

# Traditional Medicine Review

Volume 1

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## EDITORIAL

## ARTICLES

**Globalisation of Indian Traditional Medicine: Recent Strides in Standardisation of Terminologies and Diagnosis**

*P. N. Ranjit Kumar*

**Enablers for Leveraging Digital Technologies in Indian Traditional Medicine: Health Data Policy interventions**

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**Globalization of AYUSH Products: Status, Challenges and Suggestions for Growth**

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## PERSPECTIVE

**Innovation in the Indian Systems of Medicine: Rationale and Means**

*T. C. James*



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## Traditional Medicine Review

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## EDITORIAL

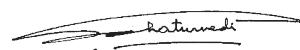
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India's efforts to globalise Ayush systems are being undertaken both through an overhaul of the domestic infrastructure in line with global healthcare trends and a strong foreign policy pitch for reforms at international health platforms like WHO. Of the several new developments in the healthcare sector, one of these is the growing need for digital technologies to accelerate quality and affordability in healthcare. Efforts in the digitalisation of Ayush are being undertaken at all levels. The use of IT for research, education, health programmes, drug regulations and health services are some important innovations to transform the ecosystem of the sector. This is certainly going to be a catalyst for the transformation of the Ayush regulatory and patient centric infrastructure. Globally, of strategic significance is the standardisation of terminologies used in the Indian Systems of Medicine. This serves as a uniform reference to all countries thereby facilitating its understanding and adoption in countries outside their original cultural and geographical domains.

This Issue presents a set of articles deliberating upon pressing subjects in the Ayush sector specially, with reference to changing imperatives for growth of the sector.

P. N. Ranjit Kumar, in his article, 'Globalisation of Indian Traditional Medicine: Recent Strides in Standardisation of Terminologies and Diagnosis', emphasises India's efforts for inclusion of Ayurveda, Siddha, Unani in the International Classification of Diseases 11th revision (ICD-11), the globally accepted disease classification system of the WHO. This is of significance as it paves the way for internationally acceptable standards for traditional medicine, including manufacture, registration of products, practices, and practitioners, and post-market provisions and will provide models for international harmonization in future. Following this, the article by Saumya Pathak and Rajeshwari Singh highlight the massive information technology (IT) applications that operate at the back-end of healthcare systems and efforts at preparedness for development of applications like those relating to electronic health records, classification of morbidity and mortality, and various clinical and public health activities in the Ayush sector. Utkarsh Ghate and Asmita Wele in their article 'Globalization of AYUSH Products: Status, Challenges and Suggestions for Growth' analyse key segments in the manufacturing sector value chain and provide a roadmap for policy focus to maximise the growth potential of the sector. In the section on Perspectives, T.C. James debates the definition of innovation as it applies to different healthcare systems and the relevance of its applicability to traditional health systems like Ayush. Finally, Krishna Ravi Srinivas offers a book review of 'Mapping the History of Ayurveda: Culture, Hegemony, and the Rhetoric of Diversity' - authored by K P Girija

I hope the readers will find this issue of Traditional Medicine Review useful in their respective spheres of influence.



**Sachin Chaturvedi**





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# Globalisation of Indian Traditional Medicine: Recent Strides in Standardisation of Terminologies and Diagnosis

P. N. Ranjit Kumar\*



P. N. Ranjit Kumar

## Introduction

In the last week of February 2020, in what was probably the last major inter-governmental conference before COVID-19 shut the world out, 16 countries met in New Delhi and re-affirmed their commitment to work together for the development of traditional medicine (TM). The growing international acceptance of Indian systems of medicine, particularly Ayurveda, Unani, and Siddha (ASU) systems, formed the backdrop of the discussions. The focus of the conference was the forging of collaboration in a critical but at the same time rather technical, area of knowledge related to these TM systems, namely the standardization of terminologies and diagnosis.<sup>1,2</sup>

The two-day event was named *International Conference on Standardisation of Diagnosis and Terminologies in Ayurveda, Unani, and Siddha Systems of Medicine -2000*, or ICoSDiTAUS-2020 in short. The participating countries at the conference emphasised the role of traditional medicine as a significant area of health care in their respective countries. The notable success of ICoSDiTAUS -2020, as we will see in subsequent paragraphs, is that it gave a fillip to the efforts to find a place for Ayurveda, Unani, and Siddha in International Classification of Diseases, 11<sup>th</sup>

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revision (ICD- 11), the globally accepted disease classification system of the WHO.<sup>3</sup>

## **Traditional Medicine in the Modern World**

The Alma-Ata Declaration of 1978 emerged as a major milestone of the 20<sup>th</sup> century in the field of public health and it is considered a modern era watershed in the history of the development of TM. The Declaration which came at the International Conference on Primary Health Care in September 1978 jointly organized by the WHO and the UNICEF with 134 countries participating, is remembered for having adopted the goal of “health for all” to be achieved by the year 2000.<sup>4</sup> Stakeholders of traditional medicine, however, remember the Declaration for the reference it made to TM. The Declaration of Alma-Ata was the first occasion when a formal international event on public health urged countries and governments to include TM as an important component of primary health care in their respective domains.<sup>5</sup>

