1. INTRODUCTION

Bhutan is known as sMen-jhong rGyal-khab, meaning the land of medicinal plants. Above the Indian plains, the country gradually rises from the luxurious jungle of the foothills, about 150 meters above sea level to the solitude of the snow-capped peaks, culminating at more than 7500 meters above sea level (ITMS, 2005).

The small Himalayan kingdom of Bhutan is situated between India and China and is totally landlocked. The total land area is only 38,394 square kilometers and the population in 2006 was estimated at 634,982 with GNP per capita income of USD 1400/- (NSB, 2006) The country has a forest cover of over 72% attributing to the presence of a rich biological diversity. These forests are home to several endangered species of flora and fauna harbouring over 7000 species of plants, 165 species of mammals and 700 species of birds (MOA, 2003). Bhutan is regarded as one of the ten global hot spots in terms of biodiversity and environmental conservation. Apart from its rich biodiversity and natural resources, Bhutan has a rich cultural heritage which is still characterised by a certain amount of traditional features like traditional medicine.

Fig. 1: Map of Bhutan

This difference in altitude, bringing almost tropical vegetation right to the vases of glaciers, has made it possible for plants of extremely different climatic and environmental conditions to grow in the same country. Tropical and subtropical forests are found in the south. Temperate and even Mediterranean plants flourish in the valleys, and very rare specimens grow up to 5000 meters. To date, more than 600 medicinal plants have been identified in Bhutan and at least 300 of these are commonly used by practitioners in the country for preparing medicines (ITMS, 2005).

The Bhutanese traditional medical system goes well beyond the notion of medicine in the narrow Western sense. It forms part of a whole - blending culture and tradition in which Buddhism is the prevailing influence. Health and spirituality are inseparable and together they reveal the true origins of any sickness. The art of healing is therefore a dimension of the sacred.
Health Indicators

As a result of the effective implementation of successive five-year plans by the Royal Government, Bhutan has achieved significant human development during the last four decades as highlighted by the national health surveys.

Table 1: Selected health indicators of Bhutan, 1984-2005

<table>
<thead>
<tr>
<th>Health Indicators</th>
<th>1984</th>
<th>1994</th>
<th>2000</th>
<th>2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infant mortality rate (per 1000)</td>
<td>102.8</td>
<td>70.7</td>
<td>60.5</td>
<td>40</td>
</tr>
<tr>
<td>Under –five mortality rate (per 1000)</td>
<td>162.4</td>
<td>96.9</td>
<td>84.0</td>
<td>62</td>
</tr>
<tr>
<td>Maternal mortality rate (per 1000)</td>
<td>7.7</td>
<td>3.8</td>
<td>2.5</td>
<td>NA</td>
</tr>
<tr>
<td>Life expectancy at birth (years)</td>
<td>48.0</td>
<td>66.0</td>
<td>66.3</td>
<td>66.3</td>
</tr>
<tr>
<td>Gross fertility rate (%)</td>
<td>169.6</td>
<td>172.7</td>
<td>142.7</td>
<td>NA</td>
</tr>
<tr>
<td>Annual population growth rate (%)</td>
<td>2.6</td>
<td>3.1</td>
<td>2.5</td>
<td>1.3</td>
</tr>
<tr>
<td>Health services coverage (%)</td>
<td>-</td>
<td>90%</td>
<td>+ 90%</td>
<td>+90%</td>
</tr>
<tr>
<td>Immunization coverage (5)</td>
<td>80%</td>
<td>90%</td>
<td>+ 90%</td>
<td>+90%</td>
</tr>
</tbody>
</table>

Source: Annual Health Bulletins,  
NA- not available

Most of the common diseases found in Bhutan are related to poor hygiene and sanitation, and are easily preventable. According to 2006 health data, the top ten causes of morbidity are as follows: 1) common cold, 2) skin infections, 3) diarrhea and dysentery, 4) peptic ulcer, 5) acute pharyngitis and tonsillitis, 6) other diseases of skin and subcutaneous tissue, 7) musculoskeletal disorders excluding arthritis and arthrosis, 8) other diseases of digestive system, 9) other respiratory and nose diseases, and 10) conjunctivitis (AHC, 2006).

Today non communicable diseases are not among the top 10 diseases. Nevertheless, it is emerging at an alarming rate, an unwelcome addition to the infectious diseases which is still of grave concern. Among the common non communicable diseases are musculoskeletal disorders, hypertension, diabetes, alcohol liver diseases and cancers. At the same time health is affected by number of factors over which an individual has very little control like socio-economic conditions and information and communication advancement etc.

As of December 2006, there were 29 hospitals, 176 basic health units, 406 outreach clinics and 1133 hospital beds for the provision of primary health care. Regarding human resources for health, there were 148 doctors, 21 technologists, 545 nurses, 480 health workers and 478 technicians, 40 Drungtshos and 58 sMenpas providing free health care services according to the government policy (AHC, 2006).

Expenditure in the health sector continues to increase with average growth rate of 18%. The high commitment to the health sector was reflected in an average allocation of 10-13% of government expenditure for health (MOH, 10th Plan Document).
1.1. Traditional System of Medicine Development: Historical Perspectives

A. Historical Perspective

It is believed that at the beginning of time, the art of healing was a prerogative of the gods and it was not until Kashiraja Dewadas, an ancient Indian King who went to heaven to learn medicine from them, that it could be offered to man as a means to fight suffering. He taught his progeny, the principles and the practice of healing and this knowledge was spread and perpetuated as an oral tradition, until Lord Buddha appeared and gave specific written teachings on medicine. These were recorded in Sanskrit and became part of early Buddhist sacred writings.

Fig 2: Medicine Buddha

It was only after reaching enlightenment and understanding of the ties binding man to this world, and the means of freeing himself from them, that Buddha could define the origin of pain, discover the way to eliminate it and teach an effective theory. It is therefore, not surprising that he became the most outstanding healer. Through his own experience he discovered the art of healing old age, sickness and death.

The divinity of Medicine Buddha, Sangay sMen-lha is represented in traditional iconography with a blue body. Ancient teachings tell us that merely seeing an image of the Medicine Buddha, or hearing the name of the Medicine Buddha can confer inconceivable benefits.

The original teachings of this system are generally attributed to the Lord Buddha, who is said to have taught the root of this tradition in the manifestation of Medicine Buddha. The essential teachings are touched upon widely in the rGud-bZhi or the Four Tantras. The historical Buddha taught the medical text Dri-med-Rig (Immaculate Lineage) simultaneously with the first turning of the Wheel of Dharma at Sarnath on Four Noble Truth. At Jagoe-Phung-po-Ri (Vulture’s Peak) he taught the text gSo-dpyad-bumpa (one hundred thousand verses of healing)

The Buddha with compassion understands the mind, nature, sense organs whether sharp or dull etc, and the secrets of sentient beings and fulfils their desires accordingly. Certainly by seeing the real Buddha, but even by merely hearing his name, one is protected from the sufferings of the lower realms and the three mental poisons (desire, hatred and close mindedness) are eliminated along with their results, the diseases of wind, bile and phlegm. So it is important to pay a special homage to Medicinal Buddha called ‘Be-dur-ya, the King of Rays’ while practicing traditional medicine.

His radiant body is azure blue. His left hand is in the meditation mudra and holds a begging bowl, full of long life nectar in his lap. As a sign that he gives protection from illness, his
right hand is outstretched in the gesture of giving and holds the great medicine, the ‘Myrobalan’ plant (Aa-Ru-Ra). The following verses or mantra if recited many times can bring immeasurable benefit in the process of healing.

“Oh Namo Bhaga-wate Bekhan-jeye Guru Bedur-ya Trabha Rajaya Tatha-gataya Arahate Sama-yaka Sam Buddha-ya Taeya-tha Om Bekhan-jeye Bekhan-jeye Maha Bekhan-jeye Raja-ya Samun-gate Savaha” (Repeat the Mantra as many times as you can)

**Fig 3: Guru Rinpoche**

When Guru Rinpoche first brought Buddhism into Tibet in the eighth century, some of the early Buddhist writings in Sanskrit were translated into the Tibetan language and enlightened rulers of that country became interested in the subject. They started promoting the development of the art of healing by organizing meetings on medicine to which, they invited healers not only from the whole of Tibet and surrounding Himalayan countries but also from China, India, and the Muslim world.

It is reported that during those conferences, all the different medical systems were examined and the best practices adopted and incorporated into the newly born gSo-ba Rig-pa which was then handed down from one generation to the next. The tradition of gSo-ba Rig-pa began at the time of great Tibetan doctors including Gyu-thog "the Elder" in the eighth century, and one of his descendants, Gyu-thog "the Younger," who lived in the eleventh century. The latter made a notable contribution in spreading the celebrated Gyu'shi or "Four Medical Tantras" and its commentary, the Vai-dur-ya Ngon-po.

**Sources of gSo-ba Rig-pa Tradition in Bhutan**

Some sources state that gSo-ba Rig-pa took shape in Tibet and Bhutan subsequently in the 8th century. The medical tradition which is still practiced in Bhutan has always been characterized by the diversity of its origins. Some principles of Indian and Chinese medicines and the ancient medical practices connected with magic and religion that existed in Bonism era before the advent of Buddhism has been assimilated into the philosophy and principles of gso-ba rig-pa. However, in essence, it is based on the great principles of Buddhism and provides a comprehensive way of understanding the universe, man, and his sicknesses.

In many ancient accounts, sickness is usually attributed to demonic causes. Local gods, demons and spirits of all kinds could be considered as responsible for certain illnesses. To obtain healing, it was necessary to practice particular rituals and only monks or magicians were in a position to do so. This medical practice, thus involved much divination in the means of diagnosing and recognizing the spells causing the illness and exorcism as the way
of treating the patient. And even though medical techniques in Tibet and Bhutan developed subsequently observation, experience, study and knowledge, popular beliefs had a definite influence in the way how traditional medicine has evolved.

Buddhism teaches that the existence of phenomena and suffering (sickness, old age and death) have a single origin, namely ignorance that prevents man from reaching enlightenment. The ignorance is the origin of the three moral poisons: desire (Dod-chag), aggressiveness or hatred (Zhel-dang), and mental darkness or delusion (Ti-mug). In turn, these three moral poisons will produce the three pathogenic agents – air (rLung), bile (mKhris-pa) and phlegm (Bad-kan), which are the origin of sickness. With its overall conception of the universe and life, Buddhism is thus a way of linking medical theory to the same single source, in which sickness finds its natural place. Only knowledge, leading to Enlightenment, can free mankind from this painful existence.

gSo-ba Rig-pa in Bhutan and Physicians of this Century

When Shabdrung Ngawang Namgyal came to Bhutan in 1616, his Minister of Religion, Tenzing Drukda who was an esteemed physician, started the spread and teaching of gSo-ba Rig-pa in Bhutan (ITMS, 2002). Although there were sporadic instances of Bhutanese being sent by their patrons to study this art of medicine in Tibet before then, it was only after 1616 that gSo-ba Rig-pa was established permanently in Bhutan.

Fig 4: Shabdrung Ngawang Namgyal

Since then, the Bhutanese tradition of gSo-ba Rig-pa has developed independently of its Tibetan origins and although the basic texts used are the same, some differences in practice make it a tradition particular to the country. The specific knowledge and experience gained by the Bhutanese over the centuries are still very much alive in this medical tradition. The natural environment with its exceptionally rich flora also enabled the development of a pharmacopoeia which is very unique in the world.

The names of many Bhutanese traditional doctors of the past who excelled in their skills have remained alive in the memory of the people long after their death. Unfortunately, very little is known of the traditional doctors who practiced in Bhutan from the time of Shabdrung Ngawang Namgyal to the time of the Wangchuck dynasty. However, according to Druk Karpo by Lopon Nado, published in 1986 at Tharpaling Monastery Bumthang, the following names were mentioned as responsible for the development of gSo-ba Rig-pa in Bhutan during that period. They were: Lopon Tshering Samdrup, Ngawang Dhargyal, Chang Gyeltshen and Lopon Tshewang Namgyal

His Majesty Ugyen Wangchuck, the first King of this dynasty had at his court a personal
physician called Drungtsho Pemba who was the descendant of a family of traditional doctors and whose father, Drungtsho Gyeltshen was said to have been the personal physician to the first King's father, Jigme Namgyal. Drungtsho Gyeltshen was born near Tongsa and was trained in Tibet in the famous Lhasa Medical School of Chagpori. Drungtsho Pemba's son Drungtsho Penjore who also studied at Chagpori acquired the fame of being the best doctor in the family and was called to serve at the court of His Majesty Jigme Wangchuck, the second King of Bhutan. The above-mentioned physicians used to send raw materials to Tibet and received the prepared drugs from Chagpori. They apparently never manufactured the medicines.

Another Bhutanese physician at the court of the second King was Mahaguru, the former Gangtey Trulku's physician. Mahaguru himself was from Gangtey Gompa and trained as a doctor there. He was a very saintly man as well as a good doctor who prepared his own medicines whenever he needed to prescribe them to his patients. On His Majesty's orders, he was provided with regular rations from Wangdi Phodrang Dzong. At the age of seventy eight, he predicted and publicly announced the time and place of his death. His son stated that he died quietly and painlessly as predicted. People estimated that he died at the age of 100.

In the first half of the twentieth century, another famous physician was Drungtsho Chimi Gyeltshen. He was born in Mongar and when he turned twenty, he went to Tibet to study medicine at Chagpori. After staying there for sixteen years, during which he rose to the highest rank for a traditional physician, he came back to Bhutan at the bidding of Asbi Kenchock Wangmo, the second King's younger sister and settled near Kurtoe. Drungtsho Chime Gyeltshen died in Lhuntshi in 1966.

Drungtsho Singye Namgyal from Bumthang Lamay Goenpa studied medicine from Drungtsho Pema Namgyal in Tshurpu, western Tibet. He came back to Bhutan and practiced privately till 1983. After that he was appointed as Physician at Bumthang Hospital by the Health Department.

B. Development of Traditional Medical Services

In November 1967, His Majesty Jigme Dorji Wangchuk the third King of Bhutan commanded the Health Department to establish traditional medicine system for the welfare of Bhutanese people and to preserve its rich culture and tradition. Accordingly, an Indigenous Dispensary was opened on 28th June 1968 at Dechencholing, Thimphu. The first persons to work in the Dispensary were Drungtsho Pema Dorji and Drungtsho Sherub Jorden, both of whom were trained in Tibet. In view of their significant contributions to the development of traditional medicine services, their short biographies are given below:
Drungtsho Pema Dorji

Drungtsho Pema Dorji was born to Ugyen Tenzin and Dechen Pelden of Dreypung Khochey and Kha long choeje (local nobilities) respectively in 1936 at Phuentshocholing Goenpa in Trongsa. He began education at an early age of six under the tutelage of his grand father, Lopen Kuenzang Wangdi. At the age of 16, he traveled to Tibet to study gso-ba-rig-pa in the renowned medical college of Chag-po-ri, under the royal patronage of HRH Ashi Kencho Wangmo. After successful completion of five years of arduous study, he returned and served as a clerk in the secretariat of late His Majesty, Jigme Dorji Wangchuck, the third King of Bhutan.

It was during his tenure as a clerk, that His Majesty commanded him to institutionalize and strengthen the age-old traditional medicine system in the country, intended to benefit every sick and justifying the name: smen-jong or The Land of Medicine (an old name for Bhutan) in the winter of 1967. Accordingly, an indigenous dispensary was opened on 28th June the following year at Dechencholing under the Department of Health Services and he became the first practicing drungtsho under public sector.

When the indigenous dispensary was upgraded to National Indigenous Hospital (NIH) in 1979 and shifted to the present location at Kawa Jangsa, he became the first Superintendent of the hospital. Right from the establishment of training programme for drungtshos and a traditional medicine unit in Trashigang a year earlier, he developed new infrastructure; strengthened training curricula; improved administration and management of traditional medical services. Gradually, the services provided through traditional medicine covered the entire nation under his dynamic leadership.

In 1993 he was conferred Directorship by the Royal Government and in 1999, he received the Druk Thuksey medal on the auspicious occasion of silver jubilee coronation of the fourth Druk Gyalpo, in recognition of his dedicated service in the area of traditional medicine. Finally, after 30 years of dedicated service, he resigned from the service in 2002 as the Director emeritus.

Drungtsho Sherab Jorden

Drungtsho Sherab Jorden was born to Kuenga Norzang and Sonam Norzom in 1935 at upper Gyechu in Lhodrag, Tibet. At the age of eight, his parents enrolled him in the monastic institution of His Eminence, Namkhai Nyingpo Rinpoche, where he began his early education. He mastered all the sciences of Buddhism including grammar under the
direct observance of Lama Gyelwa Nima.

An immense desire to study gso-ba-rig-pa swept in spontaneously when he was sixteen. Astrological calculations conducted by his paternal uncle, Tra Phab Kheychog Rinpoche, favored his intention and therefore joined the medical college at Chagpori in the same year and studied under Ngawang Choedra, personal physician to the 13th Dalai Lama. Besides five years of formal training, he received specific instructions on blood letting and cautery and the complex theory of gso-ba-rig-pa at large from Ben Tshang Amchi Samten Tingzin. Teachings and empowerments that he received from revered Buddhist masters of the time greatly enriched his versatile knowledge.

At the age of 24, soon after becoming the personal physician to H.H. Namkhai Nyingpo Rinpoche, he fled the brutal Chinese occupation of Tibet via Nye Rinchen Bumpa in Kurtoe and finally arrived at the holy site of Kurje Lhakhang in Bumthang. He reassumed his practice in Bumthang after the Royal Grandmother, Ashi Phuntscho Choden Wangchuk issued a decree, permitting H.H. Namkhai Nyingpo Rinpoche and the entourage to settle in Bhutan.

He was called upon to work alongside Drungtsho Pema Dorji, in the newly established Indigenous dispensary at Dechencholing in 1968, and ever since, he applied his expertise for the welfare of patients until his resignation in 1997. In 1993, as the chair person of the Traditional Medicine Research Committee, he was a key figure in standardization and identification of the entire materia-medica employed in preparation of traditional drugs. Aside from medical practice, he was also a prolific writer. Besides writing number of manuscript on medicine he also composed beautiful poems.

