

# Industry Consultation on Global Promotion of Indian Systems of Medicine

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Multi Purpose Hall, India International Centre, Max Mueller Marg, New Delhi

## CONCEPT NOTE

### Context

The growth of herbal sector in international trade and commerce reflects the continued relevance of traditional medicine products and Indian Systems of Medicine (ISM). Presently, the Indian herbal market is valued at Rs 5,000 crore with an annual growth rate of 14 per cent<sup>1</sup>. The global herbal market, however, is valued at US \$100 billion<sup>2</sup> reflecting India's negligible share. With judicious management of this sector India stands to gain a significant competitive edge in the international pharmaceutical and wellness industry. Acceptance of ISMs in export destinations, however, is dependent on several factors; safety and efficacy being the prime determinants.

In the recent past, efforts to streamline the industry have included measures such Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) guidelines for the industry. Rules and guidelines for licensing of AYUSH (Ayurveda, Yoga, Unani, Siddha, and Homoeopathy) products have also been modified. AYUSH promotion as a foreign policy strategy has included Memoranda of Understanding (MoUs) at bilateral levels for recognition of ISMs, AYUSH facilitation centres and information cells abroad. Export promotion schemes like quality certifications for ISM products and certification of yoga professionals have been undertaken to popularise therapeutic and non-therapeutic ISM treatments through quality benchmarks.

<sup>1</sup>Press information Bureau, Government of India, 4 December 2017

<sup>2</sup>Press information Bureau, Government of India, 6 November 2017

Despite these efforts there exists scope for augmentation. To facilitate further growth of this industry within and outside India, it is therefore imperative that present regulatory regimes are revisited for an understanding of gaps, challenges and opportunities in the global promotion efforts.

## Objectives

The Forum on Indian Traditional Medicine (FITM) has been established by Ministry of AYUSH at RIS for all related actors to come together to contribute to pragmatic policy making and strategies for promotion of ISMs. With the Ministry of AYUSH, FITM is organising an **Industry Consultation on Global Promotion of Indian Systems of Medicine** with the following objectives:

- To facilitate an effective dialogue between the private sector and government through representatives of various ministries, regulatory agencies and the ISM industry.
- To draw lessons from success of particular initiatives in the past.
- To analyse challenges in implementing specific regulations/measures and offer possible solutions towards this end.
- To provide a roadmap towards successful global promotion of the ISM products and services.

## Sessions and Themes

### *Session 1: Emerging Global Vision on ISMs: Domestic Preparedness, Norm Setting and Impediments*

The Ministry of AYUSH supports export promotion of the industry under its Central Sector Scheme for International Cooperation through facilitation of market authorization and registration for ISM product(s) with regulatory bodies of different countries. The Scheme also facilitates participation in international exhibitions, trade fairs and road shows to create awareness about the efficacy of ISM products. India's ISM exports however have been confined to a few destinations. Potential of Africa, Asia and the Gulf countries as export destinations are yet to be harnessed. Trade classification has also been a serious concern. The export of Ayurvedic products takes place under the Indian Trade Classification through two Harmonized System (HS) codes - 30039011 for systems medicaments of Ayurvedic System and 30049011 for medicaments of Ayurvedic, Unani, Homoeopathic, Siddha or biochemic systems. Individual Ayurvedic products have no separate HS codes to help track the top Ayurvedic drugs being exported.<sup>3</sup> This also creates a major bottleneck for adequate trade description. Again, normally traded commodities (NTC) under Section 40 of the Biological Diversity Act 2002 have added to the prevailing confusion on HS classifications of traditional medicines and related products. Trade barriers like Sanitary and PhytoSanitary and Technical Barriers to Trade (SPS/TBT) measures of importing countries continue and compliance with regulations of export destination

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<sup>3</sup> Press Information Bureau , Government of India, 5 January 2018

remains a challenge. Further, facilitating export through promotion of SEZs and capacity building of MSMEs is important.

In light of the above, this session will focus on:

- Role of SEZs
- Capacity building of MSMEs
- Challenges in export promotion initiatives
- SPS/TBT measures of importing countries
- Trade Classification issues, especially those related to HS Codes
- Export opportunities in Africa, Asia and the Gulf region.

