FITM
Forum on Indian Traditional Medicine

FITM POLICY BRIEF

# Export Promotion of Indian Traditional Medicine Products: Assessing Domestic Preparedness

## Introduction

The growing global interest in traditional medicine and herbal products has been driving growth in trade in related products. The oeuvre of goods includes biological resources like medicinal plants and value added products like herbal cosmetics and medicine[1] and these now form an important segment of the global pharmaceutical market. Global exports in traditional medicine, medicinal plants and associated products have grown from UD$ 128 billion in 2002 to US$ 251 billion 2016[2]. However, despite the existence of rich biological resources and traditional medicine products in India, the export of AYUSH[3] and value added extracts of medicinal herbs during 2016-17 was US$ 403.59 million[4] only. This negligible share in global exports reflects a significant gap between India's strategic vision and operational reality. The policy goal has been to fill this critical gap.

Feedback from the industry and industry-government dialogues admit that export promotion of Indian Systems of Medicines (ISM) is heavily dependent on safety and quality assurance along the entire value chain of the sector. This ranges from sustainable supply of quality raw materials to subscription to existing standards on manufacturing and clinical practices. At present, with 80 per cent of the industry being dominated by micro, small and medium enterprises (MSMEs), facilitating subscription to existing safety and quality standards through physical and financial infrastructure is a serious challenge. Export strategies for trade expansion are also inhibited due to lack of comprehensive data on trade, industry, medicinal plants and services and non-existence of detailed trade classification of ISM products. The policy objectives envisage a threefold increase in the AYUSH sector in the next 5 years. A growth of this scale requires urgent intervention in the above mentioned areas. This brief intends to assess India's preparedness on the same and explore roadmaps to address the associated challenges.

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## Quality Assurance Challenges: Issues of Safety and Standardisation

Variation in regulatory requirements of export destinations exists, though expectations on safety assurance, by and large, are uniform. These include the need to address quality, uniformity, and toxicity issues. Unlike pharmaceutical products which are formulated from single molecule chemicals produced synthetically or by isolation from natural source materials employing reproducible methods, ISMs consist of products prepared from source materials containing multiple chemical constituents, the quality and quantity of which may vary from batch to batch due to intrinsic and extrinsic factors[5]. Consequently, the quality of finished herbal products is greatly influenced by the quality of the raw materials and intermediates. Adverse events reported in relation to the use of herbal products are attributed to poor quality of products, which may involve a variety of factors, including natural (e.g., source material) and human (e.g., manufacturing/processing) factors[6]. For global acceptance, evidence based safety assurance of traditional medicine formulations across the value chain is required. It begins from standardization of raw material to finished product, including, quality checking, method of storage and method of preparation. The following issues may need urgent policy consideration.

### Raw Materials: Quality and Sustainability

Raw materials have been a contentious issue in the sector, both with regard to supply and quality. Sustained supply of raw materials has been a challenge. More than 75 per cent of medicinal plants are sourced from forests and 70 per cent of these are harvested in destructive ways[7]. With growing demand for medicinal plants, regulating access and collection practices through laws like the Biological Diversity Act, 2002, negative listing and ban on collection of some species have been undertaken. The complexity of the regulations acts as deterrence for industry. It leads to illegal trade that further endangers the resources. Promoting cultivation as a solution has been undertaken by the National Medicinal Plants Board (NMPB). Even then, it accounts for only 22 per cent of the medicinal plants procured for the industry[8].

