

**SCOPING PAPER No. 1, April 2018**

# China's Policy Initiatives for National and Global Promotion of TCM



FITM acknowledges with thanks the support and guidance of the Ministry of AYUSH for undertaking this study.

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*Published : April 2018*



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**विकासशील देशों की अनुसंधान एवं सूचना प्रणाली**

Core IV-B, Fourth Floor, India Habitat Centre,  
Lodhi Road, New Delhi-110 003, India  
Ph.: +91-11-24682177-80, Fax: +91-11-24682173-74  
E-mail: [dgoffice@ris.org.in](mailto:dgoffice@ris.org.in)  
Website: [www.ris.org.in](http://www.ris.org.in)

SCOPING PAPER

# China's Policy Initiatives for National and Global Promotion of TCM

This series of Scoping Papers presents a brief outline of major components of the studies FITM undertakes.

This Paper touches upon the nature of TCM, the industry related to it and the legislations and policies for domestic and global promotion of TCM. In the Study these will be analysed with reference to Indian Traditional Medicines (ITMs) in detail.

Through a comparative analysis with China on emerging issues in the Traditional Medicine (TM) sector, inter-linkages within the sector, and cross border dimensions, the Study aims to assess the various actors/components in the ITM sector towards inputs for policy interventions and dissemination of related programmes.

## Context

China's Traditional Medicine system has witnessed substantial growth domestically and internationally. Of the 520 essential medicines in China, 203 are Traditional Chinese Medicine (TCM) products.<sup>1</sup> TCM industry is lately valued over 786 billion RMB (about \$121 billion); almost 30 times higher than 20 years earlier, and approximately, one-third of the total medicine industry in China.<sup>2</sup> The "Healthy China 2030" plan estimates that the value of the TCM market may reach 5 trillion RMB by 2030 (US\$ 737.9 billion).<sup>3</sup> TCM forms an important feature of China's

public health system, where it is an important part of the ongoing government policy development, both in terms of medicinal products and hospital/physician practice; this is covered by China's health reimbursement system, including doctor's visits. China is also promoting global outreach of the TCM use to foster domestic economic development. Trade in Chinese medicinal products has consistently maintained a rapid growth, and the export value of Chinese medicines in 2015 was US\$3.72 billion. Frost & Sullivan estimate that the segment would continue to expand rapidly and deliver an 8.2 per cent compound annual growth rate

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\* Prepared by Prof. T.C. James, Visiting Fellow, RIS and Dr. Namrata Pathak, Research Associate, RIS

(CAGR) in sales during 2016-20.<sup>4</sup> TCM education and treatment is also increasingly becoming a part of medical treatment in many countries.

Systematic planning and implementation of the programmes have ensured this outreach of TCM. A White Paper on the Development of Traditional Chinese Medicine in China brought out by China's State Council Information Service in December 2016<sup>5</sup> states that by 2020 every Chinese citizen will have access to basic TCM services, and by 2030 TCM services will cover all areas of medical care. China, therefore, offers a multitude of lessons for emulation on the Traditional Medicine (TM) promotion through systematic planning and outreach of the TCM.

### **Rationale for the Present Study**

So far, the policies and regulations of China for TCMs have so far not been analysed in detail. Available recent literature analysing China's TCM policies and their success, especially with reference to India, is inadequate. The Living Tree (2014)<sup>6</sup> explores issues relating to policies and programmes in the area of traditional medicine in India and China. It discusses intellectual property rights, trade and R&D relating to traditional medicinal products. It also examines the scope for using traditional medicine in public health programmes in a limited way. It reviews the status of traditional medicine in both countries and also analyses how China and India can cooperate in traditional medicine sector. However, adoption of good practices of each other is left to be studied in the future. China: Traditional Chinese Medicine – Market Report Analysis and Forecast to 2020, (2015)<sup>7</sup> provides a market overview, and insights on production, imports and exports of TCM. Traditional Chinese Medicine Hospitals in China: Industry Research Report (2015)<sup>8</sup> studies the TCM hospitals from an industry perspective. Identifying Knowledge Sharing Barriers In The Collaboration Of Traditional And Western Medicine Professionals In Chinese Hospitals: A Case Study (2015)<sup>9</sup> analyses critical issues that TCM may face among non-Chinese markets/patients/professionals. Health-care Policies and Systems in

Europe and China (2017)<sup>10</sup> delves into issues relating to integration of TCMs and Western Medicine.