Alma-Ata contributed to unlocking the potential of traditional medicine to address health challenges in different parts of the world, by bringing increased attention and resources to TM practices, over the decades that have passed.<sup>6</sup> TM in many countries offers affordable and accessible healthcare and has emerged as an integral part of the primary health care system in those countries.<sup>7</sup> Another development in the post Alma-Ata decades has been the growing acceptance of many traditional medicine systems in developed countries as alternatives or complementary practices to conventional (allopathic) healthcare.<sup>8</sup>

The 21<sup>st</sup> century, thus, sees many traditional medicine systems being adopted

in areas beyond the original cultural and geographical contexts within which they arose and operated for thousands of years. The new commitment to traditional medicine which came out of the Alma-Ata Declaration, the WHO traditional medicine programmes are the two WHO Traditional Medicine Strategies covering the time-spans 2002-05 and 2014-2023 respectively.<sup>9</sup> The recognition of TM as a credible approach to healthcare and the unprecedented institutional interest across the world, have all helped to add scientific rigor and commercial vigor to the growth and development of traditional medicine systems in different countries.<sup>10</sup> One of the demands considering this increasing globalization of traditional medicine is the need for its standardization to facilitate its understanding and adoption in countries outside their original cultural and geographical domains (Choi, 2020; Payyappallimana, 2010).

## **The Standardisation Challenge in Traditional Medicine and the Significance of International Classification of Diseases (ICD)**

The immense diversity that is the hallmark of TM systems is also the biggest challenge in the way of their global dissemination (Ye and Zhang, 2017). As noted by WHO, “internationally acceptable standards for traditional medicine, including manufacture, registration of products, practices, and practitioners, and post-market provisions, will become increasingly relevant and will provide models for international harmonization”.<sup>9</sup> The earliest requirement of any such international effort for harmonization would be

developing of standard terminologies for international use, as this would facilitate worldwide scientific communications in all matters related to traditional medicines and also expedite standardization in other aspects of TM practice.<sup>11</sup> An international standard terminology would serve as a common language for the respective TM system which would enable stakeholders from different countries to learn, use and practice the system (Tsutani and Takuma 2008). If a better understanding of the different forms of traditional medicine develops across the world, it will increase the respect for these systems and will also facilitate increased safety and effectiveness in the use of TM services.

Standardized terminology is a critical ingredient for the massive information technology (IT) applications that operate at the back-end of healthcare systems. IT has been the single most transformative agent in healthcare practice (as in other spheres of human activity) in the 21<sup>st</sup> century. IT applications like those relating to electronic health records, classification of morbidity and mortality, and various clinical and public health activities have been driving the advances in the health sector.<sup>12</sup> However, these advances have largely bypassed the TM systems because of the latter's diverse cultural and linguistic characteristics which are not amenable to applications of IT.

Standardisation of common terms of each TM system provides a solution to the above challenge. Standard terminology can be the first building block for TM systems to be co-opted into electronic health records. Standard terminology can also form the basis for collection of uniform data about various practices

of traditional medicine, and further, for evolving classification systems for morbidity and mortality.<sup>13</sup> WHO has long been advocating the standardization of data collection and storage in traditional medicine (Pritzker, 2011). The Regional Strategy for Traditional Medicine in the Western Pacific (2011-2020) had observed that standardization of data collection and storage "will aid access to traditional medicine information and assist in its inclusion in evolving healthcare applications, including computerized health information systems, reimbursement policies, treatment, health care funding allocation and public health programmes".<sup>14</sup>

The Regional Strategy further asserted that "It is intended that the standardization of traditional medicine will be internationally accepted and become part of the WHO Family of International Classifications, such as the International Classification of Diseases (ICD)". This has since become a reality when a traditional medicine chapter was included in the latest iteration of ICD that is the ICD 11 which was adopted in May 2019 by the World Health Assembly and finally came into effect in February 2022.<sup>15</sup> Presently, the TM chapter has only one module, which is devoted to Traditional Chinese Medicine (TCM). This chapter, though named after TCM, covers the TM practices of three countries, namely, China, Japan and Korea. As is widely expected in accordance with preparatory work that has been under way for the last few years, the second module of the TM chapter would be devoted to ASU systems, and will take the form of a union set of diagnostic terms and classification categories covering these three traditions.

## Efforts in India for the Standardisation of TM Terminologies and Diagnosis

The WHO programmes on TM after Alma Ata have contributed notably to the systematic development of TM systems of India from the 1980s onwards. These efforts came through routes like the Appraisal Project Work (APW) and Direct Financial Cooperation (DFC) projects of the WHO.<sup>16,17</sup> They added momentum to the country's efforts to articulate and strengthen the scientific basis of its TM systems.

Early collaboration with the WHO in matters related to standardization of TM terminologies and diagnosis can be traced to 2010, considering the project on Development of Benchmarks for Training and in the preliminary work on the Standardised Terminologies of Ayurveda, Unani, and Siddha.<sup>18</sup> These efforts evolved into the more advanced Project Collaboration Agreement (PCA) between the Ministry of Ayush of the Government of India and the WHO in May 2016 for developing benchmarks for training in Yoga, benchmark for practice in Ayurveda, Unani and Panchakarma.