### *Session 2: International Manufacturing Standards and Quality Assurance*

Stability, safety and standardisation of ISM drugs and their formulations are essential requirements for building confidence in export destinations. Good Manufacturing Practice (GMP) guidelines and quality certification schemes have been introduced by the Ministry of AYUSH. However, 17 per cent of AYUSH pharmacies are still not GMP-certified; of which 58.20 per cent are of Ayurveda, 18.10 per cent are of Unani, 17.90 per cent are of Siddha<sup>4</sup>. International Standards and Certifications like ISO are crucial for international acceptability of ISMs. Lack of subscription to pharmacopoeial standards by ISM manufacturers is an issue. Ayurvedic medicines, consequently, have been reported with high incidence of serious adverse drug reactions (65.67 percent)<sup>5</sup>. Though MoUs for cooperation in the field of traditional medicines with Pharmacopoeia Commissions of countries like the US have been undertaken by the Ministry of AYUSH, facilitating recognition of Ayurvedic pharmacopoeia in export destinations is a challenge. Other major challenges in export include paucity of well documented clinical records.

With reference to the above, this session will focus on :

- Gaps between enforcement and implementation of GMP, GLP and toxicity screening.
- Facilitating mechanisms for International Standards and Certifications for ISMs.
- Challenges and solutions for greater scientific validation of ISMs through clinical research and pharmacovigilance.
- Measures to ensure subscription to pharmacopoeial standards.
- Recognition of Indian Pharmacopoeia in export destinations.

### *Session 3: Value Chain Integrity of Herbal Products*

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<sup>4</sup>AYUSH in India, Planning and Evaluation Cell, Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), Government of India, 2014.

<sup>5</sup> Pharmacovigilance Programme Of India (Pvpi) Issn:2320-7760 Vol 6 L Issue 16 L 2016,

The pharmaceutical industry, specially the ISM industry, is critically dependent on the sustained supply of medicinal plants as the primary raw material. The quality of raw material used largely determines and influences quality of the finished products; hence the value chain of the medicinal plants, beginning with the starting material, i.e., plant resources, their storage and processing, assumes particular importance in the manufacturing process of ISM products. The non-uniform practice of procuring medicinal plants as raw materials for ISM products is a challenge. Despite considerable efforts by the government only about 22 per cent of the medicinal plant production is sourced through cultivation<sup>6</sup>. The challenges that farmers face in cultivation of medicinal plants include long gestation period and high risk, insufficient institutional infrastructure to provide technical and marketing support, high transaction costs and inadequate social capital. Heavy dependence on collection from forests leads to danger of extinction of plant genetic resource on the one hand, while legislations regulating access to these forest resources (in the form of several forest laws and the Biological Diversity Act 2002) are causes of concern to primary collectors and the pharmaceutical industry, on the other.

This session will focus on:

- Value chains in the medicinal plant sector and challenges associated with the quality of raw materials supplied.
- Laws regulating access to forest resources for collection of medicinal plants and their impact on sustainability and stakeholders
- Protocols for collection of medicinal plants and herbs
- Challenges in cultivation of medicinal plants

#### *Session 4: Marketing Strategies for ISM Products and Services*

Marketing is an integral aspect of promotion for any industry. In the case of ISMs this is a necessity, given the impression of ISM products in export destinations as mere diet supplements. Unregulated internet drug sales, misleading advertisements, excessive over-the-counter (OTC) sales, non-segregation of ISM drugs from fast moving consumer goods (FMCG) products have further added to the confusion. The ISM services industry dealing with non-drug therapies are facing a similar crisis of identity where for several reasons, mainly lack of proper regulations, wellness tourism appears to dilute the classical approaches utilised in these therapies. Initiatives like AYUSH information cells in select countries to disseminate authentic information about ISMs have been undertaken. The Ministry of AYUSH has also entered into bilateral and other cooperation agreements with countries to promote AYUSH systems. Yoga's recognition by UNESCO has been one of the successful initiatives to promote international acceptance of AYUSH. However, brand building of ISM and its therapies as an authentic medical system also

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<sup>6</sup> Indian Medicinal Plants - Fact Sheet, National Medicinal Plant Board, Available at <http://www.nmpb.nic.in/content/medicinal-plants-fact-sheet>

includes appropriate regulations and training to practitioners of ISM to modernise and modify by applying recent advances according to contextual needs. A strong inter-linkage therefore exists between domestic regulations on export potential of ISMs.

Given the above, this session will discuss:

- The ISM services sector including regulations for wellness industry for quality control of non-drug therapies.
- Benchmarking yoga and ISM non-drug therapy practitioners in India and abroad.
- Benchmarking/training AYUSH medical practitioners for practicing abroad.
- Regulating over the counter (OTC) sales and misleading advertisements, segregation of consumer goods and drugs.
- Role and impact of international cooperation through global organisations (World Trade Organisation and World Health Organisation) and Indian Missions in promoting ISM products.
- Bilateral and multilateral treaties and agreements on the ISM sector

The Consultation is expected to bring forth concrete and implementable suggestions for the global promotion of the ISM products and services.

### **Future Course**

The deliberations and recommendations of the Consultation would be presented by the FITM in the form of a Policy Brief to concerned Ministries, regulatory authorities and industry organisations.