Besides, several articles and papers have studied TCMs, providing analysis on various dimensions of these systems from a policy perspective. For example, the paper on TCM Standardization Today (2017)<sup>11</sup> identifies the challenges related to standardization of TCM to gain better access to distribution channels in western markets and the benefits of harmonization of TCM standards. An Investigation Into Traditional Chinese Medicine Hospitals in China: Development Trend and Medical Service Innovation(2017)<sup>12</sup> studies the development trends of traditional Chinese medicine (TCM) hospitals in China and their medical service innovations, with reference to co-existence with western medicine (WM) at TCM hospitals.

Despite a sizeable literature on TCMs, there is no comprehensive study that helps draw lessons for promoting ISMs based on analysis of the policies and programmes which China has adopted for promotion of TCM domestically and globally. The proposed Study will analyse in detail the Chinese TCM sector that may serve as a reference for emulation for promoting Indian Systems of Medicine within and outside India. A gap analysis of the policies on the two systems (TCMs and ISMs) is also to be made as a part of the study. The final report will contain specific actionable points for promoting ISMs domestically and globally.

### **Scope**

The purpose of this Scoping Paper is to provide an overview of China's TCM sector domestically and internationally. This survey of legal, policy and institutional framework is intended to provide a foundation for future research on the most important instruments supporting promotion of TCM. It identifies the existing classification of TCMs in industry and medical education, the domestic legislations that regulate TCM industry in China, the components of TCM in Chinese public health care and medical education, the global fora used for promotion of TCM, the major export destinations of TCM and the Chinese

government policies and programmes for promotion of TCM trade and global acceptance.

## 1. Traditional Medicines in China

### *Types of medicines*

Traditional Chinese Medicine is divided into the following— 1) Chinese patent medicines, 2) decoction pieces and 3) Chinese herbs.<sup>13</sup> Chinese patent medicines are defined as any Chinese herbal medicines formulated into a finished dose form, while decoction pieces are mainly Chinese herbs, which are processed further. Historically, Chinese patent medicines account for about 50 per cent of all traditional Chinese medicines sold; but lately decoction pieces account for an increased share following their faster growth.<sup>14</sup>

### *Categories of medical practices of ethnic groups*

Apart from the TCM as practised in China, traditional medicine systems practiced by the ethnic groups also form an important feature of Chinese medicine systems. By the end of 2003, there were 157 ethnic hospitals in China. Of these, 55 were hospitals of Tibetan medicine, 41 hospitals of Mongolian medicine, 35 hospitals of Uyghur medicine, one hospital of Dai medicine and 25 hospitals of other types of ethnic medicine.<sup>15</sup>

### *Types of treatments*

TCM treatments can be categorised as follows<sup>16</sup>.

- Drug therapy includes patent medicines, decoction pieces and herbs.
- Acupuncture is the practice of inserting needles into the skin, subcutaneous tissue, and muscles at the particular acupuncture points.
- Moxibustion is a therapy that involves burning moxa (mugwort root) made from dried *Artemisia vulgaris* (spongy herb) to facilitate healing.
- Tuina is a Chinese massage therapy.

## **TCM in medical education system**

Medical education on TCM is broadly categorised into two:

**Chinese Medicine:** This includes Fundamental Courses of Chinese medicine, Basic Theories of Chinese Medicine, Chinese *Materia Medica*, Formulae of Chinese Medicine and Diagnostics of Chinese Medicine, and the classics of TCM.

**Acupuncture, Moxibustion, Tuina:** They include theories of Acupuncture and Moxibustion, Meridians and Acupoints, Selective Readings of Acupuncture Classics, and Acupuncture, Theories of Different Schools, Techniques of Acupuncture and Moxibustion, Therapeutics of Acupuncture and Moxibustion, and Medical Qigong.