The 21<sup>st</sup> century also saw the induction of information technology on a large scale in the healthcare sector in India, and despite their diversity and classic character, TM systems could not remain totally insulated from the influence of IT. Efforts began within the government bodies and outside, often with mutual cooperation, for the standardisation of terminologies and diagnosis, which were basic requirements to facilitate the induction of IT. A few of these efforts later converged under the aegis of the Central Council for Research

in Ayurvedic Sciences (CCRAS) of the Ministry of Ayush and resulted in the development of the National Ayush Morbidity and Standardised Terminologies Electronic (NAMASTE) Portal in 2017.<sup>19</sup> The portal was a landmark not just in the modernisation of Indian traditional medicine, but in the digitisation of TM systems globally, for it created a platform for testing and validation of TM diagnosis and terminologies. The Ayurveda, Unani and Siddha systems particularly gained from this initiative. The NAMASTE Portal moved to even greater strength in 2018 when the Ayush Hospital Management Information System (A-HMIS) was rolled out and linked to the former.

Another significant Project Collaboration Agreement (PCA) was signed between the Ministry of Ayush and WHO in December 2017, with the objective of initiating the development of international terminologies for Ayurveda, Unani and Siddha systems. The international interest in these developments in Indian traditional medicine systems became evident in the interaction held by the Ayush Minister with the Ambassadors of different countries to India on 20<sup>th</sup> December 2018 at New Delhi, on the subject of "Globalization of Traditional & Complementary Medicine".<sup>20</sup> In the meeting in which 15 countries were represented, there was a consensus that the stake holding countries should join and work for the globalisation of TM so that the rewards of these precious inheritances reach the entire humanity.

It was also acknowledged that the induction of systems like ASU in the ICD of the WHO would be desirable. In follow up to the PCA of December 2017, an international consultative meeting was organised at the Institute of Postgraduate

Training and Research in Ayurveda, Jamnagar, Gujarat in December 2019 for developing international terminologies for ASU. International experts of Ayurveda, Unani and Siddha from 14 different countries including India attended the meeting. India's standardization and coding efforts in TM systems took the next logical step when the Ministry of Ayush and WHO signed a Donor Agreement for taking up the work that would facilitate the inclusion of Ayurveda, Unani and Siddha in the ICD-11. The Agreement was signed on 11th February 2020, and it provided for development of what would be the second module of the TM Chapter of ICD -11.

## The Impetus Provided by ICoSDiTAUS -2020

As reported by the Press Information Bureau, New Delhi, ICoSDiTAUS-2020 was "the biggest ever international event dedicated to standardisation of diagnosis and terminologies of traditional medicine in terms of the broad level of participation covering virtually all the continents". The participants of the conference were: Sri Lanka, Mauritius, Serbia, Curacao, Cuba, Myanmar, Equatorial Guinea, Qatar, Ghana, Bhutan, Uzbekistan, India, Switzerland, Iran, Jamaica and Japan. Ten other countries namely, Antigua & Barbuda, Australia, Bangladesh, Brazil, Germany, Hungary, Mongolia, Nepal, South Africa and Trinidad & Tobago, who were keenly involved in the discussions in the run-up to the event, could not participate due to the setting in of COVID-19 travel restrictions.<sup>21</sup> However, they have continued to support the cause of international collaboration in traditional medicine for improving public health.

The New Delhi declaration on

collection and classification of diagnostic data in traditional medicine was the biggest take-away from the conference. The declaration recognised the importance of including and further developing the chapter on traditional medicine diagnoses in ICD-11. The declaration also underlined the importance of including TM systems in ICD, as it, due to its standardized categories, terms and definitions, enabled the counting of traditional medicine services and encounters, and facilitated the measurement of their form, frequency, effectiveness, safety, quality, outcomes, cost. Further, it highlighted inclusion of TM in ICD would also make their comparison with mainstream medicine possible.

The conference provided an opportunity for India to show case its achievements in standardisation of terminologies and diagnosis in the Ayurveda, Unani and Siddha systems. All participants endorsed the importance of collaborative efforts by stake-holding countries to promote these systems. The suitability of Ayurveda, Unani and Siddha systems for inclusion as the second module in the TM Chapter of ICD was also pointed out.

## The Way Forward for the Standardisation Effort

The development process of the PCA of 2017 on ASU standardized terminologies has progressed further from the meeting of December 2019 in Jamnagar. In the subsequent years, despite the disruptions brought in by the pandemic, the momentum of work was maintained. The terminology being evolved include definitions, contextual meanings, classical usages, suggested English terms and



synonyms. Through a series of meetings spread over many months and held largely through video conferences, the draft documents are being reviewed, and an international consensus on the terminology is being arrived at. The project is due to conclude with the adoption of the standardised terminology in January 2023.

Coming to the project on inclusion of Indian traditional medicine in ICD, as already mentioned in earlier paragraphs, the first module of the TM chapter devoted to Traditional Chinese Medicine has already been put in place as part of ICD 11. In many ways, TCM has opened the doors of ICD to other TM systems. The Donor Agreement signed between the Ministry of Ayush and WHO in Feb 2020 envisages that the second module of the TM chapter will be a union set of harmonized traditional medicine conditions of Ayurveda, Unani, and Siddha systems of medicine. As in the case of the PCA on standardization ASU terminologies, the work on standardization of diagnosis for inclusion in ICD was also affected due to pandemic. However, it has since gained momentum and through discussions, the alignment of the three systems with the ICD structure has been arrived at. Broad based consultations under the aegis of WHO among stake-holding countries have helped to assess and learn from their use cases and standardized terminologies in these three systems. As per the Donor Agreement work on finalising the Ayurveda module of the TM chapter which started in February 2020, will be completed in four years.

