

Traditional Medicine in India: Regulations and Trade

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In recent years, there has been an upsurge in the global interest in Traditional Medicine (TM) as an effective alternative to the modern system of medicine. The World Health Organisation (WHO) has also been taking a keen interest in the development of TM. India is one of the few countries that had introduced regulatory systems for TM quite early. It had national laws and regulations on TM from 1940 onwards which were updated several times. The AYUSH/ISM industry is also quite large. There are 8,954 manufacturing units registered with the Ministry of AYUSH.¹ A 2018 industry report by the Confederation of Indian Industries (CII) estimated the Gross Market Size of just the Ayurveda sector to be Rs. 30,000 crore. During 2017-18, India exported USD 330.18 Mn worth of herbs and USD 456.12 million worth of AYUSH and Herbal products.² With the spread of Indian diaspora in other countries, the demand for ISMs has grown in those countries. Most of the traditional system formulations are based on plants. India is estimated to use around 7500 plants. However, the easy availability of medicines and herbs gets hampered by regulations within India and the export destinations. In this paper, a brief review of such regulations that have a material effect on trade is being made.

Regulations and Standards

Of late, issues of “safety and efficacy, as well as the quality control, of traditional medicine and complementary and alternative medicines have become important concerns for both health authorities and the public” (WHO, 2005). The

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latest WHO Traditional Medicine Strategy, 2014-2024 shows that quite a good number of countries are now recognising TM as an integral part of healthcare and bringing out rules and regulations on the same. There are as many as 124 countries that have laws and regulations on herbal medicine. In the USA and Europe, herbal medicines form a major chunk of over-the-counter (OTC) drugs. In Germany, the pharmaceutical companies sell almost one third of all non-prescription drugs as herbal medicines (Vasisht and Kumar, 2002). As of 2018, around 65 per cent of member states corresponding to 125 countries reported having a registration system in place for herbal medicines. In 60 countries, herbal medicines are sold as prescription medicines, whereas in 79 countries they are sold as OTC or self-medication drugs. Generally, TM does not find a place in the list of national essential drugs in most countries. However, herbal medicines are included in the list by 34 countries.

Regulations in India

The Drugs and Cosmetics (D&C) Act, 1940³, the Drugs and Cosmetics Rules, 1945 and the Drugs (Control) Act, 1950⁴ contain the drug regulations of India. They prescribe the legal requirements for the manufacture, import and sale of medicines in Ayurveda, Siddha and Unani systems, among others. They relate to regulating the quality, safety and efficacy of the medicines. The D&C Act has very specific provisions regarding quality, standards, branding and regulations of manufacture. It also provides for an Ayurvedic, Siddha and Unani Consultative Committee to advise the governments and a Technical Advisory Board to bring uniformity in the matter of administration of the Act throughout the country.⁵ It defines misbranded,

adulterated and spurious drugs.⁶ Labelling has to be in the prescribed manner. Manufacture, sale and distribution of any drug against the licence conditions and standards are prohibited.⁷ Under the D&C Act, the Central Government has also the power to prohibit in the public interest the manufacture, sale, etc., of any ISM medicine, which does not have the therapeutic value claimed for the same. The Act also empowers the central and state governments to appoint inspectors for ISM drugs.⁸ Manufacture for sale or distribution in contravention of the provisions of the Act is punishable with imprisonment for upto to one year and in the case of spurious drugs, upto three years.⁹ The Drugs and Cosmetics Rules, 1945 lay down the details, that include, among others, standards such as of strength, quality and purity.¹⁰ The manufacturing units have to comply with Good Manufacturing Practice (GMP). Approximately 7488 units have complied with GMP by 2017.¹¹

There are also very specific provisions in the Rules regarding labelling, packing and limit of alcohol in Ayurvedic (including Siddha) or Unani drugs.¹² The label should display the true list of all the ingredients used in the manufacture of the preparation. In the case of drugs for export, (a) name of the Ayurvedic, Siddha and Unani drug (single or compound formulations); (b) the name and address of the manufacturer and the number of the licence under which the drug has been manufactured; (c) batch or lot number; (d) date of manufacture, along with the date for "Best for use before"; (e) main ingredients, if required by the importing country; and (f) the words "for export"¹³ are to be included. Expiry dates have to be prominently stated on the labels/containers of drugs.¹⁴

