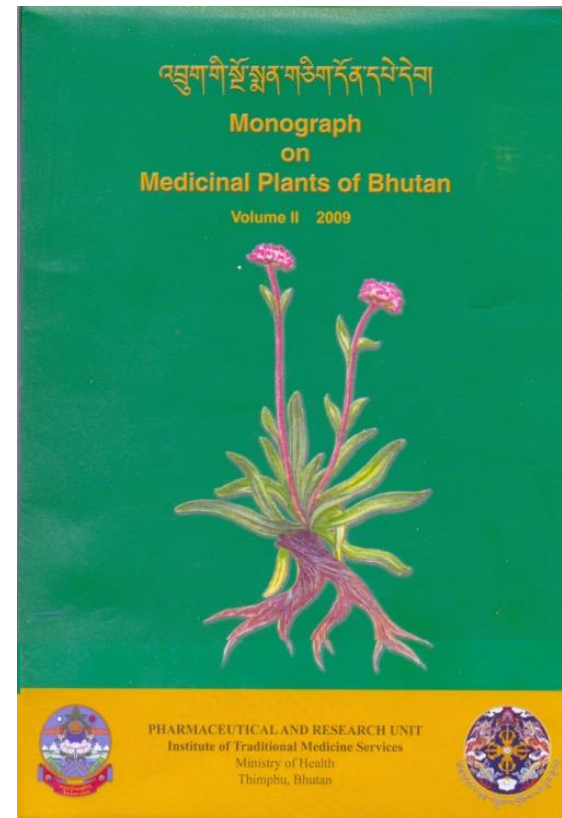
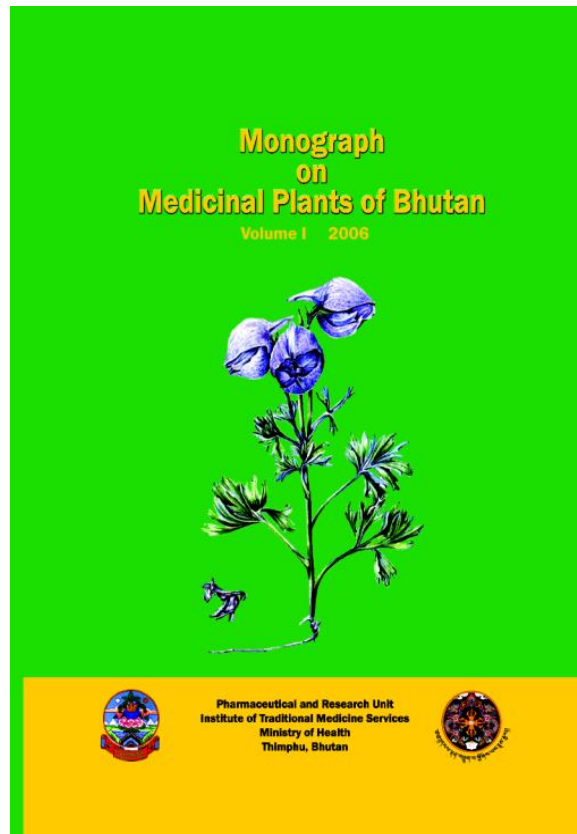
TM Monograph layout