Ayurveda, Unani and Siddha, along with other traditional medicine systems of India, are practices that have been part

of our culture for thousands of years. In recent years, thanks to conscious policies of the Government, their role in public health programmes and mainstream healthcare delivery systems have increased substantially. Set against this context, the recent rigorous efforts towards the standardisation of TM terminologies and diagnosis, especially the much-anticipated inclusion of the Ayurveda module in ICD-11, will bring in multiple benefits.

The positive outcomes of Ayurveda, Unani and Siddha getting integrated into the ICD will not be restricted to India, but will be available to all WHO member states (in practice all countries where ICD is adopted), and will be notably felt in nearly 50 countries where these systems or their closely related forms are practiced. ICD will facilitate the counting of health services and encounters of these systems, further enabling the measurement of their parameters like form, frequency, effectiveness, safety and quality.<sup>22</sup> It will generate detailed TM usage data at local, provincial, national and international levels. The scope and quality of research and reporting on all aspects of these systems will be significantly enhanced. Subsequently, the integration of TM data into electronic health records will enable them to come under regular insurance coverage and reimbursement systems, opening avenues for financial self-reliance and investment inflows. All these outcomes will align traditional medicine systems with global norms and standards in the contemporary healthcare industry. Thanks to the international participation in these efforts, their rewards will lead to healthier lives for the populations and citizens in different parts of the world.

## Endnotes

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# Enablers for Leveraging Digital Technologies in Indian Traditional Medicine: Health Data Policy interventions

Saumya Pathak\* and Rajeshwari Singh\*\*



Saumya Pathak



Rajeshwari Singh

## Introduction

Global promotion and propagation of traditional knowledge has been an important thrust area of World Health Organisation (WHO). Several steps have been taken in India to mainstream and integrate its traditional medicine (TM) in clinical practice for quality healthcare. In recent years, the trend of TM adoption has increased greatly, but the process of Traditional Indian Medicine (TIM) internationalisation needed digitization in both internal and external verticals of AYUSH. “Health for all” initiatives of “Digital India” for digital innovations in India to centralise health technologies via digital applications ranging from individual use to healthcare systems’ is of broader usage in the current context. Technically, digitization enables data-driven information person-centred care with reduced human involvement.<sup>1</sup> In this regard, focussed government investments are being undertaken in emerging areas of TIM i.e. digitization, artificial intelligence (AI) and machine learning (ML) etc. This is expected to help leverage the strength of AYUSH vertical in the health sector. In this article, we analyse the transformational changes in the Digitization of the AYUSH sector.<sup>2,3</sup> We have also discussed the linkages with science technology and innovation vertical by fine-tuning digital initiatives by obtaining a better

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user experience and improving last-mile connectivity.<sup>4</sup>

## Emerging Requirements for AYUSH under the Digital Platform

The concept of “Digital India” visualises creating a transformation for enabling a digitally equipped society that helps create a traditional health knowledge economy.<sup>5</sup> Under this scheme, India’s National Digital Health Blueprint (NDHB) encompasses the National Digital Health Ecosystem (NDHE) that proposes to ensure the availability of healthcare services across the country.<sup>6,7</sup> The NDHB was mandated to create NDHE, which supported Universal health coverage (UHC) in an efficient, accessible, inclusive, affordable, timely, and safe manner by providing a wide range of data, information, and infrastructure service.<sup>8,9</sup> In India, Electronic Health Records (EHR) archival of the patient data and documentation of clinical evidence, digital technology in health in mobile health (m-Health), Health Information Technology (IT), tele-health or telemedicine, trade of medicinal plants, digital regulatory network are the critical sectors for digitization.<sup>10,11,12</sup>

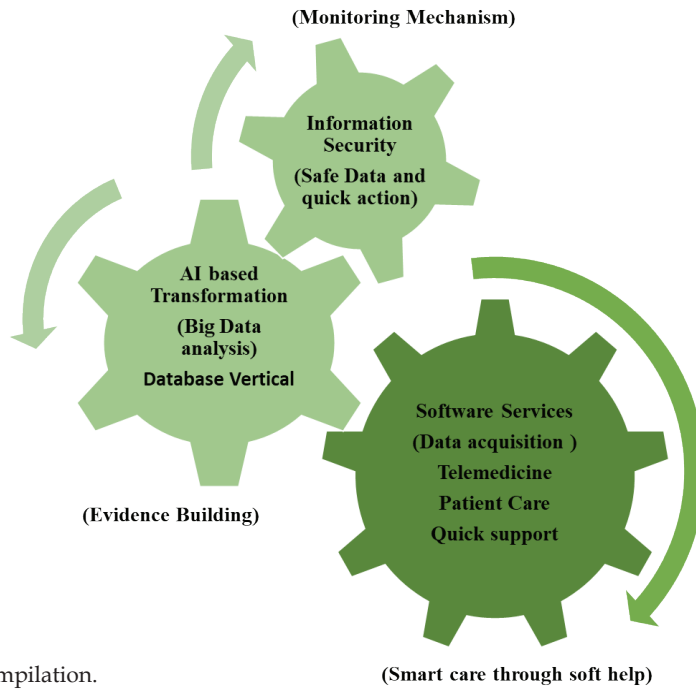
TIM is specially challenged with a need to strengthen the digital platforms for monitoring, impact assessment and accounting. In the AYUSH sector, digitization also needs to overcome the challenges of data storing and sharing, thereby supporting the decision-making process.<sup>13,14</sup> Besides, the demand for digital data sharing networks in TIM, i.e. AYUSH has specially increased during the COVID-19 pandemic.<sup>15</sup> In countries like China the incorporation of