Production and Trade

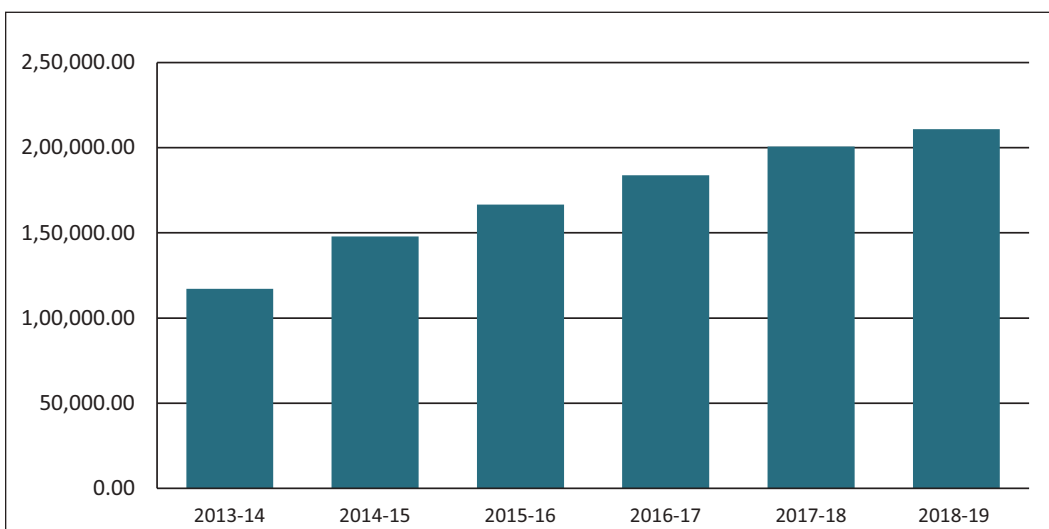
The sale of medicinal plants is taken as a fair indication of the production and trade in medicinal formulations, medicinal plants being the resource base. India has approximately 15,000 medicinal plants of which about 6000-7000 plants are used in Indian Systems of Medicine; 960 of these have been recorded in trade and 178 are traded in high volume, i.e. in quantities exceeding 100 Metric Tonne (MT), per year, according to the Ministry of AYUSH. The market size of medicinal plant in 2019 was estimated to be Rs. 4.2 billion.¹⁵ But these medicinal plants could also be used for the preparation of crude drugs and extracts also used as raw material by the pharmaceutical industry. It has been estimated that about 880 medicinal plants are involved in the Indian trade. Of these, 42 species are imported and 48 species are exported (Sen and Chakraborty, 2015).

Indian exports of 'TM' generally comprise three categories: the first one is

the medicinal plants and herbs as such, the second one, saps and extracts and the third one, formulations. The first category generally includes raw materials without any value addition and one does not know how the products end up, whether in medicinal preparations or in some other form. In some cases, they may be used as such, for example, as spices in food preparations, but mostly end up in industrial use. A major item in this category is Isabgol (psyllium husk and seeds). The second category comprises herbal juices and vegetable saps. This involves some value addition. The third one is supposed to be the real TM export. From India, mostly Ayurvedic and Unani preparations are exported. But the large exports are in the categories of vegetable saps and extracts and raw plants. (see Figure 1).

The exports of Medicaments of AYUHS systems saw a decline from the year 2013-14 to 2014-15 (Figure-2). This

Figure 1: India's Exports of Medicinal and Aromatic Plants



Notes: Value in Rs. Lakh (1 lakh = 100,000). Values reported for export of items under HS 1211.

Source: Export Import Databank, Ministry of Commerce

fall was in line with the general decline in exports of pharmaceuticals in that year. But from thereon, the exports of AYUSH medicaments have shown a general increase.

In the case of imports of raw MAPs, we have seen a huge increase in terms of value in the year 2018 and 2019 (Figure-3). It should be noted that India generally runs a trade surplus in the exchange of medicinal plants, but that gap has been vastly reduced in the past two years.