After more than 30 years of service to the humanity, he has dedicated the rest of his life to prayer and meditation in the sanctuary of Hongtsho Goenpa. Even today, he finds some time to see patients during short intervals of strict religious practice.

**Development of TRM in Bhutan**

From a single Indigenous Dispensary in 1968, the traditional medical service has grown rapidly over the years to cover the entire country. By the end of 8th five year plan (2001) traditional medicine units have been established in all 20 districts hospitals as per the national health policy. Seven more TM units have been established at the sub district hospitals and basic health unit level till January 2007 on popular demand by the people.

At the national level, the Indigenous Dispensary was upgraded to National Indigenous Hospital in 1979 and shifted to the present site in Kawang Jangsa from Dechencholing. The National Indigenous Hospital was renamed as the National Institute of Traditional Medicine (NITM) in 1988. In view of the increased functions, the NITM has been upgraded as the Institute of Traditional Medicine Services (ITMS) in 1998 with three functional units as follows:

1. **National Traditional Medicine Hospital** (NTMH) is responsible for the development and provision of quality traditional medical care including different therapies.
2. **National Institute of Traditional Medicine** (NITM) is responsible for development of human resources required for the traditional medicine services.

3. **Pharmaceutical and Research Unit** (PRU) is responsible for the manufacturing and production of medicines, conducting quality control for both raw materials and finished products, carrying out research activities and marketing of the products.

The traditional medical service functions as an integral part of the national health care delivery system. It is available in all 20 districts and is housed under the same roof of district hospitals and basic health units for mutual consultation, treatment and cross referrals of patients. The traditional medical system serves as complimentary to the modern medical services and offers a choice for the patients to seek either of the services.

The main mission is to provide traditional medicine services as an alternative choice of treatment for the people of Bhutan. It is also mandated to preserve and promote the unique system of medicine that is based on rich culture and traditional through capacity building and establishing an effective system within the framework of overall national health system.

**Institute of Traditional Medicine Services (ITMS)**

**Mandate:** Development and provision of traditional medical services

**Vision:**
Centre of excellence in the design, development and promotion of traditional medical services as complimentary to the modern health care services.

**Mission:**
Provide high quality traditional medical services through development of appropriate human resources and production of safe and potent traditional medicines.

**Values:**
- Preservation of unique culture and tradition
- Efficient delivery of quality TM services
- Improving quality of life of the people
- Ensuring sustainability in traditional medical services
- Striving towards achieving the national goal of GNH

**Core Business Areas:**
1. Human Resource Development
2. Production of Traditional Medicines
3. Provision of Traditional Medical Services
4. Research and Development
Specific aims and objectives

The specific aims and objectives of traditional medicine are:

- Promote traditional medicine system in the country
- Preserve the unique culture and tradition related to medical practice
- Provide alternative medicine as complimentary to the allopathic system
- Produce medicines required by the traditional medical system
- Conduct research and quality control of medicines
- Develop human resources required for the traditional medical system
- Achieve excellence in traditional medicine services in Bhutan

Fig. 7: Organisation chart of ITMS

```
Ministry of Health
(Secretary)

Department of Medical Services
(Director General)

INSTITUTE OF TRADITIONAL MEDICINE SERVICES
(Director)

National Traditional Medicine Hospital
(Superintendent)

National Institute of Traditional Medicine
(Principal)

Pharmaceutical and Research Unit
(Head)

Medical Services

Therapy services

Drungstho & Menpa Training Programme

Pharmacy & Research Tech. Trg. Programme

In-service training Programmes

Production Section

Research and Quality Control

Marketing Section
```
Management and Administration

The ITMS is administratively under the Department of Medical Services, Ministry of Health. Although, there is separate budget line for each of the three units under ITMS, the financial management is with Administration and Finance Division (AFD) of the Ministry of Health in view of the Government policy. However, the Director of ITMS is the drawing and disbursement officer in relation to traditional medicine budget and has full authority to use the approved budget as per the delegation of financial powers by the Government.

Table 2: Approved fiscal budget for the last six years (Nu. Million)

<table>
<thead>
<tr>
<th>F. Year</th>
<th>NITM</th>
<th>NTMH</th>
<th>PRU</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002-03</td>
<td>2.119</td>
<td>0.720</td>
<td>5.005</td>
<td>0.565</td>
</tr>
<tr>
<td>2003-04</td>
<td>2.747</td>
<td>0.880</td>
<td>5.432</td>
<td>0.630</td>
</tr>
<tr>
<td>2004-05</td>
<td>3.302</td>
<td>0.250</td>
<td>5.774</td>
<td>0.100</td>
</tr>
<tr>
<td>2005-06</td>
<td>3.333</td>
<td>2.101</td>
<td>6.630</td>
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</tr>
<tr>
<td>2006-07</td>
<td>3.288</td>
<td>0.360</td>
<td>8.728</td>
<td>1.525</td>
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<tr>
<td>2007-08</td>
<td>4.388</td>
<td>0.335</td>
<td>7.784</td>
<td>1.295</td>
</tr>
</tbody>
</table>

Source: ITMS

The five year plans and annual work plans are prepared by different units in consultation with the ITMS management as per the guidelines and format provided by the Government and submitted to the Ministry of Health for incorporation the health sector plan. Once the plans are approved by the Government the activities are implemented by the ITMS based on the approved annual budget.

In order to improve coordination and collaboration among the three Units of ITMS, regular coordination meetings are held at different levels. At the apex level, there is a weekly Senior Management Team (SMT) meeting on every Monday to review the implementation status of all planned activities. At the unit level, there is a monthly staff meeting to review their individual programmes, followed by quarterly coordination meeting where all staff of ITMS attends. These meetings are considered as very important forums to ensure effective implementation of all programmes related to traditional medicine services in the country.

The director of ITMS is also a member of various committees of the Ministry of Health, Royal University of Bhutan and other related agencies. The most notable among them are Human Resource Committee, Bhutan Medical and Health Council, Academic Board, Committee of Directors, Biodiversity Management Board, Steering Committee of EU Medicinal Plants Project etc.

The Unit heads of ITMS are given full powers to plan, implement and monitor all programmes and activities related to their areas of responsibilities. The central administration provides general directions and guidance only and ensures that all planned activities are implemented effectively through regular monitoring and evaluation.
National Traditional Medicine Hospital (NTMH)

Mandate: Provision of quality traditional medical services

Vision: Service with a Humane Face and Holistic approach

Mission: To develop and provide quality traditional medical services

Values:
- Prompt and efficient service
- Safe and effective treatment
- Concern and compassion towards patients

Core Business Areas:
1. Traditional medical services
2. Therapy services
3. Operational Research
4. Management of hospital services

Fig. 8: Organization Chart of NTMH
The NTMH has 8 Drungtshos including the Medical Superintendent for the provision of traditional medical services and therapy services. As an apex hospital for traditional medicine in the country it is responsible for providing tertiary care services and act as referral centre for the district hospitals.

The NTMH provides different therapies such as cauterization with gold and silver needles, blood letting, moxabustion, herbal bath, steam bath and application, nasal irrigation, massage with medicated oils etc. whereas, at the district TM units only cauterization with gold and silver needle is provided at the moment.

Table 3: No. of Patients treated at NTMH for the last 5 years

<table>
<thead>
<tr>
<th>Year</th>
<th>New Pts.</th>
<th>Old Pts.</th>
<th>Total</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>16458</td>
<td>14426</td>
<td>30884</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>14185</td>
<td>17732</td>
<td>31917</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>15603</td>
<td>16845</td>
<td>32448</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>14215</td>
<td>18426</td>
<td>32641</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>21457</td>
<td>21689</td>
<td>43146</td>
<td></td>
</tr>
</tbody>
</table>

Source: Annual morbidity reports of NTMH

Top 10 diseases treated at NTMH in 2006:

1. Tsha-kar (Neurological problems)
2. Ya-khrag (Sinusitis)
3. Pho-ned (Ulcer and stomach disorders)
4. Bad-kan (Gastric problems)
5. Drum-bu (Arthritis and rheumatism)
6. Chuser Pak-ned (Skin diseases)
7. Khrag-rlung (Blood pressure)
8. Rim-ned (Cough and Cold)
9. Dab-drum (Chronic injuries)
10. Bad-rlung (Combination of gastric problem and pressure)

Currently, there are no in-patient services in the NTMH due to lack of infrastructure. However, in view of the need to provide intensive care and services to the patients seeking traditional medicines, and also for clinical teaching of the students of NITM, a proposal has been submitted to the Ministry of Health for establishing inpatient services in the NTMH during the 10th plan period. It would entail the construction of 20 bedded wards and related facilities like kitchen, store, and quarter for the cooks etc.

The NTMH also provide outreach services to 9 religious and meditation centres around Thimphu valley on a regular basis.

The traditional medicine is considered more effective for chronic diseases, such as sinusitis, arthritis, asthma, rheumatism, liver problems, diseases related to digestive and nervous system etc. The reason why traditional medicine is particularly good for such
chronic diseases is because of its holistic, rounded and profound approach in the treatment.

The main objectives of traditional medical services in future are to improve the quality of services through conducting operational research and case studies in relevant areas of traditional medical practices. The traditional medicine units will be established in all health facilities in the country in a phased manner as per the draft constitution of Bhutan.

**District Traditional Medicine Units**

The district TM Unit is manned by 1 Drungtsho (Traditional Physician) and 1 sMenpa (Traditional Clinical Assistant). For the benefit of rural communities, religious centres and secluded areas, an out reach services for traditional medicine is introduced in all districts where Drungtshos and sMenpas visit these places turn wise on a monthly basis.

**Table 4: Establishment of Traditional Medicine Units**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Traditional Medicine Unit</th>
<th>Year of Establishment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Trashigang District Hospital</td>
<td>November 1979</td>
</tr>
<tr>
<td>2.</td>
<td>Trongsa District Hospital</td>
<td>July 1981</td>
</tr>
<tr>
<td>3.</td>
<td>Bumthang District Hospital</td>
<td>March 1982</td>
</tr>
<tr>
<td>4.</td>
<td>Haa Bali BHU Gr. I</td>
<td>November 1987</td>
</tr>
<tr>
<td>5.</td>
<td>Punakha District Hospital</td>
<td>January 1988</td>
</tr>
<tr>
<td>6.</td>
<td>Mongar Eastern Regional Hospital</td>
<td>March 1993</td>
</tr>
<tr>
<td>7.</td>
<td>Gaylephu Central Regional Hospital</td>
<td>November 1993</td>
</tr>
<tr>
<td>8.</td>
<td>Pema Gatshel District Hospital</td>
<td>March 1996</td>
</tr>
<tr>
<td>9.</td>
<td>Yebi Lapcha District Hospital</td>
<td>March 1996</td>
</tr>
<tr>
<td>10.</td>
<td>Samdrup Jongkhar District Hospital</td>
<td>April 1996</td>
</tr>
<tr>
<td>11.</td>
<td>Paro District Hospital</td>
<td>December 1998</td>
</tr>
<tr>
<td>12.</td>
<td>Lhuntse District Hospital</td>
<td>October 1999</td>
</tr>
<tr>
<td>14.</td>
<td>Samtse District Hospital</td>
<td>July 2000</td>
</tr>
<tr>
<td>15.</td>
<td>Damphu District Hospital</td>
<td>November 2000</td>
</tr>
<tr>
<td>16.</td>
<td>Wangdue Bajo BHU Gr. I</td>
<td>November 2000</td>
</tr>
<tr>
<td>17.</td>
<td>Gasa BHU Gr. I</td>
<td>November 2001</td>
</tr>
<tr>
<td>18.</td>
<td>Tsimalakha District Hospital</td>
<td>January 2002</td>
</tr>
<tr>
<td>19.</td>
<td>Phobjikha BHU Gr. II</td>
<td>20th December 2004</td>
</tr>
<tr>
<td>20.</td>
<td>Ura BHU Gr. II</td>
<td>1st June 2006</td>
</tr>
<tr>
<td>22.</td>
<td>Korphu BHU Gr. II</td>
<td>1st April 2006</td>
</tr>
<tr>
<td>23.</td>
<td>Daksa BHU Gr. II</td>
<td>9th May 2006</td>
</tr>
<tr>
<td>24.</td>
<td>Phuntsholing sub-district hospital</td>
<td>1st July 2007</td>
</tr>
</tbody>
</table>
Table 5: No. of Patients treated in District TM Units

<table>
<thead>
<tr>
<th>Year</th>
<th>New Patients</th>
<th>Old Patients</th>
<th>Total</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002</td>
<td>53191</td>
<td>42947</td>
<td>96138</td>
<td></td>
</tr>
<tr>
<td>2003</td>
<td>43956</td>
<td>44564</td>
<td>98520</td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>55905</td>
<td>44064</td>
<td>99969</td>
<td></td>
</tr>
<tr>
<td>2005</td>
<td>57849</td>
<td>42896</td>
<td>100745</td>
<td></td>
</tr>
<tr>
<td>2006</td>
<td>62218</td>
<td>52059</td>
<td>114277</td>
<td></td>
</tr>
</tbody>
</table>

Source: District morbidity reports

Types of Services:

As per the National Traditional Medicine Professional Service Standards published by the Department of Medical Services, Ministry of Health in 2007 different types of services at each level of health facility have been prescribed as follows:

At the National Traditional Medicine Hospital, the following traditional medical services will be available:
1. General medical care
2. Secondary medical care
3. Tertiary medical care
4. All types of therapies
5. Outreach services to religious centres
6. In Patient services
7. Clinical teaching
8. IEC in Traditional Medicine
9. Operational research

At the Regional Referral Hospital, the following services will be available:
1. General Medical care
2. Secondary medical care
3. Selected therapies like gold needle, silver needle, herbal bath, steam bath, steam application, selected blood letting, heat application
4. Outreach services to religious centres and remote areas
5. Field training centre for NITM students

At the district hospital level, the following services will be available:
1. General medical care
2. General therapies like Serkhap, Nyulkhap, blood letting, heat application, Langduk etc.
3. Outreach services to religious centers and remote areas

At the Basic Health Unit level, the following services will be available:
1. Basic medical care
2. Serkhap, Nyulkhap and Numtshuk
3. Outreach services to remote areas

**Note:**
- *The patient referral system will be from the lowest level to the highest level and the feedback from the highest level to the lowest level.*
- *Apart from the routine therapies like blood letting, heat application and acupuncture, the traditional medicine practitioners shall refrain from carrying out any invasive procedures.*
- *The Drungtshos in the Regional and District hospitals may prescribe medicines that are not included in the essential drug list, if required, which can be treated as named patient drugs.*

**Classification of TM services:**

**General Medical Care will include:**
- Routine medical check up
- Diagnosis and treatment
- Behavioral and dietary advice
- Simple therapy like Serkhap
- Maintaining proper patient record and follow up
- Referral of patients to secondary and tertiary level care facilities
- Submit monthly morbidity reports

**Secondary Medical Care:**
In addition to the above activities listed under general medical care, other therapies like:
- Blood letting
- Application of heat
- Steam application
- Herbal bath
- Moxabustion
- Application of medicated oil
- Operational research

**Tertiary Medical Care:**
In addition to the activities listed under general medical care and secondary medical care, the advanced services like:
- Nasal irrigation
- Suppository / Enema
- Stomach wash
- Steam bath
- Tra-den Serkhap (gold needle with moxa)
- Prescribing of restricted and selected medicines
- Acupuncture
- Operational and clinical research
All medical services and therapy services will be delivered as per the standard treatment guidelines and standard therapy guidelines that are being developed. The patient records and reports will be maintained as per the Classification of traditional diseases under BHMIS.

The professional standards and safety of all medical practices will be followed at all levels of health care delivery system and the Quality Assurance Division of the Ministry of Health and Bhutan Medical and Health Council (BMHC) will monitor the service standards.

**National Institute of Traditional Medicine (NITM)**

**Mandate:**
Human Resource Development for Traditional Medicine

**Vision:**
Centre of Excellence in learning and human development

**Mission:**
Develop appropriate human resources with requisite knowledge and skills for the provision of traditional medical services

**Values:**
Rich culture and tradition
High quality of education
Creativity and innovation
Efficient delivery of programmes

**Core Business Areas:**
Teaching and Learning
Continuing education programmes
Research and development
The National Institute of Traditional Medicine (NITM) is one of the premier Institute under the Ministry of Health and is responsible for the development of human resources required for the delivery of traditional medical services in the country. The NITM programmes are recognized by the Bhutan Medical and Health Council and the Royal Civil Service Commission. The Institute is also affiliated to the Royal University of Bhutan and follows the University academic programmes.

The main mandate is to develop and implement appropriate training programs related to traditional medical services in order to preserve and promote the unique system of gSo-ba-Rig-pa through education and practice. The training program for Menpa was started in 1971 as on-the-job training at Dechencholing Dispensary as per the resolution of the 32nd session of the National Assembly. The training programme for the Drungtsho was introduced in 1978 as per the Royal command of His Majesty, the fourth King of Bhutan. The Pharmacy and
Research Technician training programmes were introduced in 1998 following the establishment of the Pharmaceutical and Research Unit.

Ladakh Amchi was appointment as the first Principal in 1978 under the Royal Command. His short biography is given below.

**Venerable Thubten Lekpai Lodre**

Popularly known as Ladakh Amchi, Venerable Thubten Lekpai Lodre was born to Phuensum of Nyi-gye lineage at Khunu in 1936. He began modern education at the age of six in the Khunu Secondary School vis-à-vis the study of Buddhist literature and grammar from Khunu Lama Tenzin Jamtsho. At the age of fifteen he left for Tibet with a letter from the Khunu Lama to the Venerable Khenrab Norbu, personal physician to The Dalai Lama.

As per the prophecy of Khenrab Norbu, he underwent thorough training in so-ba-rig-pa and astrology for seven years under strict guidance of the same. He tirelessly approached myriad of renowned masters like Rahung Choedra and Khen Thubten and received countless teachings and hand to hand instructions, enabling him to master all the sciences in Buddhism. In 1964, he went to Sikkim escaping the hazardous Cultural Revolution and later settled in Kalimpong. It was there that he learned Ayurveda and practiced both the system of medicine, integrating them in a harmonious manner.