## 2. TCM Industry

In China, at present around 60,000 TCM and ethnic minority medical drugs are approved, and 2,088 pharmaceutical enterprises, which have been approved under the standards of Good Manufacturing Practice (GMP) of Medical Products, are manufacturing Chinese patent medicines<sup>17</sup>. In 2015 the total output value of the TCM pharmaceutical industry was RMB 786.6 billion, accounting for 28.55 per cent of the total money generated by the country's pharmaceutical industry, and is becoming a new source of growth in China's economy.<sup>18</sup>

## 3. Domestic Legislations/Regulations on TCM

### *Legislative framework*

China has introduced a number of legislations for regulating TCM. Many of these legislations and regulations cover modern medicine and TCM. Following are some of the major legislations and regulations:

The Drug Administration Law of the People's Republic of China, 1984: This is the main law regulating manufacturing, distribution and preparation of all medicines. This law applies to TCM also, and was amended in 2001.

Regulation on Protection of Wild Medicinal Resources, 1987: The fundamental aim of this is ensuring sustainable collection of wild medicinal resources and encouraging cultivation of medicinal plants. It classifies wild medicinal plants into the following three classes:<sup>19</sup>

- Class 1: Endangered, rare and precious wild medicinal species
- Class 2: Important wild medicinal species
- Class 3: Major wild medicinal species

The purchase and the export of wild medicinal materials, however, are under the provincial governments.

- Regulations on Protection of Traditional Chinese Medicines, 1993: This National Regulation on TCM aims at raising quality of all varieties of TCM, promoting development of TCM and most importantly protecting legal rights and interests of enterprises engaged in production of TCM.
- Regulation of the People's Republic of China on Traditional Chinese Medicines, 2003: This regulates establishment of medical institutions, research and practices related to TCM, and liabilities and penalties in case of failure to subscribe to prescribed rules for the same.
- Law of the People's Republic of China on Traditional Chinese Medicine, 2017<sup>20</sup> : It sets regulations for the TCM sector and criteria for practitioners to generate greater credibility and competency in the sector. Among others, it also calls for protection of TCM as 'state secrets'. The law covers medical services; protection and development of Chinese medicine; education of professional talent; scientific research; heritage and cultural transmission and protection; and supporting measures; and legal obligations. The law describes establishment and improvement of regulatory system, governing traditional Chinese medicine; and IPR protection and full supply chain quality control of medical materials.

## ***Policies and programmes***

The above legislations and regulations were the result of policy directives and programme advisories, which the government has issued, as can be seen from the following paragraphs:

Report on further enhancing Chinese traditional medicine work 1986 and Notification on further enhancing inheritance and development of Chinese traditional medicine 2002 were some of the early programmes for promotion of TCM in China.

The National Medium-and Long-Term Programme for Science and Technology Development (2006-2020)<sup>21</sup> sets out inheritance, innovation, modernization, and internationalization of TCM as the four basic tasks for Ministries involved in policy-making. It has further established therapy, evaluation technologies and standards of researching TCM with research development and manufacturing technologies of modern Traditional Chinese Medicine as goal. It calls for a combination of classic heritage of TCM with innovations of life-science to develop TCM. The focus is on translating TCM into clinical effectiveness. For this, it proposes a new research model, i.e., translational Chinese medicine, to utilize global scientific and technological resources, and to facilitate Chinese medicine globalization.

Innovation and Development Planning Outline for Traditional Chinese Medicine (2006-2020)<sup>22</sup> calls for a diversified and multichannel investment system in support of progress of the Traditional Chinese Medicine, which can be formed, among others, by means of international cooperation assets.

More recently, the Strategic Plan on the Development of Traditional Chinese Medicine (2016-2030) makes TCM development a national strategy with systemic plans for TCM development in future.

In Five-Year Plans, especially since the 10<sup>th</sup> Five-Year Plan (2001-2005), a series of guidelines and policies have been formulated to promote development of TCM. The 10<sup>th</sup> Five-Year Plan has also facilitated application of new technology for TCM manufacture/production. The 12<sup>th</sup> Five-Year Plan (2011-2015)

explicitly states ‘supporting the development of Traditional Chinese Medicine’ and emphasises also on paying equal attention to TCM at par with modern medicine, developing TCM medical treatment and preventive health-care services, promoting inheritance and innovation of TCM, and developing TM education and medical institutions among others. It also proposes to strengthen development of legal system on standardisation and information availability of the Traditional Chinese Medicines.

### ***Regulatory and administrative framework***

Administration of TCM is under the jurisdiction of the National Health and Family Commission. In 1986, the State Council had set-up an independent administration of TCM<sup>23</sup>. All provinces, autonomous regions, and municipalities directly under the central government have established their respective TCM administrations, which have laid an organizational basis for TCM development. The overall regulation of the TM is by the following agencies.