Big data and AI-based ML technologies are being sought to reduce the time in strengthening the network for medical record, diagnostics, regulatory networks, R&D related activities, trade and efficacy of drugs for resolving the challenges in the TCM sector.<sup>16,17</sup>

Nationally, policy support for digitisation in AYUSH has been acknowledged under the rubric of National Health Policy (NHP 2017), where the aim has been to harness the transformative potential of IT to develop an IT backbone for the whole AYUSH sector. AYUSH Grid has thus been initiated as the most promising digital platform from the Ministry of AYUSH.<sup>18,19,20</sup> Research, education, health programmes, drug regulations, health services are all set to gain from AYUSH Grid.<sup>21,22</sup> Given that healthcare professionals are directly involved in patient-centric outcomes<sup>23,24</sup> under the Ministry of AYUSH (MoA) the focus on research and development to optimise the knowledge base with the help of digital health infrastructure has been a priority.<sup>25</sup> In the long run, digitalization of the whole AYUSH sector would result in considerable creative and process re-engineering in various fields of healthcare delivery in AYUSH Systems.<sup>26</sup>

MoA has developed pilot projects such as the AYUSH Hospital Information Management System (A-HMIS), Tele-Medicine, Yoga-locator Application, Bhuvan Application, Yoga Portal, Case Registry Portal, which is time to time incorporated into the AYUSH GRID Project.<sup>27,28</sup> Digital initiatives taken up by the MoA were a crucial feature in transforming the education, research, and services offered by the AYUSH sector.

**Figure 1: System Approach for Digitization of AYUSH Vertical**



Source: Authors' compilation.

## A Systems Approach to Digital Initiatives in AYUSH

Since the last decade, the AYUSH sector has been emerging with consistency in the changing healthcare industry.<sup>29</sup> Currently, the AYUSH healthcare sector is transforming according to patient-centric needs. In this regard, the TIM is incorporating new technologies to cope with these changes to revolutionise the sector. Figure 1 elaborates the system approach in AYUSH sector for digitization by connecting information security, big data transformation by strengthening database vertical and uplifting software scenarios.<sup>30,31,32</sup> The system approach leads to impact on different sectors of AYUSH. This includes:

- Revamping market of AYUSH to reduce financial losses
- Minimising mistakes in routine

AYUSH medical practises

- Boosting AYUSH knowledge economy
- Maximising the use of resources.

To connect several vertical of AYUSH, there are several digital initiatives which are projected to boost the traditional medicine sector (Table: 1)

As highlighted in Figure 2 and Figure 3, health informatics in AYUSH is reported as one of the most appropriate mechanisms in improving the healthcare domain. The COVID pandemic led to implementation of quality parameters in well-established traditional AYUSH approaches to satisfy the healthcare-related needs of grassroots. This has led to fruitful outcomes with regard to smart care, better treatments for patients, remote service, learning with working, applications of smart processing, compatible materials, etc. for enhancing

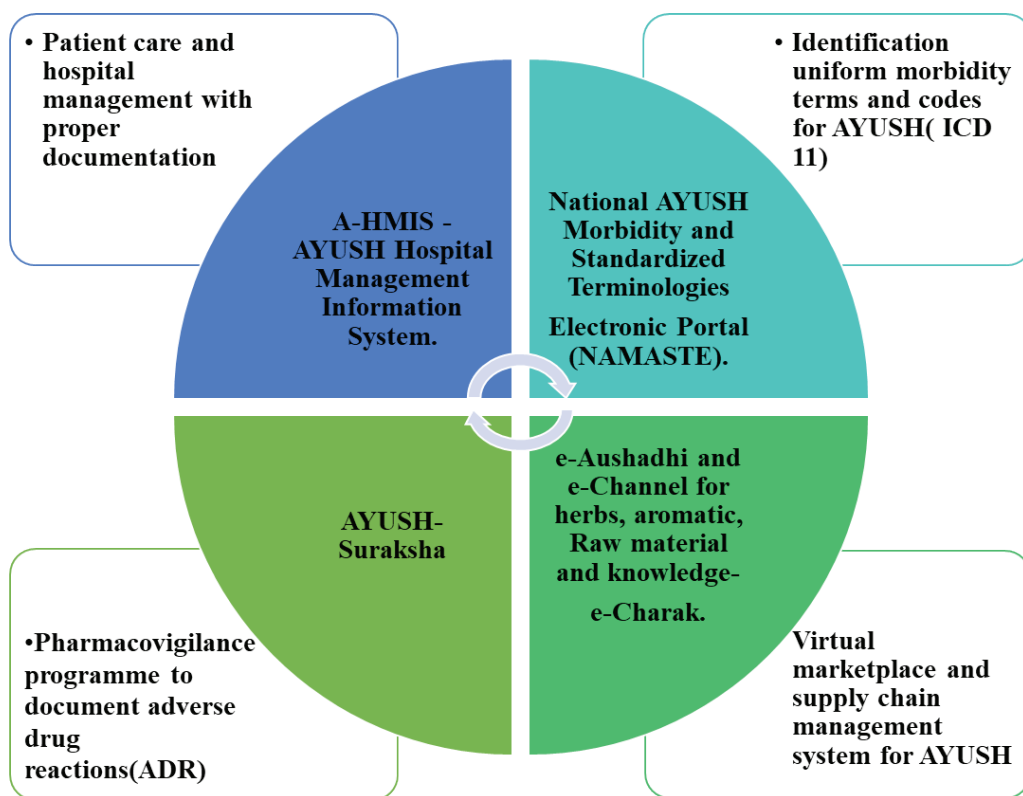
**Table 1: Major Digital Initiatives in AYUSH**