On his voyage to the holy site of Taktsang monastery in 1970, he treated many Bhutanese patients successfully and the fame soon reached the royal court of His Majesty the fourth Druk Gyalpo, Jigme Singye Wangchuck, who wisely commanded him as the first principal of the newly established training institute at Dechencholing in 1978. As a principal and lecturer, he developed standard training curricula for the five year drungtsho program; revived the traditional methodology of so-rig teaching and learning; and established institutional norms.

Besides teaching and treating thousands of patients, he attended the royal court time to time. He was an in-born writer and composed many texts including a treatise on pulse reading and urinalysis. In 1992, he became the so-rig advisor and finally attained nirvana in 1997 after two decades of invaluable service to the mankind and the doctrine of so-ba-rig-pa. Today, his students form the core structure in provision of traditional medicine services throughout the entire kingdom.
Number of graduates

The numbers of student intake for each programme were based on the actual service delivery requirement of the health sector. Since its inception in 1971, the Institute has trained 43 Drungtshos, 58 Menpas, 12 Pharmacy Technicians and 11 Research Technicians.

The draft Constitution of Bhutan reflects the wisdom of providing free traditional medical services at par with modern medicine. This would require establishing traditional medicine units in all Basic Health Units (BHU) in the country and the demand for traditional medical practitioners especially, Menpas will be increased drastically.

The demographic changes and rapid socio-economic and political development will also spur the need for more traditional medical practitioners in the country.

At present, the gSo-ba-Rig-pa education is available only in Dzongkha and Choekye, limiting the recruitment of overseas students, but the affiliation of the Institute with the Royal University of Bhutan will lead to the development of programs in English for international students so as to generate revenue as well as promote the traditional medical system at the international level.

Existing facilities

The National Institute of Traditional Medicine is located within the compound of Institute of Traditional Medicine Services (ITMS) at Kawang Jangsa, Thimphu. The total area of ITMS compound is only 5 acres and there are already 12 buildings within this area. The NITM shares infrastructure facilities of these 12 buildings as follows:

- One two-storied traditional type building is used as the Boys’ Hostel (24 beds);
- Another two-storied building – upper floor used as the Girls’ Hostel (12 beds) and part of lower floor used as Warden quarter, the other half being used as the ITMS Meeting Hall;
- One-storied traditional type building is used as Dinning Hall with Kitchen attached (capacity 36 heads);
- Ground floor of another traditional type building (Museum) is used as a Teaching Block and has four classrooms each with a capacity of 4 - 10 students only. In the upper floor of the same building adjoining to the Museum, two small rooms are used as Prayer Hall and Library.

Present infrastructures are not suitable as they were initially not built for the Institute purpose. They lack basic teaching facilities such as, classrooms, administration offices, staff rooms, laboratories, library and other recreational facilities. Hostels are in dilapidated conditions and require substantial maintenance budget every year. The existing facilities are inadequate and inappropriate both in terms of quality and quantity to provide University level education.
Based on the Govt. policy of providing free traditional medical services at par with the modern medicine as reflected in the draft constitution, the number of traditional practitioners required would be multiplied by manifold. As of July 2006, there are 29 hospitals, 9 BHU grade I and 170 BHU Grade II in the country. Therefore, the number of traditional practitioners required would be as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>National Hospital/ NITM</th>
<th>Regional Hospitals</th>
<th>District/Sub district Hospitals</th>
<th>BHU Grade I</th>
<th>BHU Grade II</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drungtshos</td>
<td>10 + 10</td>
<td>6</td>
<td>26</td>
<td>9</td>
<td>-</td>
<td>61</td>
</tr>
<tr>
<td>Menpa</td>
<td>10</td>
<td>8</td>
<td>26</td>
<td>9</td>
<td>170</td>
<td>313</td>
</tr>
</tbody>
</table>

Currently, there are only 36 Drungtshos and 46 Menpa serving in the national and district TM hospitals, NITM and PRU. The additional requirement of Drungtsho will be 25 and Menpa will be 271 based on the actual requirement. Also, from now on the attrition rate will be high as many Drungtshos will retire after reaching superannuation. In order to meet this additional requirement, there is need to increase the number of student intake for training programmes in the National Institute of Traditional Medicine.

In order to fulfill the number of additional requirement for Drungtshos and Menpas, the annual intake of students will have to be increased as follows:

<table>
<thead>
<tr>
<th>Category</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drungtsho</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Menpa</td>
<td>0</td>
<td>10</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
</tbody>
</table>

Considering the duration of Drungtsho training as 5 years and Menpa training as 3 years, we will have more than 80 students at any given point in time. If we continue the training of Pharmacy Technician and Research Technician as and when required, then the total number of students at any given point in time will be more than 100.

Since there is no capacity at present to increase the student intake, there is a need to construct a new separate teaching block with adequate class rooms and other facilities like library, multipurpose hall, demonstration laboratory, botanical garden, faculty rooms etc. The existing hostels also need to be expanded or rebuilt to accommodate more students. There is also a need to construct facilities for indoor and outdoor games. The details are as follows:

a) Teaching Block consisting of:
   8 Class rooms for 10 – 15 students,
   2 Lecture theatres for 20 – 40 students,
   1 Multi-purpose hall for 80 – 100 students,
   1 Library for 10,000 – 20,000 books,
   1 IT room for 5 – 10 computer sets,
   1 demonstration Laboratory with kitchen and store for 10 – 20 students
   6 Toilets.
b) 6 Faculty rooms,
c) 1 Director’s Office,
d) 1 General Office,
e) 1 Store room,
f) 40 bedded hostel for the boys
g) 20 bedded hostel for the girls
h) A common kitchen with store room and dining hall for 50 - 60 students
i) An in-service training hostel with 10 beds each for male and female
j) Sport facilities like Table tennis, Basketball court, Volleyball court
k) Staff quarters for essential staff

The Ministry of Health and Royal University of Bhutan will need to take the lead role in mobilizing adequate financial resources either from the RGOb or donor agencies for the development of Institute infrastructures. A detailed master plan for infrastructure development including drawing and estimates will need to be drawn up. Since the HIDP is fully engaged in other projects, we may have to hire local consultants for this activity.

One of the biggest challenges the Institute faces, is in mobilizing adequate resources for infrastructure development and improving training facilities to deliver quality training programmes. The Faculty development is another important challenge in view of the limited scope for the Lecturers to pursue higher studies like Masters and Ph.D in Traditional Medicine. There is lack of personnel with adequate expertise in the development of training programs for higher and specialized courses.

An establishment of a separate training Institute with adequate infrastructures and facilities would ensure the quality of trainings offered to the practitioners of traditional medicine, thereby improving the quality of traditional medical services in the country. Together with the infrastructure development, the faculty development also needs to be given equal importance. The current faculty members lack skills in teaching methodologies and they also needs to obtain Masters Degree for implementing Bachelors degree program.

The need for preserving our rich culture and unique tradition of gSo-ba-rig-pa as envisioned by our successive Monarchs can be achieved through establishment of such an Institute of international repute. The NITM can gradually introduce Masters programme in Traditional Medicine and conduct research in traditional medicine for the benefit of human beings.

The management and administration of NITM will be transferred to the Royal University of Bhutan from July 2008 as per the MOU signed between the MOH and RUB on 13th June 2007.
Pharmaceutical and Research Unit (PRU)

Mandate:
Production of safe and effective traditional medicines

Vision:
Sustainable production of traditional medicines

Mission:
To produce high quality traditional medicines and other herbal products based on Good Manufacturing Practices

Values:
Ensuring safety and efficacy of all medicinal and herbal products
Promoting innovation through research and development
Building team spirit to increase work output
Ensuring sustainability of natural medicinal resources

Core Business Areas:
1. Collection and procurement of raw materials
2. Production of traditional medicines in different dosage forms
3. Production of commercial products
4. Research and Quality control of the raw materials and finished products
5. Marketing of the products

The Pharmaceutical and Research Unit (PRU) was established in 1998 with the main mission of producing safe, effective and high quality traditional medicines and other health promoting herbal products through sustainable collection and utilization of medicinal ingredients. Since its establishment, all traditional medicines are produced following GMP principles with more emphasis on quality control (QC). Unlike modern drugs, traditional medicine in Bhutan is purely an indigenous product as its source, processing know-how, and the human resource capacity are all available in the country. Our preparations are purely natural and no chemicals are used.

With the commissioning of the Pharmaceutical and Research Unit, shortage of traditional medicines has been significantly reduced.
The PRU has three main sections: Production, Research and QC and Marketing.

1. **Production Section**

This section is responsible for the manufacturing of traditional medicines based on the traditional formula using latest production technology. The medicines are manufactured based on GMP guidelines and Standard Manufacturing Instruction (SMI).

The following paragraphs describe well, the current situation in the different processing units of the production section:

**Raw material store**

The present raw material store consists of only two rooms to stock up year’s supply of raw materials for 98 plus products. To step up production, the procurement of 300 varieties of
raw materials has to increase accordingly. But the procurement and/or collection is limited by the availability of store space and the seasonal nature of it.

**Grinding section**
Grinding section consist of four grinders, one machine for the size reduction to coarse powder (Hammer crusher), one for coarse grinding (Micro-pulverizer) and two machines (Impact grinder) for fine grinding. Invariably, all the materials for any product or dosage form need to be ground. On top of this, the particle size required to produce elegant products are much finer. Inherent properties of materials being fibrous tend to resist easy grinding. With presently available technology of a hammer crusher and impact pulverizers, the demand is met only with certain hiccups.

**Pills section**
Pills constitute one of the most popular dosage forms of Traditional Medicine (TM). In an ideal situation, 70% of TM must be produced in form of Pills. At present, since we do not have an automatic pill rolling machine, they are rolled on conventional coating pan. With full attention and dedication a process takes around 14 to 16 days to get one product. Out of 14 to 16 days, much of the time is wasted in drying. Production of Pills involves drying for 3 times, one after nucleus formation, second after bulk adding and the third after polishing. Finally when the product is out, the size and weight variation of individual pills is greater or lesser than desired.

**Mixing section**
Homogenous mixing of all the ingredients is a key to production of homogenous product. At present, the Unit does not have adequate mixer to mix all the products before final production into various dosage forms. Ideally, all the dosage line must have a mixing line as this will reduce the risk of cross contamination.

**Tablet section**
Here the product is first mixed and made into dough for granulation. After few hours of drying in the tray and granulation, it is compressed into tablets in 16-station rotatory tablet machine. The process of mixing, drying, granulation and compression takes about 3 to 7 days depending upon the batch size.

**Capsule section**
Although the capsule filling is semi-automatic and does not have any backlogs, the products have to be mixed and made into granules using the same mixer and dryer used for tablet because of which most of the time the machine remains occupied.

**Decoction section**
In this section all the liquid preparations like syrups, medicated oil, ointment, bath mixture, hot compression and other pre-processing activity is carried out here. Most of the preparation is extracted in steam jacket using steam. At present the main extractor is not utilized because of the wrong location of equipment and also because the manual bottling and filling in tubes consumes much time.
Pre-processing section
Many ingredients like horns, bones, seashells and minerals need pre-processing and detoxification. This would require use of intense heat and airtight compartments (Muffled). Currently, there is one electric furnace where such activity is carried out.

Packaging and finished good store
This section does the final packaging and stock entry of the finished goods and distribution to DVED. The packaging involves packing into PET containers, poly bag packing with impulse heat sealing, packing into paper envelope, bulk packing and labeling.

It is needless to mention that manually operated impulse sealer (making double layer and sealing it) consumes more time than one could imagine. This is further worsened by the need to affix hand glued labels manually. To safeguard product stability and attract consumers or present the products in a better way, packaging and labelling are the key areas.

The Production section has a mandate to produce quality Traditional Medicine based on sustainably sourced medicinal herbs and Traditional formula using modern production technology and incorporating GMP principles.

The section currently produces approximately 7 metric tons of traditional medicines and meets the requirement of district Traditional Medicine Units and the National Traditional Medicine Hospital in Thimphu. For better patient compliance and management, dosage forms are standardized. Currently, medicines are manufactured in the form of pills, tablets, capsules, syrups, ointment, medicated oil and powder. In addition, it also produces a dozen of herbal products for the local market to enhance the income of the Revolving Fund.

Research & Quality Control section
This section is responsible for assuring quality and assessing the efficacy and safety of the traditional medicines. Research efforts are focused on authentication of species, building quality parameters both for raw materials and finished products and standardization of the production processes. The main objectives of the Research and Quality Control section are:

1. To scientifically validate the efficacy and safety of traditional medicine
2. To ensure and enhance the quality and stability of traditional medicine
3. To explore the opportunities for new products using natural resources to combat existing and emerging health problems.
4. To improve production methodologies

Main activities of Research and Quality Control section
1. Building Quality Control test parameters and standards for starting material and finished products.
2. Carrying out routine quality control tests on starting materials and finished products.
3. Building monographs on each medicinal plant used in the production of traditional medicine.
4. Drug efficacy and stability trails.
5. Survey and documentation of medicinal plants, including herbarium specimen collection.
6. Survey of medicinal and hot springs in the country and identification of their medicinal values.
7. Establishing therapeutic value indices of medicinal plants.

Some of the activities that are currently done are:

**Botanical standardization.** Botanical names (to clear the differences in the names of plants probably resulting from different sources of knowledge from different Masters)

**Building quality parameters:**
   i. Test methods, both general and specific (TLC, foreign matter, moisture content) defined for as many as 98 raw materials).
   ii. SMI for products (11 products completed)
   iii. Stability tests for the products.

**Pharmacognosy** – morphological and physio-chemical studies aimed at building Monographs (20 medicinal plants).

**Operational research** – in different areas aimed at strengthening efficiency of production and the healthcare services.

**Product development activities** – different products are studied and developed on trial mainly to come up with few good commercial products that would generate income sufficient to cross subsidize and sustain the manufacturing and research. Product development has been started under the Medicinal Plants Phase II Project funded by the European Union.

**Marketing Section**
Marketing activities were initiated since 1998 onwards to streamline the procurement of raw materials and sales of medicines and other products. Since then, eight products were introduced for commercial sale in the local market. *Tsheringma* herbal tea and Tsheringma incense powder are two of the popular products at the moment. There are also few new products in the process of development.

It is anticipated that the PRU would become a self-sustaining, and a dynamic profit centre of the Royal Government with operational autonomy, producing and supplying traditional medicines and herbal products of international quality standards (cost effective, safe, and of high therapeutic value). With the assistance from European Commission (EC) under project phase II, marketing activities are expected to pick up. A marketing strategy and a plan to market products both in the domestic and international markets will be developed based on the capacity of the Unit. The market studies will also be conducted within the region and in international markets.
Table 6: Raw materials purchased during 2006

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Categories</th>
<th>Items</th>
<th>Quantity (kg)</th>
<th>Amount (Nu.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>High altitude medicinal plants</td>
<td>87</td>
<td>4995</td>
<td>1116439</td>
</tr>
<tr>
<td>2</td>
<td>Low altitude medicinal plants</td>
<td>26</td>
<td>4936.5</td>
<td>527406</td>
</tr>
<tr>
<td>3</td>
<td>Minerals</td>
<td>5</td>
<td>931</td>
<td>231209</td>
</tr>
<tr>
<td>4</td>
<td>Animal parts</td>
<td>11</td>
<td>253</td>
<td>1317028</td>
</tr>
<tr>
<td>5</td>
<td>Capsule shells</td>
<td></td>
<td>780</td>
<td>878080</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>129</strong></td>
<td><strong>112095.5</strong></td>
<td><strong>4070162</strong></td>
</tr>
</tbody>
</table>

Table 7: Marketing of the products in 2006

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Products</th>
<th>Quantity</th>
<th>Amount in Nu</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Medicines</td>
<td>9251</td>
<td>6903878</td>
<td>kg</td>
</tr>
<tr>
<td>2</td>
<td>Tsheringma herbal tea</td>
<td>16077</td>
<td>871140</td>
<td>packets</td>
</tr>
<tr>
<td>3</td>
<td>Cordy plus</td>
<td>344</td>
<td>533400</td>
<td>bottles</td>
</tr>
<tr>
<td>4</td>
<td>Mensang</td>
<td>4393</td>
<td>409190</td>
<td>packets</td>
</tr>
<tr>
<td>5</td>
<td>Incense sticks</td>
<td>311</td>
<td>46650</td>
<td>bundles</td>
</tr>
<tr>
<td>6</td>
<td>Lumen rilbu</td>
<td>6635</td>
<td>33175</td>
<td>Pills</td>
</tr>
<tr>
<td>7</td>
<td>Rinchen sna5 &amp; sna7</td>
<td>177</td>
<td>91815</td>
<td>Pkts.</td>
</tr>
<tr>
<td>8</td>
<td>Drebu Sumthang</td>
<td>74</td>
<td>10790</td>
<td>pkts</td>
</tr>
<tr>
<td>9</td>
<td>sMen sna Phyma</td>
<td>688</td>
<td>89095</td>
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<td>10</td>
<td>sMendrup Phyma</td>
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<td>101301</td>
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<td>Zangdru Phyma</td>
<td>188</td>
<td>83220</td>
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<td>Bumzey25</td>
<td>75</td>
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<tr>
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<td>Raw material</td>
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<td>140369</td>
<td>Different types</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>9321273</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Currently, available commercial products are mainly sold in Thimphu through the sales counter located within the PRU complex. We have few wholesale buyers and shops that retail our products in Thimphu. Other than these, we have just one wholesale buyer outside Thimphu in Paro.

Although one preliminary market study has been done in Bumthang, Trashigang and Gelephu, no retail agents have been identified. Identifying few agents in these towns could boost our sales. Other avenues such as art shops, museums, gift shops, hotels and restaurants need to be explored as well. It is clear that these sales from new products are contributing significant revenues to the RF.

Revolving Fund

The Revolving Fund was established in November 1996 with the noble vision to ease the financial burden on the Royal Government of Bhutan (RGoB) for the procurement of medicinal ingredients and at the same time to gradually make the Pharmaceutical & Research Unit a financially self-sustainable entity. It was approved by the Project Steering
Committee and the Ministry of Finance. Today, we no longer require funds from the Royal Government to procure medicinal herbs and other ingredients for manufacturing traditional medicines.