Quality of available raw materials has also been a serious concern. Some of the major contaminants and adulterants in plants include microbial contaminants which may be dependent on environmental factors like temperature, humidity, harvesting, handling and storage conditions of crude and processed medicinal plant materials. ISM preparations may also contain pesticide residues which accumulate from agricultural practices such as spraying, soil treatment and administration of fumigants during storage, etc. The NMPB, through Quality Council of India (QCI), has designed and prescribed a standards certification scheme titled "Voluntary Certification Scheme for Medicinal Plants Produce (VCSMPP)" based on Good Agricultural Practices (GAPs) and Good Field Collection Practices (GFCPs) of medicinal plants[9]. The challenge is to effectively implement the scheme through greater understanding and acceptability by farmers, collectors and traders of the medicinal plants. Tracing of contaminants also remains a major challenge due to existing lack of passport data for raw materials and non-transparent value chain of the industry. The supply chain of medicinal plants and herbs begins with unorganised collectors/harvesters passing through several middle men before reaching the end user industries. This makes product traceability nearly impossible. Currently, contract farming and buy-back arrangements provide the only practical alternatives for exporters whose customers require traceability.

### Product Safety: Heavy Metals Toxicity

An often repeated complaint from export destinations is toxicity associated with heavy metals in ISM products. Legal and regulatory provisions exist. Proof of safety and effectiveness required for issuing manufacturing licence for various categories of Ayurveda, Siddha and Unani (ASU) medicines is prescribed in Rule 158B of the Drugs and Cosmetics Rules, 1945.

### ISM Regulations in India

Chapter IV A of the Drugs and Cosmetics (D&C) Act, 1940, and Part XVI, XVII, XVII and XIX of D&C Rules 1945, governs Indian Systems of Medicine (ISM) products. Proof of safety and effectiveness required for issuing manufacturing licence for various categories of ASU medicines (Rule 158 B), provisions for labelling, shelf life (Rule 161) is prescribed in the D&C Rules. The Ministry of AYUSH through its drug control cell (DCC) administers regulatory and quality control provisions for AYUSH drugs including those of the D&C Act. However licensing authorities/drug controllers appointed by the State Governments are empowered to grant or renew licence for manufacturing of Ayurveda, Siddha and Unani (ASU) medicine and to take necessary action in case contravention of the legal provisions occur. The latest initiative by the Ministry of Health and Family Welfare to create a vertical regulatory structure for AYUSH in the Central Drugs Control Standards Organisation (CDSCO) in 2018, over and above the regulatory framework that is enforced by state governments, is aimed at ensuring more efficient administration of industry.

***Source :*** http://www.cdsco.nic.in/writereaddata/ayush%20regarding.pdf

A list of potentially toxic ingredients (heavy metals) does exist under Schedule E1 of the Drugs and Cosmetics Rules, 1945 as a special category. Central and State Drug Laboratories for testing ASU medicines are in place and as of now 55 laboratories are approved under the provisions of Drugs and Cosmetics Rules 1945[10]. However, unregulated and uncontrolled usage of ISM products sold as over the counter (OTC) products, diet supplements and by unqualified pharmacists continues. These require urgent intervention.

Strict labelling guidelines have been suggested as an important tool in this regard. This includes labelling guidelines making it mandatory to provide sufficient information regarding ingredients. Regulating dosage of ISM products with metal content by insistence on prescription by qualified ISM practitioners for such drugs is also critical. In this regard, development of 'prescription guidelines' for ISM practitioners that include duration, exception, mode of administration, reporting of toxicity cases is an intervention that is to be considered[11].

Pharmacovigilance is another important tool in toxicity regulation. The National Pharmacovigilance Programme for ASU drugs has largely remained inactive. Proactive pharmacovigilance cells and centres reporting adverse events, publishing data on the same and compulsory setting of pharmacovigilance cells as a part of accreditation standards for AYUSH colleges will facilitate regular and timely reporting of adverse drug reactions[12] .