Trade Classifications

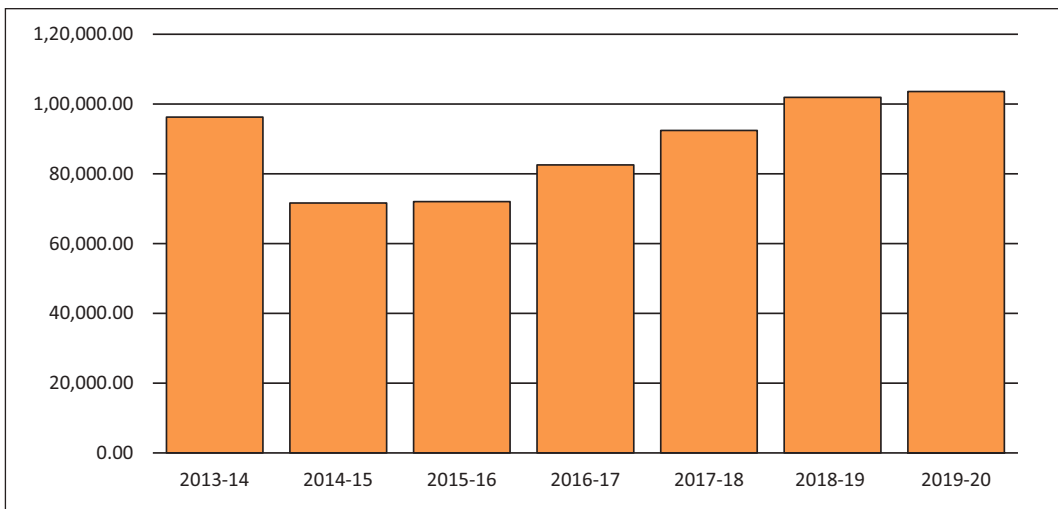
Trade classifications for TM remain a major bottleneck in trade data. The four-digit and six-digit HS code classifications have global acceptance but they do not provide targeted data on TM exports and imports. HS code 1211 relates to botanical drugs but includes plants and plant parts used in perfumery, pharmacy or for insecticidal, fungicidal or other similar purposes. In the sub-categories, they refer to certain

commonly traded commodities such as Liquorice roots (1211.10), Ginseng roots (1211.20), etc. Even within these formats, there is no universal availability of trade data on all TM products. India has been following an eight-digit classification model, which includes TM systems such as Ayurveda, Siddha and Unani besides biochemical compositions and others.¹⁶ The issue starts with evolving comprehensive classification codes for biological resources, including plants and their parts, since the trade in raw materials is both as whole plants and as parts of a plant, and many of them are TMs in themselves.

Trade Barriers

European Union (EU) and the United States of America (USA) are the major markets for trade in TM products outside BRICS. In herbal products, they have a market share of 41 per cent and 20 per cent, respectively in value terms

Figure 2: India’s Exports of Medicaments of AYUSH Systems



Notes: Value in Rs. Lakh (1 lakh = 100,000). Values reported for export of items under HS 30039011-14 and 30049011-14.

Source: Export Import Databank, Ministry of Commerce

(Deshpande, 2015). Hence the regulations in these two trade zones are material to any consideration of international trade barriers.

European Union

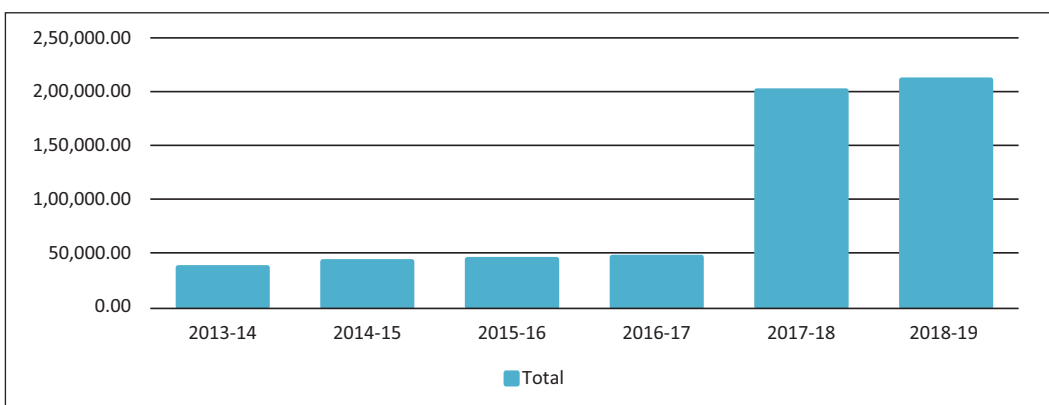
Europe regulates herbal medicinal products under the European Directive 2001/83/EC. The European Union Directive 2004/24/EC on traditional herbal medicinal products amended the provisions of the 2001 Directive to provide for a simplified regulatory approval process for herbal products. This Directive has added the following categories in the definitional article: traditional herbal medicinal product, herbal medicinal product, herbal substances, and herbal preparations. The Directive has provided for the establishment of a Committee for Herbal Medicinal Products (HMPC). Although, in 2004 the regulations simplified the registration procedure there are still many regulatory barriers where ISM products may not be able to get the registration. Some of the ISM products may contain mineral components or animal products or herbal constituents,