The initial mandate of the Revolving Fund was to:

a) Pay for all the raw material purchases required for the production of traditional medicines.
b) Accept any/all sales proceeds from the Pharmaceutical & Research Unit as an income of the Fund without requiring to be deposited into the Government Revenue Account.

As a result, all supplies of traditional medicines made to the Health Department were billed to the Ministry of Health and the sales proceeds deposited into the Revolving Fund.

Since its inception, the Revolving Fund has been able to carry out its mandate of raw material procurement successfully. Shortage of funds for procuring medicinal ingredients has never occurred. Therefore, the focus of the Fund today is more towards making the production of traditional medicines a self-sustainable and a commercially-viable entity in the long run.

The main sources for the Fund are: a) sales of commercial products and b) sales of traditional medicines. The income generated from the sales of essential traditional medicines to the Drugs, Vaccines and Equipment Division (DVED), Ministry of Health, has been the largest source. The total income from the sale of medicines to DVED for the year 2006 amounts to Nu. 6.9 millions, which is 54%, increase from the previous year. As the traditional healthcare services expand further to meet the healthcare needs, there is scope for the Fund to grow through increase in sale of traditional medicines.

There have been similar achievements on the commercial products’ front. The sales of various commercial products including herbal tea, incense sticks & powders, health promoting and other religious products, amounts to Nu. 2.4 millions which is a 78% increase from the previous year. This is attributed to the introduction of new products like CordyPLUS, Dri-Zang incense sticks (Protecting and calming) and also due to the price revision done after improvement of packaging and labeling designs for Tsheringma Herbal tea, one of our popular products. Also, this increase is due to the 2 new outlets in Thimphu that were appointed during the year.

**Fig 12:** Sales trend for the commercial products and essential medicine
Fig 13:  Sales from four best selling products

On the expenditure front, purchase of raw materials/ingredients is the main area amounting to Nu. 5.2 millions during the year. This purchase consists of high and low altitude medicinal plants, minerals, animal parts and other ingredients. Other expenditures include those incurred for packaging materials, casual labor and other overhead expenses.

Fig 14:  Graph showing the fund balance (2002-2006)

The Revolving Fund (RF) for the PRU is an important initiative within the Ministry of Health. It seeks to relieve the Royal Government of some financial burden by funding raw material purchases for our core Traditional Medicines. Of late, new product development activities such as purchase of packaging and labeling materials are also funded by the RF. Overall, the scope of the Fund is to enhance the financial sustainability of the PRU. It is therefore very critical that planning with Revolving Fund resources reflect a sound investment strategy that will increase outputs.

With regard to potential exports, the PRU does not have suitable products at the moment. However, export development has considerable potential given the high interest in the more developed economies for engaging in more holistic approaches to health. Also, because of recent and planned developments within the country, Bhutan is now gaining very much increased visibility worldwide, an enormous opportunity that we can capitalize on.
Given the primary mandate of supplying our core products, the shortages and restrictions of supply and the complexity and cost of complying with international drug standards, we obviously cannot cater to the wider market. However, niche marketing is very possible. Our niche comprises people with very strong social and environmental values and who have an interest in the Buddhist ethics that forms a large part of our collective culture - people who are not just looking at the product but into the whole process of making it and the spiritual values that lie at the core.

Provided we can sustain, further nurture and communicate these values, our customers, regardless of their location, can be assured that they purchase a product that is morally and ethically wholesome and that their money supports needy households in the Himalayas, funds R&D on traditional medicines in Bhutan and keeps this rich resource and its cultural roots alive for all our children.

Developing products for export requires further work on quality. Products are marketable only if they are certified by applicable international standards like the GMP, HACCP, ISO, etc. This requires the PRU to be able to work to these standards; from the sourcing of our raw materials up until finished products are delivered to the consumer.

Product development is an essential process and should continue developing products that ideally must all originate or evolve from gso-ba rig-pa. Local and foreign customers are concerned about the origin of health related products and clearly, products that have been in use for centuries and developed by the Medicine Buddha himself are both more efficacious and more appealing, even to those that do not share Mahayana beliefs.

The PRU will be de-linked from the Ministry of Health and become a Corporation in the near future. The Govt. has already approved for making it as a corporation to improve its efficiency in the production of traditional medicines and commercial products. The details are being worked out for smooth transition from a Govt. organization to a corporation.
2. CONCEPTS, PRINCIPLES AND PRACTICES OF COUNTRY SPECIFIC TRADITIONAL MEDICINE

2.1. The philosophy and concept

The concept of gSo-ba Rig-pa is based on the philosophy of five cosmo-physical elements known as Sa (earth), Chu (water), Me (fire), rlung (air) and Namkha (sky) in the universe. They are also linked to all aspect of our body. Earth is the source of bone, flesh, nose and the sense of smelling whereas, the water is the source of bodily fluids such as blood, saliva and provides sense of taste. Similarly, fire provides heat and colour to the body and the sky provides the space to grow and the sense of hearing. Health and wellbeing can be defined as state of perfect balance between the five basic elements and the imbalance of these five elements results in disease or ill health.

According to gSo-ba Rig-pa, the diseases are classified as rLung (air), mkhris-pa (bile) and Bad-kan (phelm) which are caused by three mental poisons known as Dod-chag (attachment), Zhel-dang (hatred), and Ti-mug (delusion) respectively. Dod-chag which is light and mobile causes attraction of the mind towards pleasant things. This attraction generates more and more eagerness which gradually induces anxiety in the mind and give rise to rLung disorders. Zhel-dang which is hot and burns like a fire causes mkhris-pa disorders to rise. Ti-mug causes Bad-kan and when manifest in brain can obscure intelligence and clarity. In traditional medicine, long chain of karmic actions and effects of evil spirits can also cause sufferings to human beings. Such cases can be pacified through conducting rituals and offerings by qualified Buddhist practitioners.

rLung is responsible for respiration, movement of hollow organs such as intestine, lungs, heart, blood vessels etc. mkhris-pa stimulates appetite, helps in digestion and maintains body temperature. It also claims to confer bravery, wisdom, and desire or ambition. Bad-kan sustains body and produces sleep. It is responsible for movement of joints, muscles and confers patience.

2.2. Principles and practice of Bhutanese Traditional Medicine (BTM)

The practice of BTM involves application of age-old medical knowledge with its holistic approach in ascertaining the latent state of an ailment through correct diagnosis and clinical judgment to determine the treatment and management incase of a diseased and provision of prophylactic dietary and behavioral advices to healthy individuals.

It is practiced as an integral part of the national health care delivery system, which is a legal and credential framework, established by the Royal Government as the core activity of the Ministry of Health. The practice is empowered by the Bhutan Medical and Health Council (BMHC).

Since all things, as stated by the theory of byung-ba-lnga, including human beings in this universe are formed from the same five elements; it is possible to ascertain the nature of deviation by analyzing the respective composition of these elements through various means.
of diagnostic technique in *so-ba-rig-pa*. Appropriate forms of treatment are then selected on this basis. Consequently, healing in *so-ba-rig-pa* occurs through the balancing of these elements to their normal harmonic state. This is possible because the five elements in the macrocosmic frame relates to the five elements in the microcosmic being which makes it feasible to alter the deviations through intake of foods and medicine having same composition.

The job of a *druongthso* is therefore to understand the human frame and situation in terms of normality-the dynamic equilibrium among the five elements based on which he measures the patient against those norms, ultimately determining the particular deviation from the normal and the degree of deviation. This is done through:

- **Examination**
- Analyzing and synthesizing the information acquired through different modes of examination
- Interpreting the signs and symptoms and their cause to the patient and identify appropriate treatment
- Actual application of the treatment consisting of diet, behavior, medication and accessory therapies
- Assessing the progress of treatment and altering the treatment and proceeding with further examination and additional treatment if necessary
- Longer-term diet and lifestyle pattern counseling and follow-up if required

Establishing the latent condition of the energies is necessary for physicians to be able to assess the patient clinically before attempting treatment of any kind. This requires a comprehensive and systematic mode of examination as follows:

a) Visual examination including traditional urinalysis albeit use of any chemical or physical reagents
b) Tactile sensation including the unique system of palpation (pulse reading).
c) Medical history taking which usually involves both *interactive hypothesis testing* and *systems inquiry* aimed at obtaining the following information about the patient:
   - Identification and demographics
   - Chief complaint and its history
   - History of past/ongoing illness including treatments and medication availed such as prescribed by competent practitioners and obtained over the counter
   - History of diseases in the family and the community
   - Diet and behavioral pattern in recent times
   - Social history (occupation, substance use, travel etc
   - Latent state of the organ systems
   - Mental state (anxiety, depression etc

Special modes of diagnosis like astrological calculations and dream analysis are sometimes employed to supplement these diagnostic methods.
Based on the clinical judgment, the *drungtsho* decides on the form of treatment that a patient needs to undergo in order to restore its elements and energies to normal state of dynamic equilibrium. Consequently, treatment in *so-ba-rig-pa* consists of four fold mode of gradual therapeutics: Diet, Behavior, Medication, and Therapy (*dpyad* - defined as a mode of treatment that eliminates or pacifies a disease through external application.

Theoretically, the treatment begins with alteration/correction of diet and behavior pattern, followed by medication and surgical interventions, later at an advanced stage of an ailment and its course of treatment. However, in practice, it depends on the nature of the disease and the competency of the physician. There is no procedure that can replace the physicians’ skills and experience in this.

In case of emergencies, which demand application of symptomatic and appropriately localized procedures, surgical interventions (non-invasive) and medication is prioritized. When the condition of the patient becomes stable, prescription of further medication along with dietary and behavioral restrictions follows.

In a chronic and less ill patient, whether functional or organic, long term observances of diet and behavior pattern are frequently supplemented by medication. Acute and chronic diseases, in which the deterioration is either imminent or already in progress, demands a continued intervention of all the modes of treatment at a time.

The treatment is patient oriented rather than the disease and differs from an individual to individual. Administration of medicine for two individuals of same age with similar condition of ailment will considerably vary both quantitatively and qualitatively. This is because the biotypology of an individual plays a decisive role in the selection and determination of appropriate treatment.

On the fourfold mode of treatment in *so-ba-rig-pa*, Dr. Yeshi Donden advises:

1. Ailments of a minor nature are treated by dieting and strict adherence to a careful programmed daily routine without medicines.
2. If a patient is suffering from a disease in a medium state of condition, decoction is prescribed.
3. In a more advanced case, medicines in the form of pills are administered;
4. In diseases of a serious nature, treatment consists of bloodletting, moxibustion, administration of medicines (and) use of (the) psycho-therapeutic process to produce emesis, and bathing in hot springs or in hot water treated with medicinal compounds.

A sound patient-physician relationship as explained in the classics with an analogy of pupil and teacher, field and farmer and etc., not only assures mutual respect, trust, shared values and perspectives but also refines the quality of information which enhances accuracy of diagnosis and selection of appropriate medication and therapy, thereby resulting in successful treatment.
Importantly, during this process the traditional healthcare providers educate the patient about the causes, progression, outcomes, and possible treatments of his/her ailments, advice for maintaining health through advices on diet and behavioral changes according to one's own constitution and seasonal changes and as well as create awareness on communicable diseases along with preventive mitigations, establishing its significance in community health.

On practical grounds, the delivery of BTM services can be classified into simple and advanced level. Simple care is provided by both *drungtshos* and *smenpas* who have first contact with a patient seeking medical treatment or care. These include treatment of acute and chronic illnesses, limited to use of simple medication, diet and lifestyle alterations lasting few days or even weeks depending on each case.

Advanced treatment are those provided by eminent *drungtshos* (assisted by *smenpas*) in patients with complex symptoms or multi-system problems and diseases in an advanced stage involving the application of various accessory therapies like cauterization and etc. besides continuing medication and dietary restrictions.
3. NATIONAL POLICY ON TRADITIONAL MEDICINE

3.1. Process of Policy Formulation

Health sector policies are derived from the National Development Plan Documents (five year plans), Bhutan 2020: A vision for Peace, Prosperity and Happiness, Enhancing Good Governance and AHC Resolutions. All these policy documents of the Govt. are based on the overall development philosophy of Gross National Happiness (GNH).

The Traditional Medicine policy was formulated by an expert committee comprising of policy makers and practicing traditional professionals. The draft policy was discussed during the Annual Traditional Medicine Conference (ATMC) and was presented to the Annual Health Conference (AHC) in 2003 for endorsement. The AHC is the highest policy making body for the health sector.

3.2. Policy Document

Since traditional medicine is an integral part of the national health care system, there was no separate policy and we follow the same health policy which is broadly stated as “Attainment of a level of health that will permit them to lead a socially and economically productive life through the provision of preventive, promotive, curative and rehabilitative services based on Primary Health Care approach”.

However, in view of the need to have a clear policy statement on Traditional Medicine, an expert committee has drafted this policy statement in 2002. “National policy for Traditional Medicine is to preserve and promote the unique system of medicine that is based on rich culture and tradition, through capacity building and establishing an effective system within the framework of national health care delivery system for the provision of quality traditional medical care.” The main mission is to provide traditional medicine services as alternative choice of treatment for the people of Bhutan.

Bhutan 2020: A Vision for Peace, Prosperity and Happiness states the importance of Traditional Medicine as follows. “We must continue to provide a place for traditional medicine in our system of health care. Traditional medicine embodies knowledge that has been accumulated over centuries and which draws upon the nation’s rich bio-diversity and of plants with proven medical qualities. As these qualities become substantiated by scientific research, there is a growing need to integrate more effectively traditional medicine with the modern system of health care. The maintenance of traditional medicine not only adds dimensions to the nation’s system of health care, but provides an alternative for those who seek one. It should also be regarded as a conscious decision to conserve a part of our rich and varied cultural heritage”. Therefore, strengthening of traditional medicine and integrating it with modern health care system is considered as an important policy objective of the health sector.

The draft constitution of Bhutan 2005 under Article 9, item 21 declares that “the state shall provide free access to basic public health services both in modern and traditional...
medicine”. This would mean that the traditional medicine unit must be established at all levels of health facilities in the country. One of the important policy for the health sector since its establishment in the early 1960s has been to provide free health and medical care to its entire citizen and it has also been reiterated in the draft constitution.

3.3. Policy Implementation

The Traditional Medicine policy is implemented by the three units of the Institute of Traditional Medicine Services (ITMS and district Traditional Medicine Units under broad direction and guidance of the Ministry of Health (MOH). The five year plans and annual work plans of the traditional medical services are prepared by ITMS and submitted to the MOH for incorporation in the Ministry’s plan for Govt. approval. All approved plans and programmes are implemented based on the availability of the fiscal budget and are monitored by the Ministry through quarterly progress reports, half yearly reports and annual reports.

3.4. Role of Traditional Medicine / Integration into National Health System

The traditional medical service functions as an integral part of the national health delivery system. It is available in all 20 districts and is housed under the same roof of district hospital for mutual consultation, treatment and cross referrals. The only exception to this is in the capital, Thimphu, where due to patient numbers, the hospital at the ITMS provides traditional medical treatment, while the Jigme Dorji Wangchuk National Referral Hospital (JDWNRH) is the biomedical centre. There is also a proposal to merge these two hospitals in the future. The traditional medicine units in the districts are directly under the control of district health administration as per the decentralization policy of the Royal Government. District Traditional Medicine units are manned by one traditional physician known as Drungtsho and one traditional clinical assistant known as sMenpa.

At the national level, there is a coordination meeting between the modern doctors of the JDWNRH and physicians of the National Traditional Medicine Hospital (NTMH) on a regular basis. Some traditional physicians from the national hospital participates in the AHC which is the highest decision making body for the health sector. There is also annual traditional medicine conference where physicians from all traditional medicine units participate to discuss about the activities, achievements, constraints and annual work plans. The recommendations of the annual traditional medicine conference are usually endorsed by the annual health conference and followed up accordingly.

The traditional medical students are attached to modern medicine hospitals for three months after completion of five years training in NITM for observation and to understand the modern medical system and different functions of the hospital. Likewise, the health workers and nursing students of the Royal Institute of Health Sciences (RIHS) are exposed to traditional medical services during their training programme through orientation visits and regular briefings. The medical doctors and other health science graduates who completed their studies from outside are also provided orientation on traditional medicine.
before inducting into the regular service. As a result, there is mutual understanding between the practitioners of both the system.

Traditional and modern medicine compliments each other and they do not need to compete. Sometimes one gives better results than other; sometimes the results are the same. Many people feel much better knowing that nothing is ignored in trying to make them well again. It is not uncommon that a patient would consult both the modern and traditional physician and collect herbal and allopathic medicines. Bhutan has a unique opportunity to constructively harness a symbiotic working relationship between traditional and religious practitioners and modern health care workers to provide culturally acceptable care to the largest number of people, as it maintains a rich fusion of modern and traditional health care under the same roof.

3.5. Ethical Issues

All health professionals including the traditional medicine practitioners, being civil servants must follow the civil service codes of conduct and ethics in addition to their professional codes of conduct, as described in the Bhutan Civil Service Rules (BCSR) – 2006. The professional conduct and ethics for the medical and health professions are mentioned in the BMHC Act and its regulations. In addition to these documents, there are number of other documents like Medicine Act of the Kingdom of Bhutan, Good Governance Plus, and Position Classification System (PCS) etc. that the civil servants are required to follow.
4. LEGISLATIONS

4.1. Registration of Traditional Medicine Practitioners

All Traditional Medical practitioners are registered with Bhutan Medical and Health Council (BMHC) to ensure safety of public health and discourage the practice of quackery in the field of medical and health professions. The applicant shall duly fill in application form and furnish in original and photocopies of the qualifications to be registered, accompanied by attested copies thereof, citizenship ID card, medical fitness certificate, entry qualification certificate, mark sheets, internship certificate and character certificate where required. The applicant shall pay the registration fees as prescribed from time to time.

All foreign medical and health professionals including volunteers practicing in Bhutan shall be registered as temporary professionals and will be liable to the same disciplinary procedures under the BMHC regulations as other professionals.

Every medical and health professional shall sign the declaration before the registrar, in a prescribed form and thereby make a solemn pledge to abide by its regulations. The Registrar, after satisfying that the applicant has complied with all the requirements, shall grant a certificate of registration in the prescribed form. The revalidation shall be done every five years after evaluating the competency through fulfillment of minimum 30 hours of continuing medical education during the last five years.