## Manufacturing Standards

Underthe provisions of the Drugs and Cosmetics Rules, 1945, good manufacturing practices (GMP) and Quality Standards prescribed in the respective pharmacopoeias are mandatory for the manufacturing of licensed ISM medicines. GMP guidelines and quality certification schemes have been introduced by the Ministry of AYUSH. Voluntary certification schemes for quality assurance of ASU products are implemented by the QCI for grant of AYUSH Standards. These include AYUSH Standard Mark and AYUSH Premium Mark. The latter is based on GMP requirements based on World Health Organisation (WHO) Guidelines and product requirements with implementation being undertaken by the Central drugs Standards Control Organisation (CDSCO). As on 2017, there were 9038 AYUSH drug manufacturing units (licensed pharmacies) in the country[13] with 17.8 per cent (of these pharmacies) still not being GMP-certified[14]; Lack of subscription to pharmacopoeial standards by ISM manufacturers is also an issue. Ayurvedic medicines, consequently, have been reported with high incidence of serious adverse drug reactions (65.67 per cent)[15].

While there are sufficient rules and regulations to ensure good manufacturing practices for formulations containing potentially toxic ingredients, their implementation is a major bottleneck. The Licensing Authorities/Drug Controllers appointed by the state governments are empowered to grant or renew licence for manufacturing of ASU medicines and to take action against defaulters acting in contravention of legal provisions. Impact of state administration of these provisions has been limited. The need for a central regulatory structure that oversees states' administration of ISMs has thus been felt. In an important policy strategy aimed at addressing this issue, the Ministry of Health and family Welfare has set up a vertical structure for AYUSH sector in the Central Drugs Standard Control Organisation (CDSCO)[16] to enforce provisions for ISM drugs in coordination with the state regulatory authorities.

## A Single Pharmacopoeia

To ensure the amount of particular active constituents in drugs and their formulations, appropriate reference standards of drugs and formulations are prescribed in pharmacopoeias. Every country has its own pharmacopoeia which manufacturers subscribe to for reference to standards, protocols and Standard Operative Procedures (SOPs). Pharmacopoeias also serve as reference standards for importing countries. MoUs with Pharmacopoeia Commissions of countries like the US for cooperation in the field of traditional medicines[17] have been undertaken by the Ministry of AYUSH. However, facilitating recognition of Ayurvedic pharmacopoeia in export destinations is a challenge, one of the reasons being the existence of several pharmacopoeias. In India, besides the Pharmacopoeia Commission of Indian Medicine and Homeopathy [It serves as an umbrella organization for Ayurvedic Pharmacopoeia Committee (APC), Siddha Pharmacopoeia Committee (SPC), Unani Pharmacopoeia Committee (UPC) ] under the Ministry of AYUSH, there is Indian Pharmacopoeia Commission (IPC), an autonomous Institution of the Ministry of Health and Family Welfare. Pharmacopoeias are also developed by agencies like Indian Council of Medical Research (ICMR). With different references and standards prescribed, the industry has selectively used these as per provisions that provide ease of business. The need for harmonisation of these monographs for uniformity has been identified by international agencies like WHO[18]. From a regulatory perspective a single pharmacopoeia will enable a uniform reference point for domestic industry and foreign regulatory bodies when considering ISM related products.

While negotiating Free Trade Agreements, India should propose recognition of Indian Pharmacopoeia, including the ones in ASU. This will facilitate trade and commerce in ISM products and increase export of the ISM products. Having a single pharmacopoeia will greatly facilitate the task.

## International Standards for ISMs

Despite existence of domestic standards and certifications, an international standard for ISM has been expressed by the industry as desirable. It has been felt that adopting an international standard like ISO/TC for ISMs will facilitate greater acceptability of ISMs. China's efforts have led to International Organisation for Standardisation (ISO) establishing the Secretariat of Traditional Chinese Medicine (TCM) Technical Commission of (code: ISO/TC249)[19] for TCM in Shanghai in 2010. India too may work towards adoption of ISO standards for ISMs for greater global market penetration.