State Intellectual Property Office: Chinese patent law protects new TM products, methods of process, and uses of TM. This includes herbal preparations, extracts from herbal medicines, foods containing herbal medicines, methods for preparing herbal formulae and new medical indications for traditional formulae. During the period 1985 to 2007, the Chinese State Intellectual Property Office (SIPO) had received 4,1482 patent applications related to TCM which accounts for 1.4 per cent of the total and the number granted was 12,690 which accounted for 3.3 per cent. Domestic applicants comprised the majority of applicants.<sup>24</sup>

The State Administration of Traditional Chinese Medicine (SATCM)<sup>25</sup> and State Food and Drug Administration (SFDA): These are important agencies in China for the regulation of traditional medicine and both formulate regulations and good practices relevant to TCM and supervise their implementation.<sup>26</sup> For a Traditional Chinese Medicine to be marketed as a drug it must be approved first by the SFDA. Specific national legislations for TCM, viz. Regulations on TCM, have

been in force since 2003. However, these regulations primarily serve to promote TCM, and do not establish criterion for safety or efficacy.<sup>27</sup> Other state agencies and provincial governments, thus issue regulations on safety and efficacy of TCMs.

## **4. Mainstreaming TCM in the Public Health System**

### ***Medical education***

Traditional Chinese Medicine has two models for education. One is the traditional master-apprentice model, which is the main method of teaching since historic times. The other is university education, which has become the main mode of TCM education. Chinese university education is divided into three — bachelor’s, master’s and PhD levels. Undergraduate education for traditional Chinese doctors takes five years. This may be followed by graduate and post-graduate studies of three year duration each. Undergraduate TCM education is divided into majors, according to the fields of specialization. The most important majors are—traditional Chinese medicine major (with emphasis on training clinicians using herbal therapy), acupuncture-manual therapy major, traditional Chinese pharmacology major, etc. There are also TCM vocational schools offering three-year academic programmes. The Chinese Ministry of Health, in its policy titled Essentials of Medical Education Reform and Development in China highlights the importance of tertiary-level TCM education and reinforces the need to integrate TCM with modern science and technology. Of late, TCM education has been made part of the primary school education too.<sup>28</sup>

### ***Health policies***

In China, integration of traditional medicine into the national health-care system and integrated training of health practitioners are officially promoted. Adopted in 1982, Article 21 of the Constitution of the People’s Republic of China promotes both allopathic and traditional Chinese medicine. Since then, health policies have reinforced importance of TCM at par with Western Medicines. Health insurance covers

both allopathic and traditional medicine. Recently, the Healthy China 2030 Plan<sup>29</sup> lays equal emphasis on TCM and Western Medicine along with promoting complementarities within the two.

## 5. Global Promotion of TCM

Traditional Chinese Medicine has spread to 183 countries.<sup>30</sup> According to the World Health Organization, 103 member-states have given approval to practice of acupuncture and moxibustion; 29 have enacted special statutes on traditional medicine, and 18 have included acupuncture and moxibustion in their medical insurance provisions.<sup>31</sup> TCMs have lately been registered in countries such as Russia, Cuba, Vietnam, Singapore and United Arab Emirates. Growth of TCM has been visualised through better quality control, R&D, promotion of TCM education abroad and use of international trade and health platforms for TCM promotions.

### *Standards and quality control systems*

Standardization of TCM is an essential part of its modernization, given the policy goal of its international outreach. The system consists of four categories of standards— basic standards, technical standards, management standards, and working standards.<sup>32</sup> During the 11<sup>th</sup> Five-Year Plan (2006-2010) period, the TCM standard system was overhauled significantly while stressing on formulation and revision of basic standards and technical standards. In 2009, the State Council of China issued Several Opinions of the State Council on Supporting and Promoting the Development of Traditional Chinese Medicine, in which “promoting the standardization of TCM” was included. In the 12<sup>th</sup> Five-Year Plan (2011-2015) outline for the National Economic and Social Development, “promotion of standardisation and normalisation of TCM” was included as one of the important tasks. Standards issued by the State Administration of Chinese Medicine include among others, 18 standards for the series of Routine and Technical Operation Regulation of Nursing Care in TCM<sup>33</sup>, thus emphasising every aspect of TCM in health-care.