4.2. Rights and Privileges of Traditional Medicine Practitioners

The registered Traditional Medicine professionals can practice in any part of the country either in Govt. institutions and private practice after obtaining the business license from competent authority. They can prescribe medicines to needy patients. While prescribing, the professionals shall adhere to limits set by their highest acquired professional qualification and be guided by the policies of the health sector implemented through Essential Drug Programme (EDP), Drug Regulatory Authority (DRA) and Quality Assurance and Standardization Division.

The other privileges include the issuance of medical certificates, deposit of medical evidence and employment. The traditional physicians are at par with modern medical doctors with MBBS degree in terms of entry grade into civil service and salary scales.

4.3. Registration of Traditional Medicines

All 98 products of traditional medicines are registered with DRA as mandated by the Medicine Act of the Kingdom of Bhutan – 2003. The following procedures are followed for registration of the medicinal products:
- Applicants shall apply for registration to the Drug Controller using the form prescribed for the purpose, furnishing all relevant information regarding the product to be registered
The product should be leveled in generic or international non proprietary name (INN)

Branded product will be registered but in INN or generic if a separate patent license is not obtained

The WHO model certification scheme on the quality for pharmaceutical moving in international commerce should be submitted along with application for the product

In case of biological and veterinary products, quality control certificates from OIE/recognized international organization should be submitted

Applicants should furnish the bio-equivalence study result in case of generic products. The Drug controller shall publish a list of products which required bio-equivalence testing

In the case of products that have established bio-equivalence test, the dissolution testing result of the product as per USP or BP should be submitted

Furnish master formulae along with the abstract of the text of gSo-ba Rig-pa, quality control certificate, packaging materials specifications and label for the Registration of gso-ba rig-pa based medicinal products.

The Drug controller shall put up all such applications before the Board

The Board after being convinced of the quality, safety, efficacy, national standards, price and other information furnished by the applicant, may approve or disapprove of registration of such medicinal products

The Drug controller, after approval by the Board, shall allocate to each approved medicinal product a registration number and shall record the same along with other particulars in the register.

4.4. Quality Assurances of Traditional Medicines

The Drug Regulatory Authority (DRA) shall be the agency that develops and implements most of the legislation and regulations on pharmaceuticals to ensure the quality, safety and efficacy of drugs and the accuracy of product information. An appropriate quality assurance system shall be instituted at all levels of drug supplies management including local manufacture and shall include all plans, processes, and procedures that conform to all regulatory requirements.

The Government shall have built in mechanisms in the public health laboratory to carry out quality testing of drugs in the country for both private and public sector. The Govt. shall also allocate at least 2-3% of annual drug budget to cover the cost of quality assurance and drug testing.

All drugs used in both public and private sectors shall be registered with the National Drug Regulatory Authority and regular inspections shall be carried out to prevent and control sales of counterfeit and sub standards drugs in the country. The list of registered products shall be published in the public domain by the DRA and a National formulary containing the list of all the registered drugs shall also be published. Appropriate drug information shall be provided and made available both to the patients and the health professionals.
4.5. Traditional Medicine Pharmacopoeia

Bhutan is referred to in early Tibetan sources as *Lho- sMen-jong* – the “Southern Valleys of Medicinal Herbs” and as in the Tibetan pharmacopoeia, Bhutanese medicines are largely herbal based, with some use of animal and mineral products. Around 265 different raw materials in total are used and from this, around 100 medicines are currently produced at the PRU following WHO GMP guidelines. Production is fully mechanized and around 7 tons of traditional medicines are produced annually for supply to all TM units in the country. One factor inhibiting biomedical research into these medicines is that they contain multiple ingredients, a minimum of five up to a maximum of 35 ingredients in one compound. Bhutanese medicines thus face the same problems as those of other Asian systems in terms of biomedical testing regimes.

Most of the high altitude medicinal plants are collected from Lingshi Drungkhag under Thimphu district which is four days walk from the nearest road point during July to August every year. The local farmers are collecting the medicinal plants from the wild and bring to our drying centre. The farmers are paid as per the fixed rates per Kg. basis. The medicinal plants are sorted, washed and dried in the drying centre before transporting on horse back to the road-head in Paro or Thimphu. Perhaps, medicinal plant collection may be one of the first economical activities initiated and sustained in this highland. While other highlands like Gasa, Trashi Yangtse and Bumthang districts are being explored to introduce as alternative collection sites, Lingshi has been collection centre for high altitude medicinal plants since 1967. Similarly, the low altitude medicinal plants are collected during December –January every year from Langthel geog under Trongsa district in central Bhutan. There is also a natural drying unit in Langthel

While, there is currently an abundance of wild medicinal plants available, wild plants are a challenge to search for and to find, often growing in remote and dangerous locations. In the long term, sustainability is essential and farmers are being encouraged in sustainable collection and cultivation of medicinal herbs. The intention is that medicinal plants can be grown by the farmers as a cash crop, in the same manner as fruits and vegetables. A ready market already exists in India and other countries for any produce in excess of Bhutan’s own needs.

4.6. Traditional Medicine Formulary

The first edition of the Traditional Medicine Formulary of Bhutan was brought out in the year 1983 and since then there were several revisions, but were not published until now. The first edition had 205 formulatons with standard quantities and indication. The second edition has only 98 fromulations with all the necessary information such as individual ratios, substitutions, indications, dosage, dose and mode of administration incorporated into it. This edition is prepared based on the current Essential Traditional Medicine list, which is reviewed and revised after every 3 years by the Traditional Medicine Research and Development Committee (TMRDC). Like Essential Drug list and Bhutan National Formulary of biomedicine, the Traditional Medicine Formulary of Bhutan will be regularly
updated with more information and will be developed into a National Pharmacopeia in the future.

Traditional medicines are manufactured strictly based on the traditional formulations, using conventional equipments and integrating quality assurance system. The formulations are directly extracted from the texts of \textit{gSo-ba Rig-pa} medical system, wherein the individual ratios are in traditional measurement system of \textit{bsang, zho and karma} indicated in this publication as STD Qty. (Standard quantity). The Qty. for 1 kg (Quantity for 1 kg) is derived from STD Qty. for conventional measurement by dividing individual STD ratio by the sum of STD Qty. Wherever possible, the effort is being made to substitute the animal ingredient with plant ingredient without compromising the efficacy, safety and quality of traditional formulations and strictly as per the texts.

The formulary is to document the master formulae to serve as a ready reference for manufacturing, dispensing and prescribing. This publication may also be useful for registering traditional medicine with Drug Regulatory Authority of Bhutan. Every attempt has been made to avoid the use of equivalent biomedical terms and at the same time provide, as much information as possible without diluting traditional meaning and essence. But, some of the biomedical terms are inevitable, as they describe the same conditions.

Additional information will be gathered and added in the future editions to make the formulary comprehensive for wider spectrum of users. It is hoped that this edition, will serve as a guide for the manufacturer and practioners of traditional medicine and help in promoting and strengthening the age old medical system of \textit{gSo-ba Rig-pa} in the country. The formulary however, should not be used as a guide for self medication.

\section*{4.7. Essential Traditional Medicine List and Process of Development}

The current traditional medicine list consist of 98 products which are supplied all traditional medicine units in the country. However, in view of the need to streamline like modern medicine list as per the Essential Drug Programme, the categorization of Essential Traditional Medicine list was also undertaken in 2007 with the following objectives:

\begin{itemize}
  \item To ensure a regular supply of safe, effective and need-based medicine of acceptable quality and at reasonable cost to the majority of the population
  \item To promote and monitor rational prescribing and good storage and dispensing practices
\end{itemize}

\textbf{Process of Development and Criteria}

\begin{itemize}
  \item The initial list was drawn up by the In-house Drungtsho Adviser to the Pharmaceutical and Research Unit in consultation with senior Drungtshos of the National Traditional Medicine Hospital and In-charge of the production unit of PRU.
  \item Categorization was based on \textit{gS-ba Rig-pa} text although many Drungtshos feels that it is incomplete and jumbled
\end{itemize}
• Ideally, the level of health facility to which medicine is supplied should be based on morbidity pattern, training and experience of the prescribers and treatment facilities available in the health unit.

• Top 10 diseases from 14 districts and National Traditional Medicine hospital was used as the basis for selection at different levels of health facility.

• The list was reviewed by the National Drug Committee before publication
5. AVAILABILITY OF TRADITIONAL MEDICINE IN THE COUNTRY

5.1. Production

In the past, all traditional medicines were produced manually. Small scale mechanized production started only in 1982 with support from World Health Organization. From 1998 onwards, the manufacturing Unit was upgraded to the Pharmaceutical and Research Unit (PRU) and now all products are produced mechanically following GMP principles.

According to gSo.ba Rig.pa, more than 2990 different types of raw materials are known for use in the manufacture of Traditional Medicine and about 600 medicinal plant species have been identified in Bhutan. However, the Unit currently uses about 300 ingredients to manufacture 98 compounds that constitute as National Essential Traditional medicine list and 14 additional products for commercial purposes.

The main resource base around 90% of the prevailing traditional medicine is medicinal plant and the remaining part is derived from animal and mineral origins. The high altitude medicinal plants are sourced from altitude ranging from 3500 to 5000 meters above sea level (msl) and low altitude from 200 to 1500 msl. Although most of the plant ingredients are collected from wild, some of the species are now being cultivated/domesticated by the farmers. Perhaps medicinal plant collection may be one of the first economical activities initiated and sustained in this highland.

Of the total 18.51 tons of raw materials procured (PRU inventory 2005-06), about 15.7 tons (85%) of it were collected within the country. The remaining 15% are mostly imported from India. The Unit procures or collects around 15.5 metric tons of raw ingredients on the average and this quantity is expected to double within the next 5 to 10 years. This would ultimately exert pressure on the natural resources if conservation issues are not addressed and strategic utilization and sources not identified.

In order to enhance and scale up production capacity as well as incorporate the principles of Good Manufacturing Practices with total quality assurance system and to meet the growing demands for the traditional medicine, the existing production facilities will be upgraded and new infrastructure built.

Despite earnest efforts to cope with overall production, there are few bottlenecks that remained with production mostly in terms of achieving the desired outputs from certain machines and fulfilling the mandates. Acquiring right technology to keep up the pace with contemporary industries by use of ICT to boost efficiency and obtaining appropriate standard such ISO, ICH, GMP etc is regarded as a part of dynamic process of management. Introducing management tools like Management Information System (MIS) with inventory system will systematize ad-hoc production planning based on actual requirements from DVED, Department of Medical Services. The MIS will also help us to monitor productions and to assess production status, lead time etc.
5.2. Storage and distribution

The Traditional Medicines which are produced at the PRU are delivered to the Drugs Vaccines and Equipment Division (DVED) of the Ministry of Health on a weekly basis, where it is stored for distribution to different TM Units in the country.

The traditional medicines are supplied through the normal medical supply system from the DVED based on 6 monthly drug reports from different traditional medicine Units. The store management at the district level is fully integrated with the modern medicines. The procurement of equipment and other supplies are also done through the DVED.

5.3. Imports and Exports

The PRU is importing some raw materials for production of traditional medicine from India through annual tender. These includes mainly minerals and low altitude medicinal plants. In 2006, 33 items of raw materials worth Nu.1210835 were imported from India. These include costly items like saffron, white sandal wood, red sandal wood, gold powder, clove etc. that are not available in Bhutan. Capsule shells worth Nu. 878080 were also imported during the year from India.

In 2007, 24 kg of sMensang powder and 108 packets of calming incense sticks worth Nu. 56336 were exported to Taiwan, China. Discussions are being held for the exports of Tsheringma herbal tea to Singapore and Thailand

5.4. Herbal Garden: Cultivation, Collection, Storage

Community Based Sustainable Management of Medicinal Plants has been established and some species are introduced for cultivation in collaboration with the Medicinal and Aromatic Plants (MAP) Division of the Ministry of Agriculture. The ongoing second phase of the EC project is further focused on the technical and organizational methodologies, development for sustainable conservation, collection and /or domestication of a range of high altitude medicinal plants. The focus is on the development of medicinal plants industry at all levels including sustainable collection and /or production and marketing of herbal products to function the Unit as a self-sustaining commercial entity.

More than 24 species of high and low altitude medicinal plants have been domesticated and cultivated on trial basis by more than 100 farmers in 10 districts (MAP, 2007). Some species like Ruta (Saussurea Lappa) were so successful and has exceeded the annual requirement of PRU.

For the sustainable production of traditional medicine, the sources of raw materials for the production have to be ensured through sustainable collection and utilization. The increase in collection of medicinal plants from wild will have detrimental impact on biodiversity if conservation issues are not addressed strategically. The farmers are now being trained in good collection practices and encouraged in sustainable collection and cultivation of
medicinal herbs. To diversify collection sites, the alternative sources for medicinal resources are identified and some potential herbs introduced for cultivation.

Even the focus of ongoing EU Medicinal plant project is on the technical and organizational methodologies development for sustainable conservation, collection and/or domestication of a range of high altitude medicinal plants and the development of medicinal plants industry at all levels including sustainable collection and/or production and marketing of herbal products.

Today one of the challenges we face is the lack of proper drying system and hence retention of quality of herbs after harvest. The problem is complicated by the fact that the collection time for high altitude plants coincides with peak monsoon season, when the humidity is highest and the sunshine is a rare experience. This contributes to wastage of herbs on one hand and deterioration of quality on the other.

To address this concern and promote the judicious use of medicinal plant resources, the following strategies are in place:

a) **Minimizing wastages.** To minimize wastages and sustain the production of quality Traditional Medicine, Lingshi under Thimphu and Langthel under Trongsa were selected as collection and drying centers for high altitude and low altitude medicinal plants respectively. The Lingshi drying centre is operated by the energy generated from 10-kilowatt (kw) micro-hydel; but since the capacity is only 10 kw, the quantity of energy generated became more and more inadequate as the collection increases. This influences the supply of both quality and quantity of traditional medicines around the country.

b) **Training on sustainable collection.** With the technical assistance from MAP, farmers are regularly trained in sustainable collection methods and good collection practices including some aspects of plant biology. The intention is to ensure long-term survival of wild populations and their associated habitats.

c) **Introduce alternative collection sites.** Lingshi has been collection centre for high altitude medicinal plants since 1967. For sustainable collection, other highlands like Gasa, Ha and Bumthang are being explored to introduce as alternative collection sites.

d) **Cultivation of Medicinal plants.** To ensure long-term sustainability of medicinal plants, farmers are encouraged in cultivation/domestication of medicinal herbs. The intention is that farmers can grow medicinal plants as a cash crop in the same manner as fruits and vegetables. For any produce in excess, a ready market already exists in India and other countries.

**Good collection practices:**

Following the WHO guidelines on good agriculture and collection practice for medicinal plants and using its outline as the basis for evaluation, the current collection practices of
Pharmaceutical and Research Unit, depending on plant parts (roots, leaves, fruits, seeds, flower, etc.) to be collected include:

a) **Permission to Collect.** The collection permits are obtained from Department of Forest, Nature Conservation Division and Park Management prior to collecting any natural resources or medicinal plants from the wild. Although the concern local communities carry out actual collection, the Unit depending on the requirements obtains the permits. If it is for export, phytosanitary certificates, export permits and CITES certificates are sought from Bhutan Agriculture and Food Regulatory Authority (BAFRA) and National Biodiversity Centre.

b) **Technical planning.** Prior to initiating a collection expedition, the annual requirements are calculated, geographical and population density of the target medicinal plants species are determined, seek collection permits and organize collection team conversant in ethnographical information, identification, etc. and comprising of quality expert and personnel for sorting, cleaning, drying, storage and bulk transportation.

c) **Selection, identification and authentication of medicinal plants.** The medicinal herbs are selected as per the traditional text and pharmacopoeia and the samples identified by traditional medicine experts according to the texts. The farmers are regularly trained in basic plant biology and identification of right species. Further, to help authenticate the species the medicinal plants herbarium has been established and quality control section assures the quality and authenticity of the collected herbs.

d) **Collection.** As far as possible, the collection practice ensures the long-term survival of wild populations by determining the population density of the target species at the collection sites. The local communities are also trained on collection of roots and barks and tools to be used. The herbs are collected during appropriate season depending on plant parts (roots, leaves, fruits, seeds, flower, etc.) to be collected and as prescribed in the traditional text. Usually the bulk collection season starts from July to September and December to February for high and low altitude medicinal plants respectively. The collected raw medicinal plants are then subjected to preliminary processing of cutting, sorting, washing and drying and are kept protected from insects, rodents and other pests before transporting to the processing unit.

e) **Personnel.** While embarking on collection task, the management ensures that the collection coordination team has adequate technical knowledge on collection process and that the local collectors have sufficient knowledge of the species targeted for collection. The team has the duty to convey awareness on protection and conservation of plant species, as well as social benefits of sustainable collection of medicinal plants. The team also has to take necessary measures to ensure safety and welfare of all personnel involved in the collection.

With farsighted vision of our leaders, we manage to keep our environment intact, if we are to reap dividend from our rich heritage, we need to take cautious developmental strides. Research in traditional medicine and natural resource base presents a great potential.
However, building leadership in research and drug development is resource and knowledge intensive activity and must accord top priority and capacity building must be given importance.

5.5. Utilization of Traditional Medicines

The number of patients using traditional medicines is steadily increasing over the years. The system is quite popular among the elder population and about 10-30% of the patients in the district hospitals are using traditional medicine. The National TM hospital in Thimphu treats about 150 – 200 patients per day in the winter and 200 – 250 patients per day in the summer months.