The BIS Sectional Committee (FAD26 Ayurveda) is mandated with standardisation in the field of ISMs with reference to terminology and quality of standards of ingredients and products. The BIS is also the nodal agency coordinating with ISO towards inclusion of Ayurveda in ISO/TC/249. BIS has been engaged in dialogues with regard to the process of setting up an ISO secretariat for ISMs in India. Interviews with related personnel at BIS and members of delegations participating in plenary meetings of the ISO/TC249 indicate that the process is

**ISM Trade**

Europe has the largest share in global trade in TM (US $ 326.72 bn in 2016), followed by Americas, mostly North America led by the USA. Export destinations of ISM products include both developed and developing countries. The nature exports range from raw materials to formulations. Emergence of developing countries in global trade has seen new trends that include declining prices if raw materials, derivatives and extracts and rising prices for formulations. India has experienced growth in exports during global buoyancy (2003-07) and also during recession. India's sectoral share of bulk products exports increased from 89.78 per cent in 2003 to 94.47 per cent in 2016, though its exports of raw materials have declined from 6.32 per cent in 2003 to 2.77 per cent in 2016.

***Source***: Mohanty., S.K.2018. Trade Dimensions of Traditional Medicine: Some Issues for Discussion, [Powerpoint Presentation] FITM Industry Consultation on Global Promotion of Indian Systems of Medicine. 18th May 2018, New Delhi

expected to be complete by 2020. Support from at least five member countries at the ISO would be crucial towards this objective. In addition, submission of a glossary of terms on ISMs to ISO, to identify suitable technology that can explain the scientific basis of ISMs at the earliest to the ISO is also recommended.

## Trade Expansion

India ranks 9th in global exports of traditional medicine[20]. Exports of ISMs have focussed on European and American markets (approx 60 per cent) (Table 1). There are strong export linkages with African states and immediate SAARC neighbourhood or ASEAN countries (except Vietnam and Myanmar) or Gulf countries which ISM industry is yet to explore. Industry's initiatives on strategies for hitherto unexplored export destinations will greatly enhance ISM exports. Trade expansion based on 'focus market' and 'focus products' strategy will be greatly enhanced by the following interventions.

### Single Window Clearance

AYUSH promotion as a foreign policy strategy has included Memoranda of Understanding (MoUs) at bilateral levels for recognition of ISMs, and setting up of AYUSH Facilitation Centres and Information Cells abroad. Export promotion schemes like Voluntary Quality Certification of Pharamaceutical Products (CoPP) and Quality Certifications Schemes such as AYUSH Premium Mark and certification for yoga professionals have been undertaken. With regard to the next steps, industry representatives opine that similar to other export items, single window clearance for ISM products also be introduced. This would require intervention at the highest level of government to resolve inter-ministerial and inter-agency differences.

### Trade Classification: Expanding Harmonised System (HS) Codes

Classification of products determines the regulations on products in export markets. A detailed classification of Harmonised System (HS) codes at the level of National Line also provides information on the flow of products in international and domestic trade. Consequently, it assists in developing marketing strategies based on the data generated. Lack of classification and consequently lack of precise data on ISM products has hindered export promotion.

Based on existing requirements, expansion of HS National Lines to 16-digit lines may be provided to accommodate various features of traditional medicines and medicinal plant products. Within trade classification, traditional medicines and medicinal plants need distinctive treatment since they are different from other normally traded products.[21] Trade of these products are allowed on the basis of (a) traceability condition (wild/cultivated/mixed), (b) specific parts of a plant (root or steam or leaf, and so on), etc. Such conditions are not applied

for other products. Hence, for smooth trade practices, specification for tradable products (part of a plant or product) has to be embedded in the HS classification. Separate HS codes at the National Lines for ISM and plant species may be allocated for medicinal plants, medicines, dietary supplements, cosmetics, etc. It has also been suggested by the industry that traditional medicines being special products, the condition of having threshold level of trade may be waived while allocating new HS National Lines for these products[22].