<i>Category</i>	<i>Initiative</i>	<i>Details</i>	<i>Year</i>
<b>Education</b>	<a href="#"><u>AYUSH next</u></a>	Knowledge dissemination platform	2021
	<a href="#"><u>e-MEDHA Catalogue</u></a>	Book repository	2020
<b>Health Services</b>	<a href="#"><u>HMIS (portal)</u></a>	AYUSH health care delivery systems, AYUSH Electronic Health Records (EHR) and morbidities codes	2018
	<a href="#"><u>NAMASTE (portal)</u></a>	Portal for standardised terminologies & morbidity codes for AYU&S medicines	2017
<b>Research</b>	<a href="#"><u>AYUSH Research Portal</u></a>	AYUSH research articles. Evidence based searchable dimension	2011
	<a href="#"><u>Showcase of Ayurvedic Historical Imprints (SAHI)</u></a>	Compilation of Ayurveda based medical heritage from pre-historic period to modern times	2020
	<a href="#"><u>AYUSH Manuscripts Advanced Repository (AMAR)</u></a>	Repository for Ayurveda, Yoga, Unani, Siddha and Sowa- Rigpa Manuscripts and catalogues.	2020
<b>Drug related (Administration and supply chain),</b>	<a href="#"><u>e-Aushadhi (portal)</u></a>	*For online licensing of AYUSH Drug.	2019
	<a href="#"><u>AYUSH Suraksha (portal)</u></a>	Reporting Pharmacovigilance and misleading advertisements.	2011
<b>Medicinal plants</b>	<a href="#"><u>e-Charak (portal and mobile app)</u></a>	E-platform for trade of medicinal plants	2016
<b>I n t e r n a l governance</b>	<a href="#"><u>AYUSH Information hub</u></a>	AYUSH related authentic and verified information for Public access	2021
<b>IEC</b>	<a href="#"><u>Yoga locator</u></a>	Yoga Practises	2019
	<a href="#"><u>m-yoga</u></a>	Yoga Practices in association with WHO	2021
	<a href="#"><u>AYUSH Sanjeevani</u></a>	AYUSH practices during COVID-19	2020

Source: [\(7\)">https://doi.org/10.1016/j.jaim.2021.07.014.\(7\)](https://doi.org/10.1016/j.jaim.2021.07.014)

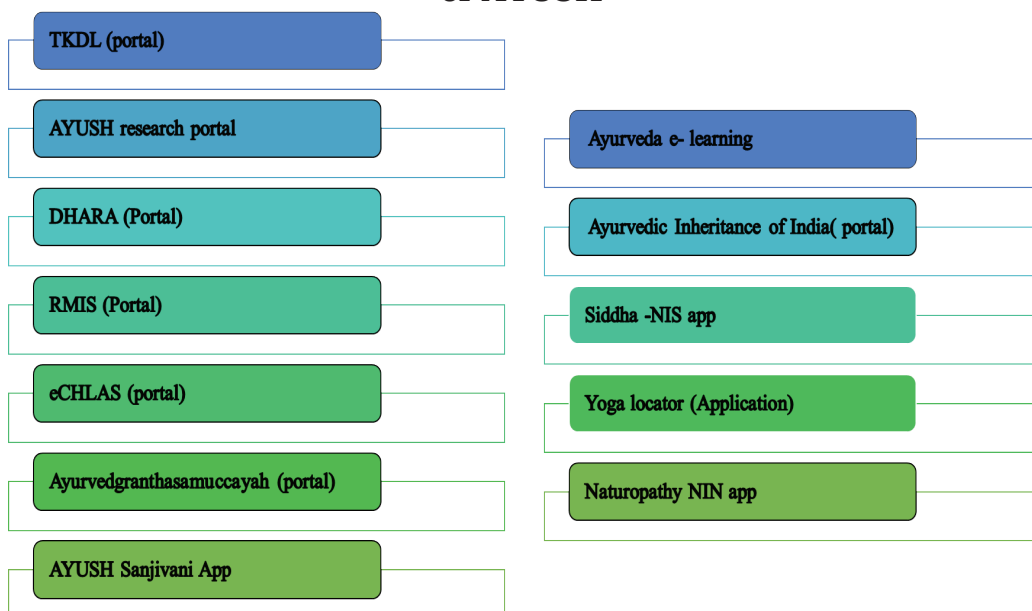
\*Ayurveda, Siddha, Unani and Homoeopathy drugs and related matters and to create a transparent system for procurement, storing, and distributing high-quality drugs and supplies making it a one complete space for drug supply chain management System in AYUSH.