The State Administration in cooperation with other departments has released 5 national and over 480 TCM industrial standards.<sup>34</sup> Some important international standards subscriptions are as follows:

- Good Agricultural Practices (GAP): GAP for TCM herbs, referred to as Chinese crude drugs (CCD) in Chinese official documents, is intended to control many factors affecting production quality of medicinal plant materials to standardize various crude drug production processes and even the whole process so as to ensure that TCM herbs are authentic, safe, effective, and consistent in quality. TCM herbs cover CCD, herbal medicines, ethno-drugs, and introduced botanical drugs.
- Good Manufacturing Practices (GMP): GMP for herbal products in China was developed based on the WHO-GMP. Especially in the recent years, China has made remarkable achievements in the development of traditional Chinese medicine industry. By the end of 2004, 871 enterprises had adopted practices under the GMP reform<sup>35</sup>.
- Good Laboratory Practice for Non-Clinical Laboratory Studies (GLP) and Good Clinical Practice (GCP): Under Article 30 of the Drug Administration Law of the People’s Republic of China, 2001, GLP and GCP are regulated.
- Good Supply Practice for Pharmaceutical Products (GSP): Article 16 regulates the GSP of TCM under the Drug Administration Law of the People’s Republic of China, 2001.
- ISO/TC249: A major thrust of national strategy of China has been to establish Traditional Chinese Medicine international standards. In 2010, the Secretariat of Traditional Chinese Medicine Technical Commission of International Organisation for Standardisation (ISO) (code: ISO/TC249) was established in Shanghai.<sup>36</sup> It is the only technical commission for Traditional Chinese Medicine.

### *Research and development*

Since the 10<sup>th</sup> Five-Year Plan, a series of guidelines and policies to promote R&D in TCM have been



formulated. During the 13<sup>th</sup> Five-Year Plan (2016-2020) period, biopharmaceuticals, an important part of the bioscience industry, are highlighted among the strategic emerging industries for development. They include sub-industries such as synthetic pharmaceuticals, modern traditional Chinese medicine (TCM), biopharmaceuticals and medical devices. According to a set of Guiding Opinions<sup>37</sup> from the State Council, innovations would be strengthened through collaboration on key R&D projects, through commercialisation of pharmaceuticals, advances in medical devices, and modernisation of TCM. The ‘Healthy China Action Plan’, during the 13<sup>th</sup> Five-Year Plan (2016-2020) period, would include development of TCM as a part of the component of the Action Plan. China has enacted management methods for awarding scientific and technical progress of TCM (trial) in 1988. The Significant New Medicine Innovation and Production Programme supports construction of innovative drug research and development technology platform for TCM.

### ***Internationalisation of TCM education***

China’s efforts to internationalise TCM education has ensured its expansion to 30 countries and regions which have opened a couple of hundred TCM schools to train native TCM- workers. The World Federation of Acupuncture-Moxibustion Societies, headquartered in China, has 194 member organizations from 53 countries and regions, and the World Federation of Chinese Medicine Societies has 251 member organizations from 67 countries and regions.<sup>38</sup>

### ***World Health Organisation (WHO) and TCM***

The Chinese government works closely with the WHO and has hosted the first WHO Congress on Traditional Medicine in Beijing in 2008, and has played an important role in drafting the Beijing Declaration adopted by the Congress on 8<sup>th</sup> November 2008. The partners of the WHO Congress on TM were Ministry of Health China, and World Federation of Acupuncture-Moxibustion, among others. The Executive Board and World Health Assembly also adopted resolutions on TM based on the initiatives by China. China is

also engaged in and has financed development of the WHO TM strategy. The WHO has included traditional medicine, represented by TCM in the new version of the International Classification of Diseases (ICD-11). As a result of the initiatives of the Chinese government, the 62nd (2009) and 67th (2014) World Health Assemblies passed two resolutions on traditional medicine, and urged its member- states to implement WHO’s Traditional Medicine Strategy 2014-2023.