**Table 1: Major Export Destinations of ISM Products (2016)**

| Partner Country | Value ($Mn) | Share in World |
|---|---|---|
| United States | 4749.24 | 44.66 |
| EU | 1404.29 | 13.21 |
| United Kingdom | 407.85 | 3.84 |
| South Africa | 361.28 | 3.40 |
| Russian Federation | 285.08 | 2.68 |
| Kenya | 225.62 | 2.12 |
| Nigeria | 205.13 | 1.93 |
| Australia | 186.29 | 1.75 |
| Germany | 152.19 | 1.43 |
| Sri Lanka | 152.03 | 1.43 |
| Brazil | 139.18 | 1.31 |
| Canada | 133.02 | 1.25 |
| Myanmar | 120.53 | 1.13 |
| Netherlands | 117.05 | 1.10 |
| Philippines | 115.52 | 1.09 |
| France | 111.15 | 1.05 |
| Tanzania | 108.98 | 1.02 |
| Ghana | 108.41 | 1.02 |
| Vietnam | 105.11 | 0.99 |
| Uganda | 102.32 | 0.96 |
| World | 10633.27 | 100.00 |

***Source***: Mohanty., S.K.2018. Trade Dimensions of Traditional Medicine: Some Issues for Discussion, [Powerpoint Presentation] *FITM Industry Consultation on Global Promotion of Indian Systems of Medicine*. 18th May 2018, New Delhi

The global trade classification at 6-digit HS undertaken by the World Customs Organisation (WCO) allocates new HS codes from time to time based on volume of global trade. At present, the number of products allocated for Traditional Medicines (TM) and Medicinal Plants (MP) are less in number (mostly 6 digit) mainly due to lack of pressure from the countries associated with this sector. With growing global trade of medicinal plants and related products, India may mobilise countries with similar interests to negotiate with the WCO in the next Round of Negotiations to allocate more HS lines for these products.

## Conclusion: The Way Forward

Growth of ISMs requires urgent intervention in key areas. Data generation is the link that determines outcomes on any initiative taken with regard to the above mentioned areas. The existing paucity of comprehensive data on trade, industry, medicinal plants and services has been a serious bottleneck towards pragmatic policy formulation. Capacity building of MSMEs through physical and financial infrastructure is another critical factor that will determine the successful implementation of standards subscription. Cooperation between the Ministry of AYUSH and related agencies such as the BIS, Directorate General of Foreign Trade (DGFT), Export Inspection Council (EIC) and Ministry of MSME will be beneficial in capacity building of MSMEs and the industry in general. These include utilisation of programmes like Design Clinic Scheme for Design Expertise to Micro, Small and Medium Enterprises of Ministry of MSME, and utilisation of infrastructure like the laboratories of EIC for laboratory accreditation of ISMs. Other areas of critical importance include, as discussed earlier , single window clearance for trade facilitation and uniformity of regulatory structures and bodies. For instance, different export promotion councils cover different codes under the HS trade classification as per their mandate; medicinal plants as raw materials are largely dealt with by Agricultural and Processed Food Products Export Development Authority (APEDA) and the semi finished and finished products are dealt with by Pharmaceuticals Export Promotion Council (Pharmexil) and Chemicals, Pharmaceuticals, & Cosmetics Export

Promotion Council (Chemexil)[23]. Existence of multiple agencies hinders information generation on product classification. Policy efforts in the recent past have attempted standards setting of the entire value chain including good collection/ cultivation practices (of medicinal plants) and manufacturing practices. Enforcement of these standards, however, has been a challenge. Limited acceptability of domestic standards by export destinations is also an issue which the Ministry of AYUSH and the NMPB may address by educating domestic and international regulatory bodies about domestic standards. These would convince the manufacturers and collectors/cultivators of medicinal plants and herbal produce on utility of subscription to such standards which promise little return on investments at present. The domestic industry may also devote more attention and resources towards generating quality peer reviewed studies. Adherence to international norms including acceptance of voluntary certification schemes like AYUSH Premium Mark will go a long way in that direction.