**Figure 2: Health Informatics for Digitization of AYUSH**



Source: Authors' compilation.

**Figure 3: Digitization of Academic and Communication Initiatives of AYUSH**



Source: Authors' compilation.

patient satisfaction.<sup>32,33,34,35</sup>

## Research and Innovation Verticals for Digitalization of AYUSH

Innovation in AYUSH is projected to create new forms of value addition.<sup>36,37,38,39</sup> In this regard, the upstream research entities at the institutional level in AYUSH universities or public research institutes, funded by governments, and the downstream research entities, mainly funded privately have emerged as knowledge partners. This has resulted in a strengthened ecosystem of AYUSH science. Many computational studies are also emerging to identify medicinal plants using complex data sets in order to provide authentication reports. In the long run, India's shift to creating a knowledge economy of the AYUSH sector will make it possible to participate positively in the globalization of trade and finance.<sup>40,41</sup>

## Gap and Challenges

The AYUSH sector in India has digitally evolved and played a significant role in epidemic control during the recent COVID-19 crisis.<sup>42</sup> Broadly, holistic view and pattern identification are the two features of AYUSH that distinguishes it from allopathic medicine. For digitization of AYUSH systems, some of the platforms (eg NAMASTE portal) evaluate the value of AYUSH based on the theory-based and evidence-based medicine<sup>43,44</sup>. There is however a pressing need for responding to the concern of the international medical community toward its safety, efficacy and evidence building about AYUSH medicine (i.e. AYUSH Suraksha Portal). In May 2019, a chapter on traditional medicine in the 11th revision of the WHO

International Classification of Diseases (ICD-11) is a welcoming step producing knowledge base and dissemination of AYUSH resources for wellbeing.<sup>45</sup>

However, challenges remain. These include:

1. Lack of common standards for data and databases leading to a lack of centralised data.
2. Lack of trained and oriented human resources in the AYUSH sector with good knowledge of IT.
3. Infrastructure, hardware and software related challenges.
4. Lack of dedicated financial resources and sustainable recurring expenditure.
5. Lack of assessment of cost-benefit analysis and utility of these applications in AYUSH Sector.

Considering this, it is essential to incorporate a multidisciplinary approach, applied information science, systems biology, and complexity science in the AYUSH system to bridge the gap between life and diseases. Data and machine learning based approaches and theories can help us better understand the AYUSH system's multiple component formulas, quality control, and multi-target effects of the system for providing better healthcare and wellness. The answers to these critical issues may promote further innovation of the Indian traditional system of medicine, specially as TIM is now aiming for global acceptance.

## Conclusion

Digitization targeted to the individual patient, is the major thrust area in the present times across the world. To leverage digital technologies in TIM, dealing with its



socioeconomic impact, paying particular attention to digital inclusion, patient empowerment, data privacy, and security, legal and ethical issues with protection of personal data is imperative. Establishment of Global Centre for Traditional Medicine in India by WHO is an important step that would supplement the growth of AYUSH industry in a holistic manner. This will help in building on existing strengths spanning research and healthcare to create and grow new TM industries in India. To strengthen the TIM ecosystem in India there is a need to harness home-grown innovations and incorporate data-driven technologies that have the potential to transform the way the health system works and support well regulated, faster and cheaper health care. The paper discussed the opportunity and scope of AYUSH vertical to develop new electronic healthcare structures, regulation, diagnostics with well-structured data sharing networks in the form of several programmes. The study also highlighted the key takeaway taken from other countries e.g., China for leveraging Traditional Chinese medicine (TCM) and a way forward for a strengthened digital network of AYUSH.

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# Globalization of AYUSH Products: Status, Challenges and Suggestions for Growth

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## Introduction

The scenario after the COVID-19 pandemic has brought the modern and traditional medicine systems on a level playing field. The situation demands assessment of the capacity of the Indian traditional medicine sector to take up the challenge of delivering healthcare products to the global population. A review of the status of AYUSH products across the globe in terms of exports has identified issues of positioning the products, quality compliance with GMP, country specific and WHO quality standards, poor number and quality of publications, and fewer patents and IPRs. The article analyses the opportunity presented to AYUSH sector, particularly for its products and ways in which it can be harnessed with a strategic policy implementation coupled with timely approach.

## AYUSH Exports: Major Product Categories

AYUSH exports are done in different categories as per the standard norms of international trade. A noteworthy analysis of category wise AYUSH exports as indicated in Table 1 shows that the share of retail medicines has limited share of the total export, while bulk raw drugs dominate. Raw drugs i.e. herbs have half (53 percent) of export value of the total AYUSH sector. Among medicaments, Ayurveda has a lion's share

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**Table 1: AYUSH Export Category Wise- 2013**

HS Code	Commodity	Rs. Crore	US \$ Million	Percent of Total
1211	Herbs	1137	174	53.2
	AYUSH medicants not for retail	129	19.8	6.0
	Retail Medicants			0.0
30039011	Ayurveda	125	19.2	5.8
30039012/3/4	Unani, Siddha, Homeopathy	2.43	0.4	0.1
	Not for retail medicaments			
30049011	Ayurveda	723	111.2	33.8
30049012/3/4	Unani, Siddha, Homeopathy	27	4	1.2
	Total	2142.5	329.6	100

*Source:* <https://data.gov.in/resources/country-wise-export-ayush-and-herbal-products-2013-14-2015-16-ministry-ayurveda-yoga>

while Unani, Siddha, Homeopathy have a minority share.