### ***Trade promotion***

Traditional Chinese Medicine has become an important area of health and trade cooperation between China and the Association of South East Asian Nations (ASEAN), European Union (EU), Africa, and Central and Eastern Europe and a key component for people-to-people exchange between China and the rest of the world. Hong Kong, Japan, US and EU are major export destinations of TCMs. While EU showed major growth (49.15 percent) in TCM herbs/plant extracts; Hong Kong, Japan and US were export markets for Chinese Patent Medicines (54 percent ).<sup>39</sup> Trade in Chinese medicinal products has consistently maintained a rapid growth; and export value of Chinese medicines in 2015 amounted to \$3.72 billion.<sup>40</sup>

## **6. Indian Traditional Medicine (ITM)**

### **Landscape and Lessons from China**

Indian Systems of Medicines (ISMs) also boast of a long history with widespread use across the country. As of 2016, there are about 4,78,161 registered medical practitioners of the Ayurvedic, Siddha, Unani and naturopathy systems.<sup>41</sup> There are 318 Ayurveda, 10 Siddha and 48 Unani Colleges, affiliated with various universities of the country, 190 colleges in Ayurveda 3 in Siddha and 12 in Unani imparting post-graduate education in different specialties.<sup>42</sup>

India is the largest producer of medicinal plants.<sup>43</sup> Yet, the growth ISMs both in domestic health-care and international trade is far from achieving its potential. The total commercial demand for herbal raw drugs for the year 2014-15 has been estimated at 5,12,000 MT and the total trade value at Rs. 5,500 crore only.<sup>44</sup>

India's export of AYUSH and value added extracts of medicinal herbs during 2016-17 is \$ 403.59 million<sup>45</sup>. This is less than one per cent of the estimated global market of \$ 70 billion.<sup>46</sup> Also, so far, ISMs are recognized only in few countries like Sri Lanka, Nepal, Bhutan, Malaysia and Bangladesh. Given the slow growth of the sector, the Indian National Policy on Indian Systems of Medicine (2001), for example, identifies the need for efficacy trials for therapeutic claims of patent medicines. More recently, the National IPR Policy 2016 and the National Health Policy 2017 seek promotion of traditional medicine. As compared to TCMs, ITMs have clearly not reached the extent of expansion and penetration in the domestic health system, international trade destinations or to the global medical fora.

## 7. Gap Analysis

Adoption of best practices from around the world will contribute towards more efficient policy interventions on promotion of ITMs. The successful expansion of TCM in domestic healthcare, recognition of TCM at the international health fora such as WHO and major trade destinations makes it imperative for India to study strategies and policies adopted by more successful countries like China for drawing lessons for its future strategies and policy formulations for ISMs.

The aim of this Study, therefore, is to undertake a comparative assessment of China's policies and programmes for promotion of TCMs *vis-a-vis* Indian policies, identify the gaps and deficiencies that need to be addressed towards more efficient integration of ISMs with general medical care within India on the one hand and its global promotion on the other. It will also look into the challenges in upgrading the system towards an equal footing with modern medicine.

## 8. Conclusion

Within the above context, the study underway sets out to answer six important research questions on the role of the following law and regulatory instruments by China to mainstream TCM domestically and globally.

- What are the basis of classification of TCMs in industry and medical education?
- Which domestic legislations regulate TCM industry?
- What are the components of TCM in public health-care and medical education?
- Which global fora are used for promotion of TCM?
- Which countries are the major export destinations of TCM?
- Which policies regulate trade/international promotion of TCM?

## Focus of Study

### I. Domestic Rules and Regulations

Mainstreaming of TM- public/private health care, education and industry  
Standard setting  
Safety, efficacy and quality control

### II . Global Promotion

Export and international trade classification  
MoUs with other countries - education and industry

### III. Gap Analysis

## Endnotes

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### About FITM

The Forum on Indian Traditional Medicine (FITM), set up by the Ministry of AYUSH at RIS, is a platform aimed at contributing towards creation of pro-active strategies for promotion of Indian systems of medicine.

Among others, it supports studies on the issues pertaining to traditional medicines in India and countries that India could emulate from.

Core IV-B, Fourth Floor, India Habitat Centre Lodhi Road, New Delhi-110 003, India., Ph. 91-11-24682177-80  
Fax: 91-11-24682173-74, Email: [dgoffice@ris.org.in](mailto:dgoffice@ris.org.in), Website: [www.fitm.ris.org.in](http://www.fitm.ris.org.in), [www.ris.org.in](http://www.ris.org.in)

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