## Endnotes

1 The World Health Organization describes herbal medicines to include herbs and/or herbal materials and/or herbal preparations and/or finished herbal products in a form suitable for administration to patients) as a part of the global pharmaceutical market.

2 Mohanty., S.K.,2018. Trade Dimensions of Traditional Medicine: Some Issues for Discussion , [Powerpoint Presentation] *Industry Consultation on Global Promotion of Indian Systems of Medicine* 18th May 2018. New Delhi . Available at , http://ris.org.in/pdf/fitm_18may2018/Prof.S.K_Mohanty.pdf.

3 AYUSH stands for Ayurveda, Siddha, Unani, Yoga and Homeopathy.

4 Answer to Lok Sabha Unstarred Question No.1016 , 21st July 2017

5 See http://www.who.int/medicines/areas/quality_safety/quality_assurance/V-2ndGlobalReview-RevisedDraft-WHO-GHPP-March2017.pdf pp- 7

6 Revised Draft: WHO Guidelines on Good Herbal Processing Practices (GHPP) for Herbal Medicines, WHO/SDS/TCM R-Draft WHO guidelines for comments 4 March 2017 http://www.who.int/medicines/areas/quality_safety/quality_assurance/V-2ndGlobalReview-RevisedDraft-WHO-GHPP-March2017.pdf

7 Press Information Bureau, Government of India, 31 August 2016

8 See https://nmpb.nic.in/content/medicinal-plants-fact-sheet

9 Press Information Bureau Government of India, 9 December 2016

10 Press Information Bureau , Govt of India, 6 February 2018

11 Patwardhan ., K. Pathak.J. and Acharya Rabinarayan. 2017. Ayurveda Formulations: A Roadmap to address the safety concerns , *Journal of Ayurveda and Integrative Medicine*

12 *Ibid*.

13 http://ayush.gov.in/sites/default/files/Licensed_Pharmacies_1.pdf

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15 Pharmacovigilance Programme Of India (Pvpi) Issn:2320-7760 Vol 6 L Issue 16 L 2016,

16 See http://www.cdsco.nic.in/writereaddata/ayush%20regarding.pdf

17 Ministry of AYUSH , Annual Report 2016-17. pp-142

18 WHO. 2015. Who Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report

19 see https://www.iso.org/committee/598435.html

20 Mohanty., S.K.,2018. Trade Dimensions of Traditional Medicine: Some Issues for Discussion , [Powerpoint Presentation] *Industry Consultation on Global Promotion of Indian Systems of Medicine* 18th May 2018. New Delhi . Available at , http://ris.org.in/pdf/fitm_18may2018/Prof.S.K_Mohanty.pdf.

21 *Ibid.*

22 *Ibid.*

23 Chaturvedi, S. 2014. *Dynamics of Traditional Medicine Industry*: Issues in Trade , Technology and Standards in Chaturvedi S, Ladikas M, Lifeng G., and Srinivas K..R.(ed) *The Living Tree*: Traditional Medicine and Public Health in China and India , Academic Foundation , New Delhi . pg-179.

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## About FITM

The FITM has been established in the RIS with the participation of the Ministry of AYUSH as a common platform for all actors and stakeholders to contribute to pragmatic policy-making in the area of Traditional Medicine (TM) and Traditional Knowledge and to develop pro-active policies and strategies. The broad objectives of the FITM are to: undertake/ commission studies on various issues pertaining to Indian TMs, IPRs and regulatory frameworks for traditional medicinal knowledge; examine trade policy with reference to TMs; prepare cogent and coherent policy and strategy responses on emerging national and global developments; provide critical inputs such as policy briefs, briefings and reports to the Government of India in a continued and sustained way; and to facilitate interactions with experts and stakeholders and policy-makers from India and abroad. It would also provide Fellowships and Scholarships for studies in the area of TMs, arrange invited talks by national and international experts, and organize periodic consultations.

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