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HAMP Monograph

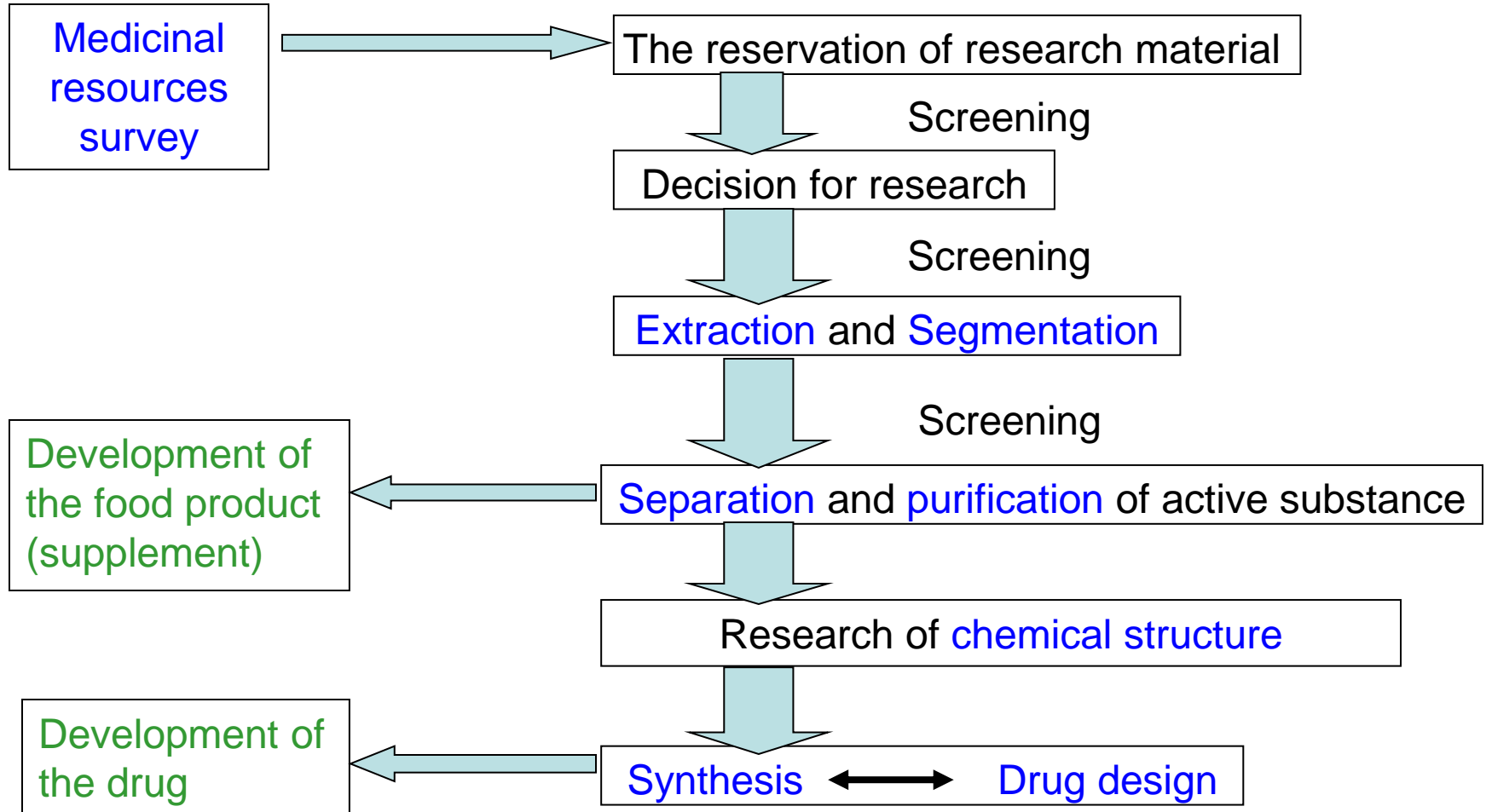


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Research Potentials

- Discovery of new drugs through understanding the different mechanism of drug action and additive and synergistic effects of the multi-ingredients.
- Ethno-pharmacology
- Bio-prospecting
- Clinical trials
- Toxicity and stability studies
- Biological and agriculture research
- Research on substitution of species
- Translation of the gso-ba rig-pa texts
- Studies on ethno-medical practices
- Standardization and building quality parameters
- New product development (Sowa Rigpa proprietary medicine)
- Clinical studies on *Tshachus* (*hot springs*) and *Menchus* (*medicinal waters*)

Exploring Natural Resources



R&D Highlights

- Discovery of anti-malarial compound from high altitude medicinal plants – *Meconopsis simplicifolia*, *Aconitum Oroychryseum* & *Corydalis calliantha*.
- Patent filed for molecule isolated from *Meconopsis simplicifolia*.
- Developed new products such as cream, teas, herbal drink, essence & fragrance, oils, etc.
- Antimicrobial activity study of Sowa Rigpa formulations.
- Study on knee osteoarthritis, migraine, ringworm, etc.

Ongoing Research Efforts

- Developing monographs on high altitude medicinal plants and new medicines.
- Resource mapping for alternate sources and cultivation trials.
- Surveying, Mapping and Database for Medicinal plants of Bhutan.
- Herbarium development
- Documenting and developing registry for local and spiritual healing practices.
- Digitizing ancient Traditional medicine artifacts.
- Digitizing formulary composition abstracts.
- Translating ancient text into national language.

Challenges

- Complexity of method (s) of study.
- Complexity in building quality parameters and the regulatory authorities introducing stringent regulatory mechanisms.
- Limited/lack of adequate infrastructure/facilities within the Country.
- Lack of Technical expertise and investment in R&D.
- Limited scope for in-vivo studies.
- IPR related issues – process and costs.
- Uncertainty in toxicity studies.
- High risk of contamination.
- Risk in bio-prospecting.

But all said and done ...

Research is hope for the future

- bridging gap between past and present
- using ancient wisdom with modern technology.
- marrying science with religion/philosophy.
- ensuring safety and efficacy of treatment.
- ensuring sustainability – healthcare services and natural resources.
- saving traditional Sowa Rigpa knowledge and handing over to the future generations.

Research is the Way Forward

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The Way Forward

- Strategic planning
- Resource Mobilization
- Human resource development
- Up-gradation of facilities
- Improve documentation
- Build linkages and collaboration. Transfer of technology.
- Recognition and Patenting.

TASHI DELEK

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