The annual consumption of traditional medicines for 2006 was 3828 kg out of which about 40% was consumed in the National Traditional Medicine Hospital at Thimphu. Among the 20 district hospitals, the highest consumption of TM was Paro Hospital with 429 kg followed by Punakha Hospital with 189 kg. The top 10 users of TM excluding the NTMH are as follows:

Table 6: Top 10 Users of Traditional Medicines in 2006:

<table>
<thead>
<tr>
<th>S.No.</th>
<th>TM Units</th>
<th>Amount of Medicines</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Paro Hospital</td>
<td>429 kg</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Punakha Hospital</td>
<td>189 kg</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Mongar Hospital</td>
<td>141 kg</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Trongsa Hospital</td>
<td>138 kg</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Tsimalakha Hospital</td>
<td>131 kg</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Haa Bali BHU I</td>
<td>107 kg</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Bumthang Hospital</td>
<td>99 kg</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Yebi Lapcha Hospital</td>
<td>79 kg</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Pema Gatshel Hospital</td>
<td>68 kg</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Samtse Hospital</td>
<td>65 kg</td>
<td></td>
</tr>
</tbody>
</table>

Table 7: Top 10 Consumption of Traditional Medicines in 2006

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Name of Medicines</th>
<th>Quantity</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Da-li 18</td>
<td>168 kg</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Poe-kar 10 pa</td>
<td>160 kg</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Agar -20</td>
<td>157 kg</td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Sam-nor</td>
<td>135 kg</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Do-rap</td>
<td>134 kg</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Nyi-kel</td>
<td>124 kg</td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Tas-num</td>
<td>111 kg</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>Da-shel</td>
<td>110 kg</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>Gur-gum 13</td>
<td>90 kg</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>Se-du 5 pa</td>
<td>80 kg</td>
<td></td>
</tr>
</tbody>
</table>
6. IMPACT OF WTO & TRIPS AGREEMENT ON TRM: PATENTING, LAWS GOVERNING TRM

Patent is an exclusive right granted to protect an invention, which is a product and process that provides a new way of doing something, or offers a new technical solutions to a problem. An invention must be patented by filing an application with the Registry of Industrial Property, Ministry of Trade and Industries to be granted rights conferred by a patent. Criteria for grant of patent, right of filing of patent applications, grant of patents, rights conferred by patents, duration and renewal of patents, compulsory licenses, invalidation of patents and penal provisions for infringement of patents are found in Part II of the Industrial Property Act of the Kingdom of Bhutan, 2001, which is now under revision in compliance with TRIPS Agreement of the WTO.

The call for more effective and equitable protection for traditional knowledge (TK) is a broad policy challenge. Intellectual property (IP) protection is one partial solution, but the response to this general challenge needs to go well beyond even extended and adapted concepts of IP. The response can include preserving and safeguarding TK against erosion and loss, and can involve regulations governing the environment, cultural policy, indigenous rights, and protection of sacred sites. So far as IP protection is concerned, the main options are:

- Making better use of IP rights by capacity building, administrative initiatives, and community based initiatives, and programs for better recognizing and defending traditional knowledge and cultures as legitimate and valuable IP assets of the communities that have developed them.
- Extending or adapting the conventional systems of IP rights, to include sui generic elements that are especially designed to improve the way these systems serve the particular interest of TK holders.
- Creating a distinct category of rights in TK as such through sui generis IP systems designed specially for this subject matter.

A comprehensive approach is likely to consider each of these options, and the boundaries between them are not rigid. For example, a number of conventional copyright laws also include sui generis elements for TK protection for folklore. Sui generis elements for TK protection are also being developed in trade mark and patent law.

Traditional healers could protect their TK under article 39 of TRIPS. In order to be classified as a trade secret, the knowledge needs to (a) be “secret in the sense that it is not generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the circumstances to keep it secret.”

The advantages of keeping the knowledge secret are that the protection lasts forever, no expensive applications need to be filed, the knowledge does not enter the public domain and the knowledge does not have to be new or inventive. In addition, traditional knowledge holders can make their knowledge available to interested parties. By signing a royalty
payment agreement the traditional knowledge holder(s) can earn some money while the knowledge remains secret (Ragavan, 2001). However, there is no safeguard in case others discover the secret.

The Medical & Health Council Act (2002) officially recognises practitioners of traditional medicines and defines “traditional medicines” as indigenous medicine recognised as a full-fledged branch of medical science. The director of the Institute of Traditional Medicine Services is appointed as a member of the Medical & Health Council.

The Medicines Act (2003) establishes the registration, licensing, manufacture, storage, transportation, distribution, sale, import and export of medicinal products. Article 34 (xxi) (c) defines “medicinal products” to include “any other substance or device declared by the (Bhutanese Medicines) Board to be a medicinal product or a medicine or a drug and this may belong either to modern or traditional system of medicine;” The Drugs Technical Advisory Committee not only consists of, amongst others, a qualified medical doctor, a qualified veterinary doctor, and a qualified pharmacist, but also has a Drungtsho as a member. A Drungtsho is a practitioner of traditional medicine registered under the Medical & Health Council. These arrangements reflect the importance of traditional medicines in Bhutan.

In the modern era of globalization, there are a number of international treaties and conventions related to trade in medicinal products. It is important to understand and study the risks and benefits of such treaties so as to safeguard the national interest concerning public health and ensure access to pharmaceuticals. Therefore the Government must keep the health of the public and access to pharmaceuticals in the forefront while undertaking and signing any bilateral or international treaties related to trade in health.

The Govt. shall take advantage of all the flexibilities and safeguards within the TRIPS Agreement for the promotion of public health and ensuring access to pharmaceuticals. The Ministry of Health shall collaborate with the Ministry of Trade and Industry (MTI) and other relevant agencies in the area of Intellectual Property Rights (IPR) in developing legal framework that enhances access to essential drugs including grant of compulsory licensing and parallel importation.

Traditional knowledge although being a relatively old concept is taking a new dimension in that it is being protected legally with the passing of Biodiversity Act of Bhutan 2003 by the National Assembly. Bhutan is probably one of the first countries in the region to take this step.

The Biodiversity Act 2003 is enacted for the following reasons:

- Bhutan is considered to be in the region of a biological ‘hot spot’ and has a huge base of associated traditional knowledge.
- Many research firms have expressed in ‘bioprospecting’ in Bhutan and one development avenue is to work in partnership with other countries.
• Access to biological diversity especially to foreign entities prior to the Act was largely unregulated.
• There is a need to protect against exploitation from potential partnership projects while also gaining shared benefits by allowing regulated access
• Bhutan is a party to CBD (Convention of Biological Diversity) and hopes to become a member of WTO.
7. HUMAN RESOURCE DEVELOPMENT

7.1. Existing Human Resource in Traditional Medicine

The development of human resources for traditional medicine like any other professions was accorded high priority by the Government and as a result, there is no shortage of essential staff for traditional medical services. Unlike modern medicine, all the Traditional Physicians and Traditional Clinical Assistants were trained within the country. Other essential staffs like Pharmacy Technicians and Research Assistants are also trained within the country.

However, the Traditional practitioners were unable to obtain PG degrees like Masters and PhD in traditional medicine due to placement problem in the region. For the first time in the history of Traditional Medicine, we have managed to send 2 Traditional Physicians in the beginning of this year to Mongolia Health Science University to pursue Master degree in Traditional Medicine. There is a plan to develop and introduce Master Degree programme in Traditional Medicine within the country by 2011 under the auspices of the Royal University of Bhutan.

There are mainly two categories of human resources for the provision of traditional medicine service in the country. They are Drungtsho (Traditional Physician) and sMenpa (Traditional Clinical Assistant). For the research and production of traditional medicines, human resources with scientific background like Pharmacist, Chemist, Ethno botanist, Pharmacologist, Pharmacy Technician and Research Technicians are employed.

Table 8: Current Numbers of Human Resources available for TRM services:

<table>
<thead>
<tr>
<th>S.No</th>
<th>Category</th>
<th>No.</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Traditional Physicians (Drungtsho)</td>
<td>56</td>
<td>All position levels including NITM Lecturers</td>
</tr>
<tr>
<td>2.</td>
<td>Traditional Clinical Assistant (sMenpa)</td>
<td>68</td>
<td>All position levels</td>
</tr>
<tr>
<td>3.</td>
<td>Pharmacist</td>
<td>3</td>
<td>Two position levels</td>
</tr>
<tr>
<td>4.</td>
<td>Pharmacologist</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Chemist</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>Marketing Officer</td>
<td>2</td>
<td>Two position levels</td>
</tr>
<tr>
<td>7.</td>
<td>Engineer</td>
<td>2</td>
<td>Two position levels</td>
</tr>
<tr>
<td>8.</td>
<td>Admin support staff</td>
<td>18</td>
<td>All three units</td>
</tr>
<tr>
<td>9.</td>
<td>Research Assistant</td>
<td>10</td>
<td>Two position levels</td>
</tr>
<tr>
<td>10.</td>
<td>Pharmacy Technician</td>
<td>17</td>
<td>Three position levels</td>
</tr>
<tr>
<td>11.</td>
<td>GSC staff</td>
<td>8</td>
<td>For all 3 units</td>
</tr>
<tr>
<td>12.</td>
<td>ESP staff</td>
<td>6</td>
<td>For all 3 units</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>166</td>
<td></td>
</tr>
</tbody>
</table>
7.2. Training Programmes: Syllabus, Clinical Training, Community Medicine

The National Institute of Traditional Medicine is responsible for the development of human resources for traditional medicine services. Currently, there are four regular training programmes for traditional medicine services as follows:

Table 9: Different Training Programmes

<table>
<thead>
<tr>
<th>Type of Course</th>
<th>Degree/Certificate awarded</th>
<th>Duration of course</th>
<th>Entry qualification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drungtsho (Traditional Physician)</td>
<td>Bachelor Degree</td>
<td>5 years</td>
<td>Class XII passed</td>
</tr>
<tr>
<td>Menpa (Traditional Clinical Assistant)</td>
<td>Diploma</td>
<td>3 years</td>
<td>Class X passed</td>
</tr>
<tr>
<td>Pharmacy Technician</td>
<td>Certificate</td>
<td>2 years</td>
<td>Class X passed</td>
</tr>
<tr>
<td>Research Technician</td>
<td>Certificate</td>
<td>2 Years</td>
<td>Class X passed</td>
</tr>
</tbody>
</table>

The Syllabus for Drungtsho Course

The curriculum consists of mainly four broad modules also known as four Medical Tantras in the study of Traditional medicine popularly known as gSo-ba-Rig-pa education. They are:

- **rTsa-rGyud** (Root Tantra)
- **bShed-rGyud** (Explanatory Tantra)
- **sMan-Ngag-rGud** (Secret Tantra)
- **Phyema-rGyud** (Other Tantra)

In addition to these four main subjects, they also study the following subjects:

- **Shel-gong / Shel-threng**
- **Zin-tig**
- **Tsi** (Astrology)
- **sMengi-Phen-nue Jor-dey**

Therefore, the actual curriculum consists of the following subjects:

1. **rTsa-rGyud** (root tantra)

1.1. Introduction to gSo-ba Rig-pa - This course provides the students an overview of traditional medicine, its history, origins and development. It provides a brief discussion of the gSo-ba Rig-pa education, the profession and the opportunities in the practice of traditional medicine.
1.2. **gLeng-gzhi gLeng-long** - This is a preliminary to the succeeding subjects. It also discusses the alternative treatment methods like *tsha-chu* (hot springs) and *sman-chu* (medicinal water).

1.3. **rTsa-ba gSum and sDong-`grems** - This course provides brief description on the origins of diseases, its management and treatment.

2. **bShed-rGyud** (explanatory tantra)  
   Pre-requisite: *rTsa-rGyud*

   2.1. **Grub-pa lus** - This course provides a basic understanding of human anatomy and basic principles of physiology. It also provides a detail discussion on the science of birth, living and death.

   2.2. **phel-grib ned and Bya-ba sPyod-lam** - This course deals with the detail discussion on the nature, causes and origins of the diseases. It also deals with the concept and fundamental importance of behavioral pattern in the management of conditions.

   2.3. **Tsho-wa zas and sByor-wa sman** - The course provides the detail description on the management and control of diets and its benefits. It also familiarizes the effect of four elements (Earth, Water, Fire and Wind) on 6 different types of taste.

   2.4. **Cha-byed and nGos-bzung brtag-pa** - This part covers extensively the use and requirements of different kinds of instruments for therapies and their mode of usage. It also covers as a separate part, the importance and the different methods that can be used in the diagnosis of diseases.

   2.5. **gSo-thabs and gSo-ba po** - This part covers extensively the different methods of treatment. It also covers the moral principles of practice (ethics) that governs the Drungtsho profession.

3. **sMan-Ngag-rGyud** (Pre-requisite: *rTsa-rGyud* and *bShed-rGyud*)

   3.1. **Nyes-gsum and Khong-ned** - This course intends to familiarize the students with the fundamental concepts of three humors of the bodily system namely wind, bile and phlegm. It also discusses the diseases and conditions of the abdomen region.

   3.2. **Tsha-ba, lus-Stod, Don-Snod and gSang-ned** - This course provides the detail study on the diseases of fever related, upper torso reproductive and vital organs including their aetiology and organ-system involvement.

   3.3. **Thor-ned, lhan-sKyes rMa and Byes-pa gSo-ba** - This course provides the detail study in the origin, cause and management of vascular, neural, skin diseases etc. This part also covers the study on diseases of reproductive organs, digestive system, and pediatrics.
3.4. *Mo-ned, mTshon-rma* and *Dug-ned* - This part covers the detailed study on the signs and symptoms of the gynecological diseases, cause and treatment of poisons, and wounds resulting from the accidents.

3.5. *gDon-ned, rGas-pa* and *Ro-tsa* - This part covers the study of psychotic conditions and geriatric diseases. It also discusses on rejuvenation with emphasis placed on the maintenance or normal organ systems.

4. **Phyema-rGyud** (Pre-requisite: *rTsa-rGyud, bShed-rGyud* and *sMan- Ngag-rGyud*)

   4.1. *bRtag-pa rTsa-chu* - The course deals with the principles of diagnosis particularly through Pulse reading and Urine analysis.

   4.2. *Zhi-byed sman* - The fundamental concepts of pharmaceutical dosage forms, their classification, principles and process involved are discussed. It familiarizes the student with the pre-formulation, detoxification, formulation and preparation of various dosage forms.

   4.3. *sByong-byed las.* - This course provides an overview of therapies particularly by treatment through excretion, irrigation, etc.

   4.4. *Jam-rtsub dPyed* - This part covers techniques in the wide range of therapies like blood letting, moxibustion, serkhap, cupping, hot and cold compression, herbal steaming, herbal bath, herbal massage etc.

5. **Shel-gong** (Pre-requisite: *bShed-rGyud*) - This course covers the uses and origins of precious materials, mineral and animal parts. It also provides the morphological studies, uses and diversity of herbal plants.

6. **Zin-tig** (Pre-requisite: *sMan-Ngag-rGyud*) - This part focuses mainly on the different aspects of treatment modes and methods. It also discusses the specific uses of each drug with respect to the types of diseases and the methods involved in preprocessing and formulation.

7. **Astrology**

   7.1. *byung-rtsi sNgon-‘gro* - This course provides an introduction to the astrology and intends to familiarize with the classical abbreviations used in *dha-tho*.

   7.2. *Dha-tho lde-mig* - This part discusses the method and gives detail instructions on reading and interpreting the *dha-tho*.

**sMenpa (Traditional Clinical Assistant) Course**

The *sMenpa* course is 3 years after class 10 and they receive a Diploma in traditional
medicine on successful completion of the training. The number of student intake is based on the requirements of the Health Ministry and the job is guaranteed after the training. This program is also recognized by the Bhutan Medical and Health Council. The medium of instruction is in Dzongkha and Choekye.

The Curriculum consists of:

1. **rTsa-rGyud**

1.1. Introduction to *gSo-ba Rig-Pa* - This course provides the students an overview of traditional medicine, its history, origins and development. It also provides a brief discussion of the *gSo-ba Rig-pa* education, the profession and the opportunities in the practice of traditional medicine.

1.2. *gLeng-gzhi gLeng-slong* - This is a preliminary to the succeeding subjects. It also discusses the alternative treatment methods like *tsha-chu* and *sman-chu*.

1.3. *rTsa-ba gSum* and *sDong-grems* - This course provides brief description on the origins of diseases, its management and treatment.

2. **bShed-rGyud** (Pre-requisite: *rTsa-rGyud*)

2.1. *Grub-pa lus* - This course provides a basic understanding of human anatomy and basic principles of physiology. It also provides a detail discussion on the science of birth, living and death.

2.2. *phel-grib ned* and *Bya-ba sPyod-lam* - This course deals with the detail discussion on the nature, causes and origins of the diseases. It also deals with the concept and fundamental importance of behavioral pattern in the management of conditions.

2.3. *Tsho-ba zas* and *sByor-ba sman* - The course provides the detail description on the management and control of diets and its benefits. It also familiarizes the effect of four elements (Earth, Water, Heat, Wind) on 6 different types of taste.

2.4. *Cha-byed* and *nGos-bzung brtag-pa* - This part covers extensively the use and requirements of different kinds of instruments for therapies and their mode of usage. It also covers as a separate part, the importance and the different methods that can be used in the diagnosis of diseases.

2.5. *gSo-thabs* and *gSo-ba Po* - This part covers extensively, the different methods of treatment. It also covers the moral principles of practice (ethics) that governs the *Drungtsho* profession.

3. **Phyema-rGyud** (Pre-requisite: *rTsa-rGyud, bShed-rGyud*)

3.1. *bRtag-pa rTsa-chu* - The course deals with the principles of diagnosis particularly through Pulse reading and Urine analysis.
3.2. *Zhi-byed sman* - The fundamental concepts of pharmaceutical dosage forms, their classification, principles and process involved are discussed. It familiarizes the student with the pre-formulation, detoxification, formulation and preparation of various dosage forms.

3.3. *sByong-byed las.* - This course provides an overview of therapies particularly by treatment through excretion, irrigation, etc.

3.4. *Jam-rtsub dPyed* - This part covers techniques in the wide range of therapies like blood letting, moxibustion, *ser-khap*, cupping, hot and cold compression, herbal steaming, herbal bath, herbal massage etc.

5. **Astrology**

5.1. *byung-rtsi sNgon-gro* - This course provides an introduction to the astrology and intends to familiarize with the classical abbreviations used in *dha-tho*.

5.2. *Dha-tho lde-mig* - This part discusses the method and gives detail instructions on reading and interpreting the *dha-tho*.