which will debar them from registration as traditional herbal medicinal products. The requirement for registration is that the products are to be taken without supervision by a medical practitioner. Most ISM drugs are to be used under the supervision of a medical practitioner of that branch.

United States

The US is using the term complementary and alternative medicine (CAM).¹⁷ The National Centre for Complementary and Alternative Medicine (NCCAM) defines CAM as “a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine.” Complementary medicine is used together with conventional medicine, whereas alternative medicine is used in place of conventional medicine. Botanical products, depending on the circumstances may be regulated as drugs, cosmetics, dietary supplements, or foods. The US was the first country to introduce Global Manufacturing Practice (GMP) regulations covering herbal medicines through the

Figure 3: India’s Imports of Raw Products



Notes: Value in Rs. Lakh (1 lakh = 100,000).

Source: Export Import Databank, Ministry of Commerce.

Drug Amendments of 1962.¹⁸ In 2007, the FDA issued mandatory current good manufacturing practices (cGMP) for dietary supplement manufacturers and distributors.¹⁹ Most of the developed countries prefer to have standardisation of herbal drugs, as to quality, efficacy and safety. Many of the exporters to those countries face issues on these grounds,²⁰ but adaptation to the changed conditions will have to be made and responsible governments will have to reassure their people that marketing permissions are given only for medicines, drugs or food items which are safe for human or even animal consumption.

The Way Forward

The global herbal market is projected by different agencies to grow to \$ 5 trillion by 2050. The goods for trade include medicinal formulations, medicinal and aromatic plants, plant material extracts, plant materials, spices, herbs and cosmetics and dietary supplements. This throws open wide opportunities for countries with vast biological resources like India. According to data available from the Ministry of Commerce, Export- Import Databank, India's export of medicaments in AYUSH constitute less than 1 per cent of India's total export of pharmaceuticals in value terms. Moreover, the exports of Medicaments of AYUSH registered a Compounded Annual Growth Rate (CAGR) of just around 1 per cent between 2013-14 and 2019-20 compared to CAGR of 7.99 per cent registered for the total pharmaceutical sector. That would mean the export of Indian TM is not a significant proportion of India's pharmaceutical exports.

If TM systems have to emerge as

alternative or complementary to conventional systems, they will have to be put on an even keel with the conventional system in human resource and infrastructure. For this, it should ensure the availability of qualified practitioners, researchers and regulators of TM. For this, more educational and research institutions will have to be established. With industrialisation and wide spread use of insecticides and pesticides, the quality and purity of raw materials, viz. plants and plant parts, used in TM formulations is emerging as a subject that may affect the quality of the medicines. Not being laboratory created or industrially produced synthetic chemicals, maintaining the same quality in TM formulations with raw natural or semi-processed natural ingredients is a challenge in itself.

An issue in the raw material sector is the shortage of genuine and uncontaminated herbs and plants that go into the making of medicinal formulations. This can be met only by incentivising farmers to grow more medicinal plants, maybe on a commercial scale. The creation of reliable and comprehensive statistical databases on raw materials is a *sine qua non* for the TM formulation industry. It will also be a boost to the agricultural sector. Drug master files and national dossiers on each plant need to be developed to convince the world that TMs are not mere hearsays but proper and time-tested systems.

The major difficulties in regulating herbal medicines identified in the WHO Survey are to some extent applicable to the TM sector as a whole. These include lack of research data, lack of appropriate mechanisms for control of herbal medicine, lack of education and training and lack

of expertise within the national health authorities and control agencies. These are issues that are amenable to solutions with adequate governmental or regulatory interventions. Legislative and executive initiatives are required. Educational and research institutions will also have to be strengthened.

In order to get wider acceptance globally for TM, countries like India should first integrate its own TM systems such as Ayurveda into the mainstream. TM manufacturers and traders will have to adjust to current regulations and standards in all countries. This includes ensuring quality and safety standards for products, processes and practices. GMP certification is increasingly becoming a necessity. Proper documentation, certification of quality and standard analysis, etc., are required increasingly. Along with such measures, they also need to press for international trade classifications that recognise different medicines in different systems, raw materials, etc. separately.