6. **Zintig** (summary of medical practice)

8. *sMen-jor Ni-pa Cho-gdue*

9. **Practical training**

Several years of clinical apprenticeship under close supervision and direction of eminent physicians besides strenuous study and precise knowledge about the theoretical perceptions expounded in the medical classics, form the basis for training of a traditional physician and Menpa. The existing training programs emphasize on practical and clinical teaching as an integral part of the broad curricula. The NITM collaborates with clinical departments of the NTMH and different sections of the PRU for practical training and attachment of the students.

9.1. **Clinical training**

Students are allotted three hours each in a week for practical training in NTMH and PRU. They are placed in different clinical departments of NTMH and different sections of the PRU on a rotation basis, attached with senior drungtshos and smenpas. In the initial stages they observe their mentors practicing and later begin assisting him in providing different services under strict supervision and specific instructions. This provides students with first hand experience in patient management, dispensing, application of different therapies and so forth and directly prepares him for the professional responsibilities that lie ahead. The examination board assesses practical skills at the end of the semester through practical performance and demonstration.
In PRU, the students (under the guidance of the in-house consultant: chief traditional physician) observe and assist in production, formulation, and quality control activities. More importantly, they participate in research activities, familiarizing and equipping them with new technology and new ways of thinking so that they are able to investigate, find and present the knowledge of past in a manner applicable to the present. This provides an ardent means of improving innovative capacity of the students and strengthening their ability to explore the immense potential that the BTM has to offer. It not only prepares drugtshos and smenpas to take up relevant jobs in the PRU but also enables to embark on new areas like production and quality control which traditionally was their domain.

9.2. Field visit/study

As a part of the training curriculum, students go for field trips to identify a wide range of *materia medica* and multitude of mineral springs and hot waters throughout the kingdom, demanding full time attendance. This is in direct connection to the core competencies of a traditional physician who recommends certain hot spring or mineral spring to supplement prolonged medication besides being able to identify medicinal ingredients correctly.

These add to dynamism of the programs offered by the institute, maintaining its relevance at a time when the interest and compatibility pattern of the patients are changing rapidly. It is for this reason that the programs were smoothly operated for the past many years.

Pharmacy Technician Course

The Pharmacy Technicians course is for two years after class 10 passed leading to an award of certificate on Industrial Pharmacy on successful completion. During the first year, their main subjects of training are:

1. General pharmacy with introduction to various dosage forms and their methods of preparation,
2. General chemistry,
3. Introduction to pharmacognosy with emphasis on the history, source, and collection of animal and vegetable drugs,
4. Botany, and
5. *gSo-ba Rig-pa*
6. Practical on pharmaceutics.

The subjects during the second year are:

1. Pharmaceutics encompassing physical pharmacy, dosage forms, dosage design, posology, drug delivery and all the production processes
2. Good manufacturing practices
3. Quality assurance,
4. Relevant analytical and plant chemistry,
5. Introduction to pharmacology with emphasis on therapeutics,
6. Introduction to bio-pharmaceutics with emphasis on pharmacokinetics and pharmacodynamics,
7. Pharmacognosy with emphasis on distribution, commerce, identification, composition and preservation of animal and vegetable drugs, and
8. gSo-ba Rig-pa besides practical on pharmaceutics.

The two year course of Pharmacy technician specializing in the production therefore requires skills in three major areas:

1. First area is gSo-ba-rig-pa, which requires understanding of the raw materials used in preparations of medicinal products of the Traditional System of medicine. Understanding of pre-processing methods required for purification, detoxification, and modulation of the above raw materials and understanding the compounds manufactured at the premises and the dosage forms they are presented in.

2. The second area of understanding is related to the skills in Pharmaceutics which requires from the trainee to understand the dosage form design i.e. intricate methods in development and production of dosage forms like tablets, pills, capsules, ointments, medicated oils, emulsions, syrups etc. In addition this area requires the trainee to understand the technology involved in the production of all these dosage forms.

3. The third important area of understanding is the requirement of Good Manufacturing Practice for pharmaceutical manufacturers. This is an area that ensures safety, hygiene, controlled production, quality control etc. The principles of GMP and rules and regulations implemented through following these principles are of priceless value in achieving the required quality of the product that claims to be a medicine.

In order to create a comprehensive syllabus to enable the trainee to acquire all the relevant skills and knowledge, the curriculum has been prepared in reference to the 3 years course for Pharmacy Assistant offered elsewhere in the world and in consultation with NITM lecturers and draft version of the training programs prepared during the EC project.

Research Technician Course

The Research Technicians course is for two years after class 10 leading to an award of Certificate in QC and Research.

The Research technicians undergo same theoretical training as Pharmacy technicians by introducing additional subjects like:

1. General Chemistry
2. Ethno Botany
3. Plant Chemistry
4. Introduction to Pharmacology
5. Introduction to Biopharmaceutics
6. Production processes
7. Quality Control
8. Laboratory Research.

Their on the job guided and supervised trainings are focused on quality control and research activities.

8.3. Special Therapeutic Procedures

Therapies are primarily classified into two viz. non-invasive and invasive. Non-invasive therapies include fomentation; medicated bath; and massage, whereas blood-letting and cauterization constitutes invasive category. Combination of both is popularly known as pchyyed-nga or 5 therapies which are known as panchakarma in Ayurveda system.

*Ser-khab or golden needle therapy*

It is the most popular form of cauterization used today. Golden needle measuring 3-4 cm in length and an average diameter of 1 mm, with a careful twist on the distal end for holding moxa, is heated red hot and applied on identified points without inserting deep in to the derma. The process begins with a prayer to the pantheon of medical deities; followed by recitation of medicine Buddha mantra. Different points correspond to different diseases and the degree of heat applied varies accordingly.

Excess cauterization on channels, tendons and etc. can cause paralysis and obstruction in the passage of rlung. Keeping the heated cauterizing agent for too long on the skin can cause severe burns.

Less or inadequate heat on the other hand will display no therapeutic efficacy. Therefore, care is taken to optimize the intensity of the heat and time of application.

It is indicated for: indigestion, dropsy, gouts, rheumatic arthritis, lymphatic disorders, epilepsy, insanity, neurological disorders, tumors associated with cold disorders, mkhrispa associated with cold, malignant tumors, Inflammation associated with throat and muscles, and Inflammation associated with rlung and almost all type of cold disorders.

It is not advisable for patients with hot diseases associated with blood and mkhripas. It is avoided on: eyeballs, auditory canal, tip of the nose, on and around genital organs, on six hollow organs right after a meal. However, it’s possible after a minimum of two hours after the intake of meal.

It is also avoided during rain and snowfalls, which can nullify the effect of heat energy, produced by cauterization and expose the wounds to infection. Different date, day and time are inauspicious for cauterization at different points of the body. This is because of the constantly moving life force. Therapies of any kind should be avoided on the latent location of the life force.
8.3.2. **Nyul-khab or silver needle therapy**

All the general considerations including shape and size of the needle; point and time of application etc. remain same as that of golden needle therapy except for the material of the needle which is pure silver.

Both the golden and the silver needles are said to have similar therapeutic efficacies and thus they are often applied to supplement one another. However the later is specially indicated for: lymphatic disorders, abscesses, dermatitis, wounds and swelling, whereas the former is more effective for diseases involving the different channels and the nervous system.

8.3.3. **Me-btsa or moxibustion**

The leaf of *tra-wa* (*Leontopodium leotopodioides* (Wild.) Beauv.) is properly thrashed with a stick to remove impurities. It is then kneaded with ashes prepared out of burnt nettle leaves. The mixture is rolled in a traditional paper to form a shape that is narrower at the two distal ends and broader in the centre so that slicing it in the middle with a sharp blade produces two small cones of moxa. Size and number of moxa (which decides the amount of heat) depends on the nature of diseases and their corresponding points.

The cone is properly placed on the identified point with help of garlic paste. Fire is then ignited on the tip of the cone and allowed to burn gradually towards the base. If three or five cones are used at a time, then the cone on the principle point is first ignited and the next cone is ignited when 1/3 of the first cone is burnt. The same follows for rest of the cones.

When the combustion comes to an end, the remains are gently blown using an arrow sized bamboo tube and a set of post moxibustion observances are prescribed.

Similar to golden needle therapy, it is indicated for: indigestion, dropsy, gouts, rheumatic arthritis, lymphatic disorders, epilepsy, insanity, neurological disorders, tumors associated with cold disorders, *mkhrispa* associated with cold, malignant tumors, inflammation associated with throat and muscles, and inflammation associated with *rlung* and almost all type of cold disorders.

It is not advisable for patients with *tsha-ba* or hot diseases; on eyeballs, auditory canal, tip of the nose, on and around genital organs, and on six hollow organs right after a meal. It is also avoided during rain and snowfalls; inauspicious date; day; and time as decided by the latent position of the constantly moving life force.

8.3.4. **Snun-tshug or heated oil cauterization**

Powder of nutmeg (*Myristica ficafragrans* Hount) and *sgo-ned* (*Carum carvi* L.) is wrapped in a cloth piece and then heated in an oil bath of *til*. It is then applied on the identified points.
It is indicated for: fainting, paralysis, giddiness, movement of heart, insomnia and disturbing sound in the ears and all types of rlung diseases.

8.3.5. **Gtar or bloodletting**

The gyud zshi classifies blood-letting into the following four types:

i) blood-letting with a lancet

ii) blood-letting through cupping and

iii) blood-letting with animal horn

iv) using leeches for blood-letting (not discussed as it is no more extant)

Following are the general therapeutic actions of successful blood-letting:

- clearances of infected blood
- recovery of illness related to channels
- reduces pain and swelling
- drain out accumulation of pus and dries up other morbid lymphatic accumulations.
- emaciated gains body mass
- decreases obesity

**a) Blood-letting with a lancet: Incision**

A tsag-bu or sharp edged instrument is used to incise the identified blood vessel. Different decoction is prescribed for different diseases 3 days prior to the day of actual blood-letting. A tourniquet is used near (usually above) the point of venesection. The marked blood vessel softly massaged till it becomes tight and bulged, ensuring proper flow of infected blood.

The identified blood vessel is gently pressed with the physicians’ left thumb and slightly pushed downwards. These are five different methods of incision:

i) glo-phug or puncturing/ piercing

ii) sgang- gshags or vertical incision

iii) dol-chod or horizontal incision

iv) myi-len or incision by hooking

v) smyug-kha or slanting incision

Quantity of blood oozed out is variable according to the seriousness of the disease and overall health of the patient. In general, blood flow is stopped when the normal blood begins to flow.

The indications are: traumatic fever (grams-tshed), disturbed fever (khrugs-tshed), infections, swelling, wounds, gout, rounded red rash on the skin associated with sores on specific organs, erysipelas, abscesses, leprosy, and disorders of liver, pancreas, eye, head and in general, all the hot diseases caused by imbalance of blood and mkhripas.

It is not advisable for: diseases influenced by evil spirits, emaciated, expecting mother. Post-natal period, dropsy, chronic metabolic disorder resulting in wasting of bodily
constituents, low power of digestion, cold diseases arising as a result of *bad-kan, rlung*, old age, children below 16, amnesia, exhausted by work and stress, and right after application of eliminating therapies like purgatives, emetics, nasal irrigation and etc.

Blood-letting is avoided on vital spots of the body; auspicious days as predicated through astrological calculations; and latent spot of the life force.

**b) me-bum or cupping**

Cupping is often used for blood-letting. As this procedure, involves some bleeding, the same general consideration and precautions as per blood-letting apply.

The cupping jar is made of copper, glass and such other materials. It is 16 *sors* (length equal to the breadth of a finger) in circumference and 10 *sors* in height; its mouth is narrower with 4 *sors* in diameter. The size and shape can also vary according to the different points of cupping. In absence of a proper cupping jar, other containers of same shape and size can improvise it.

After having exposed the part for cupping (normally a fleshy, and not a bony one), a piece of paper is burnt inside the cup. The amount of cupping is decided by the pain, point of cupping and overall fitness of the patient. However, prolonged cupping and the fire involved can produce ulcers on the skin.

Indications: Girdle pain and pain in the thoracic region due to aggravation of *mkhripas, rlung* and neurological failures. External tumors and boils. Pain in the chest, ribs and spinal columns and heavy breathing due to trauma

**c) ra-jib or cupping with horn**

White and soft horns (right horn) of yak (*Bos grunniens Linnaeus*) and oxen are used to prepare cupping horn. It is five *sors* in length and its mouth is 2-3 *sors* in circumference with a soft tip having a hole of the size of a mustard seed. The tip is connected to flexible tube which is in turn is connected to a syringe.

The process begins with recitation of special mantra for 100times. The point is carefully selected and disinfected. Cupping horn is then applied on the point with its base on the skin. The syringe is pulled for about 5-10minutes. Then the horn is removed and the raised point is incised at five points and the horn is applied once again to suck the blood. It is indicated for: arthritis and rheumatism, painful swelling of joints, distraction of joints due to trauma, abscesses, and painful points at which cupping is inapplicable

Cupping horn is strictly prohibited in infectious swelling, ulcers in initial stages, and excess of hot energy and phantom tumors caused by wounds. The wounds produced during the process should be treated carefully. If the pain doesn’t respond to a single cupping, then it is repeated for couple of times.
8.3.6. *chu-lum* or medicated bath

Whole or part of the body is dipped in a tub containing water at 30-45 degree Celsius. The ingredients used in this therapy (and the fomentation discussed below) primarily consists of five herbs known as *bdued tsi-nga* or the five ambrosia:

1) *shuk-pa* (*Cupressus torulosa D. Don*)
2) *wom-bu* (*Myricaria prostrata et. Hook.*f)
3) *mishey-dhum* (*Ephedra saxatilis Royle*)
4) *mkhen-kar* (*Artemisia vularis L.*)
5) *dali* (*Rhododendron anthropogonoides maxim*)

They are roughly grounded and boiled in water for 4-5 hours along with other specific subsidiary ingredients. After that it is thoroughly mixed with suitable amount of yeast and then allowed to ferment in an airtight container at normal room temperature. The mixture becomes ready in a month’s time. 100-200 grams of the mixture is added in a bath tub containing 60 litres of hot water. The time of bath varies from 15-30 minutes depending on the general condition of the person and the latent state of disease. Water is removed and fresh water and new dose of mixture is again added for the next patient. Herbal bath and steam bath is the most popular traditional therapy next to golden needle cauterization among the general Bhutanese.

This is recommended for paralysis, chronic ulcers, *rlun* disorders; stiffness of joints and so forth. It is contraindicated for fevers, dropsy at the initial stages, hypertension, giddiness; infection; emaciated; loss of appetite and etc.

8.3.7. *rlang-lum* or steam bath

The medicinal mixture containing around 37 herbal ingredients are boiled with help of electric heaters beneath a bed with many square holes which is covered with clean linen. The patient lies freely with help of a pillow and a clean towel covering the entire body which ensures proper fomentation with minimum escape of steam. Each patient takes around 15-30 minutes.

This also induces perspiration which is an effective therapy for elimination of *mkhrispa* (and most of the hot disorders). This is generally recommended for back pain; general body fatigue; paralysis; both chronic and obstinate skin diseases; swelling; stiffness of joints and so forth. However it is contraindicated for odema; infection; emaciated; and loss of appetite.

8.3.8. *rlang-dhug* or steam fomentation

It is a localized fomentation where the steam is focused on particular point of ailment with help of an insulated pipe attached to the nozzle of a pressure cooker.
It is popular for gouts and arthritis, sinusitis (as a preliminary therapy for nasal irrigation); fractures; muscle fatigue; *bad-rlun*; indigestion; colic pain; abscesses and etc. It is contraindicated for conditions like dropsy; edema; jaundice; leprosy; and obesity.

8.4. **Acupuncture**

The Acupuncture was not practiced in Bhutan till 2005 due to lack of practical skills among the traditional practitioners. One Japanese Acupuncturist was appointed in 2005 on a contract basis in the National Traditional Medicine Hospital at Thimphu. During his 2 years service in Bhutan, he has trained one national counterpart and she is able to provide basic acupuncture treatment to the people. Acupuncture treatment is very popular and the Unit treats about 15 – 20 patients every day. There is a plan to incorporate acupuncture subject in the training curriculum for the Drungtshos and sMenpas following the WHO guidelines.

8.5. **Panchakarma**

Although, the Panchakarma known as *sPyad-*nGa in *gSo-*ba *Rig-*pa was part of the system, it was not practiced widely in Bhutan due lack of practical skills among the traditional practitioners. In 2006, a group of 5 Traditional Physicians were sent to Jamnagar in India for training in Panchakarma with the main objectives of reviving and strengthening the panchakarma services in Bhutan for the benefit of the people.

8.6. **Yoga**

Although, some form of Buddhist meditation with visualization of Medicine Buddha and other deities and recitations of mantras are advised as a means of healing process, yoga is not widely practiced in Bhutan at present.
9. RESEARCH AND DEVELOPMENT

9.1. Organization of Research

Small scale research works on the Bhutanese traditional medicine was started since 1988 with the financial and technical assistance from an Italian NGO called DISVI to initiate scientific validation of the traditional medicines. In 1994, EC MPP phase I came in, and the research and production sections were merged under one Unit and was renamed as Pharmaceutical and Research Unit (PRU). The Research section under the PRU has four main research areas and each section is responsible for performing their specific task and also to collectively contribute to the research on Pharmaceutical products and scientific validation of traditional drugs and medicinal plants:

i. **Ethnobotany**: Standardization of botanical nomenclature and the documentation of ethno-medicine.
ii. **Pharmacognosy**: Macroscopy and microscopy analysis of crude materials.
iii. **Medicinal Chemistry**: Screening of phytochemicals and identification of bioactive molecules.
iv. **Pharmacology**: Clinical validation of gSo-ba Rig-pa’s therapeutic claim.
v. **Instrumentation**: Instrumental analysis and analytical investigation of raw materials and finished products using HPLC, UV spectrometry and Densitometry.

However, lack of adequate logistic and budgetary support compounded by lack of strategic planning and proper guidelines have led to the slackening of research activities despite much effort. Thus, to facilitate and enhance research and development activities at ITMS, Traditional Medicine Research and Development Committee (TMRDC) has been established in July 2005, with the main objectives to:

a) Preserve the unique system of health care based on gSo-ba Rig-pa.
b) Improve the quality of Traditional Medicine Services through appropriate research and development activities.
c) Streamline research activities and their management for better results and its application.
d) Achieve excellence in Traditional Medical Services through Innovation and Research.

Today, research on traditional medicines has become increasingly important as the drug regulatory authorities in different countries are introducing stringent regulatory mechanisms which even threaten the existence of the traditional medicine. Questions on efficacy, quality and safety have put pressure on the need to do research on traditional medicines.

Research on traditional medicines has a great potential in discovering new drugs and understanding new mechanism of drug actions. Many drugs used in treating life threatening diseases have been discovered starting from the indigenous knowledge and practices. Thus, one could in a way argue that traditional medicine is the father of modern medicine.
There are numerous areas of research that would not only help clear the wrong perceptions about the traditional medicine, but also help it to find its place in the modern days. There is a need to clear the doubts of the scientific community on the safety and efficacy. Research can also help in ensuring the sustainability and continuity of the traditional medicines. Researchers must look at the various areas of research – both at the utilization of the resources as well at ways of sustaining this age-old healing tradition through the cultivation of the medicinal plants. Through research we must also learn to formulate the remedies for the prevailing diseases and look for remedies of the newly emerging diseases.

Some of the research areas can be summarized as follows:

a) **Ethno-pharmacology** – traditional medicines as a source to drug discovery, new drug leads. A good and effective drug could be developed by just starting research on the traditional knowledge on use and treatment.

b) **Clinical trials to evaluate and confirm treatment and therapeutic efficacy.** Research could determine whether the formulations are effective against diseases and also determine therapeutic interval and doses, thus helping to ensure the safety.

c) **Toxicity (heavy metal contents and microbial contamination) and stability studies.** These studies will help to ensure the safety of the products.

d) **Biological and agriculture research for preserving the plant species used in the traditional medicines.** Knowledge on the identification not supported by the proper knowledge on the collection and cultivation can lead to depletion as a result of unscrupulous harvesting. Research can determine the endangered species and look at cultivation or domestication and propagation in the wild.

e) **Research on the substitution of one species of plants with another and formulation of different combinations and remedies.** Such studies could help ensure sustainability as well as to protect the endangered animals or plants. This can be achieved jointly with the expertise of the traditional physicians and the modern day scientific approach.

f) **Translation of the existing gso-ba rig-pa texts into languages that can be easily understood by the youth and foreigners.** This could also include documentation of knowledge that is not published but orally communicated from generations to generations.

g) **Studies on ethno-medical practices.** Such kind of studies could help to identify healing practices that are unique to a locality from where different medicinal plants could be identified. It will not only be an opportunity to document and protect the best practices to enrich the formal system but also to correct and regulate the unsafe practices.

h) **Standardization and building quality parameters of the formulations.** This includes doing botanical standardization as well as pharmacognostical studies. This will help to build Monographs and ensure the quality and safety of the products.

i) **Product development** – this is another area where the natural products could be developed as a means to sustain the research on traditional medicines. Product development will help to utilize the resources without compromising the conservation and sustainability of resources in the wild.
j) **Studies on the benefits and curing properties of various hot springs.** Such studies would help to come up with indications for different hot springs.

Research on traditional medicines is not easy as it is thought to be. Researchers understand the vastness and immensity of scope but cannot easily reap the fruits. It is challenging and demands a lot of resources. It is complex and time consuming due to the multi-ingredient nature of the formulations. Difficulties are faced in defining quality parameters for traditional medicines.

Some of the challenges can be summarized as follows:

**Limited expertise:** Expertise in the area of research in traditional medicines is limited. The researcher must not only be equipped with knowledge and expertise on the modern research but should be equally equipped with knowledge on traditional medicines. In fact, the researcher should know how to blend the modern knowledge with the ancient practice and wisdom. At times it is difficult to come at a point of agreement between the two schools of thought - modern versus ancient thinking.

**High costs:** Machines are costly and breakdown possibility is high due to the properties of the materials used. One common feeling is that we always tend to expect more output on time when there is bigger investment. If there is a mismatch there are doubts and queries on the performance.

**Complexity of method of study:** Evaluation study designs are not suitable in traditional medicines. Researchers argue that research protocols that distort the therapeutic relationship between patient and physician cannot fairly evaluate the effectiveness of traditional medical systems. To fairly test the efficacy of traditional medicine, we must make sure that the treatments that are evaluated are the best that traditional medicine has to offer. But that will not be the case if our research design interferes in the relationship between the traditional doctors and their patients.

It is suggested that an observational study would be more appropriate than the standard experimental clinical trial in the initial phases of studying traditional medicine. In traditional medical system as treatment ranges from the spiritual wellbeing and dietary and other psychological and spiritual aspects of healing, it would be difficult to assess the efficacy of the traditional medicines. The results of the study could at times be misleading thus disturbing the harmony of the system within the healthcare system.

**Uncertainty in toxicity studies:** It is difficult to evaluate toxic substances used in traditional medicines. While the toxicity of the individual metal/substances is understood, it is difficult to assess how the toxicity of this metal/substance is reduced when it is used in a combination with so many other ingredients. Example Aconitum although very poisonous in nature does not exhibit its properties when used in the formulation in combination. This could be because one or more other ingredients in the formulation could be neutralizing the toxic effects of other substances in the formulation.
Difficult stability studies: Unlike in allopathic formulations where the expiry dates are fixed on the basis of stability of the principal or active ingredients, it is difficult in the case of the traditional medicines where the formulations contain more than one ingredient and the principal ingredients are not known.

Complexity in building quality parameters: The parameters built as of today are mostly qualitative and not quantitative. In most of the materials where the principal active molecule is unknown, it is difficult to quantify.

Inappropriate environment for in-vivo studies: Conducting studies on animals in an environment where there is a strong culture of respect for animals is not easy. It is not possible to convince and involve a Drungtsho in research as he is a practitioner of gso-ba rig-pa that has so much to do with Buddhism and is not in favor of killing animals, thus limiting the scope of animal research.

IPR and patent issues – if research is to be given due recognition and consideration, there is a need to patent the findings and publications. But the amount of money required is huge and there is presently not adequate infrastructure and facilities in place. The process is complex and awareness on patenting and registration of products is low. It is important to encourage patent registration of traditional and community knowledge products and processes to protect the existing knowledge.

Due respect and attention should be given to local healers and herbalists to promote discovery and invention based on traditional knowledge and practices.

There are high risks of contamination of the traditional medicine with western influences when both are researched and practiced together side by side resulting in the loss of knowledge and tradition over the time. For example, a traditional physician using a sphygmomanometer to read the blood pressure of a patient rather than pulse reading which has so many parameters to consider. Such practices have high possibilities of diluting or contaminating the original practices in the ancient science of healing.

Risk in bio-prospecting - risk of overexploitation of the resource itself as scarcity of the resources and danger of extinction may not necessarily be considered due to certain vested interests by different parties.

Lack of adequate research facilities within the country. There is no research institution in the country that could closely work with the ITMS/PRU and cater to its needs.

High costs for institutional linkages – there would be costs to be shared and the cost of losing the traditional knowledge and expertise is quite high if necessary measures are not put in place.

9.2. Policy Issues

The research policy relates to the policy of the Ministry of Health and any resolutions that are related to policy issues are discussed and decided by the TMRDC which is the highest body in terms of research in traditional medicine in Bhutan.
The broad policy statement of traditional medicine research is “to merge traditional medical system with modern science and technologies through protection of intellectual property rights, so as to facilitate the provision of good quality traditional medicine as well as supplementary herbal products”

9.3. Infrastructure of Research Facilities

Currently, PRU has few incomplete sets of equipment under each research area. Phytochemistry section shares the basic general equipment like oil extractor, water bath, pH meter, UV lamp and glass wares with other sections. Major equipments like HPLC and UV spectrometer that can do qualitative analysis of phytochemicals including major chemical group identification, provided the standards of the chemicals are available in-house, can be also shared by other sections. Other basic equipments includes preparatory plate chromatography preparator, rotary evaporator, high vacuum pump evaporator, sintered funnel attached to suction pump, melting point and boiling point apparatus (Reichert hot-stage) and digital polarimeter.

These equipments are very essentials for extraction and determining melting point and boiling point of the phytochemicals and are not expensive. Therefore, first initiative of R&D section shall be to establish these basic equipments. However, having these basic equipments doesn’t lead the research anywhere because extraction is followed by another sequential phytochemical screening process called isolation, fractionation, structure elucidation and identification. For these activities, advance equipments such as IR, AS, MS, GCMS, NMR, X-ray Crystallography and 3-Dimension Computer Modeling are required. We will not afford to buy such equipments, which also need trained and experienced researchers in operating and analyzing their data. These equipments shall be outsourced through collaborating initiatives.

Pharmacology section has the basic equipments like Microbiological Incubator, Autoclave, Centrifuge, Fridge and Oven. The equipments available in this section are also incomplete. As animal testing is not feasible, a basic in-vitro screening laboratory shall be established at first. Complete in-vitro laboratory would require Laminar Flow Hood, Spectrophotometer with micro-plate reader (24 wells and 96 wells plate reader), Inverted Phase contrast Microscope, Fluorescence microscope, Standard established cell lines, Liquefied Nitrogen Tank, Cell culture flasks, Micro filtration unit for cell culture, Cell medium, CO2 Incubator for cell culture, Manual/Automated cell counter, Gel Electrophoresis, Gel documentation apparatus, Analytical/Statistical software, Cytometer, Class II Biohazard Cabinet, Vacuum pump, Refrigerator and Freezer, Sterilizer, Micro-carriers, and Microscope. These sets of equipments could be bought under the EU MPP II Project.

Botany and Pharmacognosy section has the equipments like Microtome (section cutting), Lab furnace (total ash value determination), Microscopes (visualization of cells). It is included in the investment plan to buy basic equipments like Fine and Course abrasive (Leica/Reichart) and Conventional knife (12cm and 16 cm) equipments but MSP cannot afford to buy SEM (Scanning Electron microscope) at present. Those works requiring the use of SEM shall be outsourced.
9.4. Human Resource Development for Research

Another important component is human resource development, which is the key index of the standard, quality and safety of the research works. Without development of human resources and updating their skills time to time, Research and Development of the Pharmaceutical and Research Unit will remain stagnant.

Currently, R&D of the PRU has 8 staff. Three of them are Senior Research Assistant who has diploma certificate in research assistantship, three are Research Technicians who has certificate in Bhutanese traditional medicine and two are Senior Research Officers who has master degrees in pharmacology and phytochemistry. Three Senior Research Assistants have been further trained one year each in the field of pharmacognosy, ethno-botany and instrumental analysis.

However, their skills need to be updated urgently and also they should be urgently oriented on research methodology, occupational health and safety and good laboratory practice which could capacitate them in proposal writing, data collection techniques and produce quality work ensuring safety research environment.

For example, Chemist for undergoing specialization would focus the study on selected unstudied medicinal plants (20 medicinal plants are already identified as unexplored) where he/she would do extraction, purification, structure elucidation and identification of bioactive molecules in the outside university. Doing the above research would solve many issues i.e. once the above activity is done one can easily build quality parameters using the identified marker compounds, build product certificates and standardize raw materials, finished products, formularies and extracts. Doing this research would also scientifically validate the gSo-ba Rig-pa medical claim thus strengthening the Bhutanese traditional medicine.

Similarly, Pharmacologist would focus his study on finished goods as well as raw materials and conduct clinical testing while out for the training courses and Pharmacognosist would focus on selected unstudied medicinal plants and conduct microscopical studies. All in all, research is such that they are interconnected and one thing is certain that one person cannot have know-how on all the fields mentioned here. Thus, there is need for training Research Staff in different fields.

Clinical trials, safety and efficacy

Given the budgetary constraints compounded by lack of advanced necessary research facilities and technical expertise, not much work has been done in regard to clinical trials. However, there are few phyto-chemical and bioactivity studies done on selected materials. Biological activity studies conducted so far in ITMS are as follows:

1. Antibacterial and antimicotic test for 20 medicinal plants in 1992
2. Antidiabetic test for Young-was bzhi-thang (product) in 1994
3. Antidiabetic test on Brassica juncea in 1994
5. Delphenium brunonianum and its validity as a substitute of Musk in 1995
6. Invitro anti malarial and bacterial activity studies on Aconitum orochryseum and Corydalis gerdæ, in 2004

Antimicrobial screening of medicinal plants extracts and traditional drug compounds could be initiated at PRU. The immediate action plan is to establish an in-vitro screening lab. in the PRU with the help of a TA, so that primary screening models are established and studies initied in the PRU. Establishment of in vitro lab would greatly contribute to the scientific validation of traditional medicines and product development. It will also enable the PRU to set quality parameters such as determining microbes, setting and monitoring microbial limits, identification and study of microbes present in the raw materials and products, and to assess the pathogenicity and toxicity of the microbes present.

For any drug research, the core component is the pre-clinical and clinical studies. Such studies will tell us quantitatively how effective our formulations are. It will also help us to explain the probable mechanism of action. Without accruing proper pre-clinical data with accepted protocols, we cannot move on to clinical phase of studies and without clinical data, population willing to accept our formulation may dwindle with time.
10. INTERNATIONAL COLLABORATION

10.1. WHO collaboration in TRM

Since 1982, the WHO has been providing technical and financial assistance for the development of traditional medicine services in Bhutan. A short term consultant (STC) was provided in 1983 to develop traditional medicine formulary and in 1995, another consultant was fielded-in for the development of Medium Term Programme for development of traditional medicine in Bhutan. The WHO has also provided different machines and equipment for the production of traditional medicines.

Some traditional practitioners have participated in some Regional and International Meetings with WHO support from time to time. The WHO has also provided fellowships for study tour of traditional practitioners to regional countries. Since 1995, the WHO has supported the traditional medicine programme for specific activities like conducting annual traditional medicine conference, supply of equipment and reference books, in-service training workshops and survey of medicinal plants, through inclusion in their biennium budget on a regular basis.

There is a need to develop a long term master plan for traditional medicine programme with technical support from WHO.

Table: WHO Biennium Budget for Traditional Medicine

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Biennium</th>
<th>Regular Budget (USD)</th>
<th>Activity components</th>
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</tr>
<tr>
<td>2.</td>
<td>1998 – 1999</td>
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</tr>
<tr>
<td>3.</td>
<td>2000 – 2001</td>
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<td>4.</td>
<td>2002 – 2003</td>
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<td>FEL and S&amp;E</td>
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<td>5.</td>
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<td>LCS, APW and S&amp;E</td>
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<td>6.</td>
<td>2006 – 2007</td>
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<td>APW, LCS and S&amp;E</td>
</tr>
<tr>
<td>7.</td>
<td>2007 - 2008</td>
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</table>

10.2. Bilateral Collaboration in TRM

In 1988, an Italian NGO named DISVI was involved in supporting indigenous hospital in Thimphu by constructing some infrastructure and carrying out research on medicinal plants. These facilities included a laboratory, outpatient department, hostel and a library for training. It has made possible for the introduction of modern scientific methods into practices of traditional medicine. Plants and other materials used in medicinal formula were tested for their chemical and pharmaceutical contents. Over the next four years, National Institute of Traditional Medicine (NITM) was established with support from DISVI. NITM as the centre for development of traditional medicine became a base for future development of traditional medicine, whose activities range from training to research, production of medicine and treatment of patients.
The Ministry of Health has signed an MOU with the Health Sciences University of Mongolia in 2006 for placement of Drungtshos for the Master degree programme in traditional medicine and also for institutional linkages. The possibilities are also being explored for establishing linkages with traditional medical institutes in Tibet for similar purpose.

10.3. Multilateral / Regional Collaboration: ASEAN, SAARC

Although, there are no specific programmes on traditional medicines, the regional bodies like SAARC have from time to time included traditional medicine as one of the agenda for meetings. For example, the first SAARC Health Ministers Meeting in New Delhi in 2005 discussed the need for collaboration and cooperation in traditional medicine among the regional countries. Bhutan is also considered as a member of the BIMSTEC network for traditional medicine development

Unlike modern medicine and public health programmes, the traditional medicine system has received least attention of the international donors except few organizations like WHO and EC. The EC project, both during the first and second phase concentrated mainly for the cultivation of medicinal plants and development of pharmaceutical unit. The much needed support for the development of traditional medicine education programmes and the provision of traditional medical services in the country remained unaddressed.
11. FUTURE TRENDS IN THE GROWTH AND DEVELOPMENT OF TRM IN THE COUNTRY

The traditional medicine system in this country has come a long way since its inception in 1968 due to strong political commitment of the Royal Government of Bhutan. It is one of the most sustainable methods for the health care delivery system, as all traditional medicines are manufactured in Bhutan, and the human resources are developed within the country.

The Traditional Medicine Services in Bhutan is fully integrated with modern health care delivery system and is available in all 20 district hospitals. There is a plan to establish Traditional Medicine Units in all Basic Health Units in the country. This change of Government policy would require heavy investment in the traditional medicine services for the development of human resources and for the production of traditional medicines. Currently, the Institute does not have a separate teaching and academic block and there is no scope to increase the number of enrollment for Drungtsho and sMenpa training. The production capacity of the Pharmaceutical and Research Unit also needs to be upgraded in terms of raw material collections, production machines and materials and space to meet the growing demand of Traditional Medicines. The National Traditional Medicine Hospital does not have adequate space for the providing different therapies.

The future challenges are to develop appropriate infrastructure for all 3 Units under the ITMS and to improve the quality of services through research and development programmes. There is also a need to develop Master Degree Programme in Traditional Medicine within the country with the help of experts from WHO and other organisations under the auspices of the Royal University of Bhutan and the Ministry of Health.
APPENDICES:

1. TRM: Country map indication TRM centres
### 2. Human Resources in TRM: Categories and Number:

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**NRH** = National Referral Hospital (National Traditional Medicine Hospital)

**RH** = Regional Hospital

**DH** = District Hospital

**BHU** = Basic Health Unit

**References:**

1. BMHC (2005) Bhutan Medical and Health Council Regulations, Thimphu
4. ITMS (2005) An Introduction to Traditional Medicine Services in Bhutan
8. Men-tse-khang (2001) Fundamentals of Tibetan Medicine, Dharamsala, HP India