Standardisation faces many hurdles on account of difficulties in the identification of plants, genetic variability, variations in growing conditions, diversity in harvesting procedures and processing of extracts, and lack of information about active pharmacologic principles (Kumar et al., 2016). But with the development of a proper database these issues can be successfully addressed.

In order to satisfy quality concerns, clinical trials using modern technology are also required to obtain marketing approvals as medicines in countries, which are not countries of origin of such TM. However, new and separate protocols for such trials will have to be developed since current ones are essentially for synthetic

chemical or biomedicines. As the TMs are mostly proven therapies through long usages and without serious adverse side effects, though no clinical trials in the modern sense had been done in the past, the risks for volunteers are much less than in the conventional pharmaceutical sector.

As a trade strategy, the priority will have to be on those items that have less difficulty in getting registration and marketing approvals in other countries. This will help in establishing market presence and once that is achieved, spread and penetration will be easier.

Conclusion

India can significantly improve its healthcare by exploring the scope of the traditional systems of medicine), which are cost-effective compared to the modern medicinal system. The TM's general approach is to aim at comprehensive and wholesome wellness of the patient by removing the infirmities in the individual's system caused by the impact of environment, food and habits. To achieve that, the medicinal formulations industry, including the raw material sector, has to be developed and sustainable access and trade in the products have to be encouraged. While ensuring quality and standard, the regulations have to take into account the differences and distinctions with the conventional health care sector and the peculiarities of the TM systems.

Endnotes

- ¹ Ministry of AYUSH Dashboard. Online at: <https://www.ayush.gov.in>
- ² PIB, 2019. Export of Herbs and Herbal Products. Press Information Bureau of India: <https://pib.gov.in/Pressreleaseshare.aspx?PRID=1558955>

³ Drugs and Cosmetics (D&C) Act. No. 23 of 1940. The Act has been amended a number of times, the last one being of 2008.

⁴ Drugs (Control) Act, No. 26 of 1950.

⁵ Drugs and Cosmetics (D&C) Act, 1940, Section 33D.

⁶ Ibid, Section 33E, Section 33EE, and Section 33EEA.

⁷ Ibid, Section 33EEC.

⁸ Ibid, Section 33F and Section 33G.

⁹ Ibid, Section 33(1)b.

¹⁰ The Drugs and Cosmetics Rules, 1945. Rule 111

¹¹ Outlook India. 2017. 1,179 ASU&H drug manufacturers not compliant with GMP: Govt. Online at: <https://www.outlookindia.com/newscroll/1179-asuh-drug-manufacturers-not-compliant-with-gmp-govt/1212369>

¹² The Drugs and Cosmetics Rules, 1945. Part XVII

¹³ Ibid, Rule 161A

¹⁴ The Drugs and Cosmetics Rules, 1945. GSR 764(E) dt. 15.10.2009.

¹⁵ Muringatheri, M. 2019. Medicinal plants in good demand. The Hindu. Online at: <https://www.thehindu.com/news/national/kerala/medicinal-plants-in-good-demand/article30239519.ece>

¹⁶ ITC is an 8 digit product classification code used in India only which is a modification of 6 digit HS code (also known as HTS Harmonized Tariff Schedule) used all over world.

¹⁷ Public Health Service Act [42 U.S.C. 262 (a) (1)]. Section 351 (a)(1)

¹⁸ FDA. Guidance for Industry: Current Good Manufacturing Practice in Manufacturing, Packaging, Labelling, or Holding Operations for Dietary Supplements; Small Entity Compliance Guide; 2010.

¹⁹ Therapeutic Goods Administration, Department of Health, Australian Government. 2012. Pan Pharmaceuticals Limited: Regulatory action & product recall information. Online at: <https://www.tga.gov.au/product-recall/pan-pharmaceuticals-limited-regulatory-action-product-recall-information>

²⁰ Some of the suggestions in this section are based on the discussions in an informal consultation organised by RIS in preparation

to the BRICS Wellness forum in which many prominent AYUSH industry people and academics participated. We are especially thankful to the suggestions made by Dr. R B Puranik, Dr. D C Katyar, Dr. Ashok Pandey, Dr. Vaidya Vinod and Dr Ramanathan.

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