Raw drugs comprise the bulk of India's export of AYUSH sector and are ever-growing. AYUSH and herbal products comprised Rs. 401 crore/ year i.e. 0.75 percent of the export of Rs. 140,000 crore of all medical product exports from the country.<sup>8</sup> Among the exporting countries, China is at the top position while India closes in at second (World Bank, 2018) The export value of Traditional Chinese Medicine (TCM) is 3.5 times higher<sup>9</sup> than that of AYUSH. The notable difference is due to value addition and cultivated farm produce of herbs in TCM whose export consists of 90 percent value added finished products or medicines and only 10 percent raw herbs (Table 2). But AYUSH export consists of 88 percent raw drugs and 12 percent value added products (Table 1). Secondly, TCM produces many raw drugs from farming and some from the wild

(Brinckmann, 2016, Li et al, 2015), as the latter source is unreliable. AYUSH, on the other hand, has little from farming sector and majority from the wild (See Table 2, Ved and Goraya, 2006). This is a major limiting factor as the forest productivity is limited, unsustainable over the long term and is unreliable, varying greatly from year to year based on the climatic variations that are increasing much lately. A major driver of TCM export are the committed Non Resident Chinese (NRC) buyers residing abroad in large numbers Chinese community in foreign countries perhaps uses TCM to greater extent than Indians use AYUSH. Thirdly, TCM sector has systematically studied and published its potential herbs using modern parameters and has many patents and innovative products acceptable to non-Chinese takers (Li et al, 2015, James and Pathak, 2018). In Russia, Vietnam and Australia TCM is a pharmaceutical

**Table 2: AYUSH and TCM Difference- Value Addition**

Ayush and TCM export- US \$ Million/yr (2015-16)					
	Aspect	AYUSH#	Percent of total	TCM**	Percent of total
Category					
	Herbs	278	70	363	10
	Medicines	123	30	3140	90

Sources: # <https://data.gov.in/resources/country-wise-export-ayush-and-herbal-products-2013-14-2015-16-ministry-ayurveda-yoga>, \*\*- Lin et al, 2019.

entity while in other countries it is sold as either supplement, nutraceutical or as food. Yet, TCM export has reached a plateau and growth has stagnated for last 4 years<sup>10</sup> despite having a sound policy since 1997<sup>11</sup>. This may be helpful to AYUSH policymakers in deciding ahead.

It is also important to note that spices such as ginger and tea leaves are included in the TCM export data<sup>11,12</sup>, which are excluded from AYUSH export items. In export, majority of the medicinal plants are sent as raw/ crude drugs. Some are registered in different countries as food supplements or nutraceuticals. Very few single herbs like Ashwagandha and Turmeric or the famous combination Triphala (Three myrobylan fruits- Amla-Embellic, Behera-belleric, Harra-Chebolic) are included in Herbal pharmacopoeia of the USA. Various Ayurvedic formulations for wellness, beneficial to conditions like joint pain, digestive disturbances enter the EU, US Australian territory through online mode or channels of Maharishi Ayurveda, Chopra Ayurveda center or Ayurveda college, California<sup>5</sup>. In The Middle East (GCC countries) and Southeast Asia including South Korea, due to inheritance of TCM for thousands of years, the exports are comparatively easier. Latin America and African continent have just begun to

acknowledge AYUSH systems, which will be new markets to explore. TCM already has penetrated both the markets, which may make it easier for AYUSH to prosper.

### Size and Trend Analysis of Related Sectors

AYUSH products comprise of herbal medicines - powders, tablets, capsules, prash, oils, medicinal and aromatic herbs, flowers, spices, tinctures, processed foods etc. Also, for each of the category except medicaments, separate data is available. The spice products, grains (see Table 3) show an increasing trend because they adopted to the new standards and rules. They also invested in testing and processing facilities and did the requisite documentation.

As seen in Table 4, AYUSH and organic products have the lowest value of about \$ 1 Billion/ year each, but spices' export value is 3 times, while horticulture (fruits-vegetables) is 5 times. Beauty (cosmetics), personal care (PC) products (tooth paste, soap, toiletry) export is 10 times the AYUSH export value. Global population especially in the developed countries is interested in natural products over chemical ones. Ayurvedic companies like Dabur, Himalaya Herbals,

**Table 3: AYUSH and Related Sectors Export Trend**

Value \$ Billion/ year

YEAR	AYUSH- all	Spice**	Organic#
2000	0.08	0.3	0
2005	0.1	0.5	0.1
2010	0.3	1.2	0.1
2015	1.1	2.5	0.2
2018	1.0	2.8	0.7

Source: \*- [http://www.dgcisanalytics.in/dgcis/EXIM-Analytics#/home?\\_g=\(\)](http://www.dgcisanalytics.in/dgcis/EXIM-Analytics#/home?_g=())

\*\**: Review of Export performance of Spices during 2020-21 (Spices Board of India, Min. of Comm., GoI. (www.indianspices.com/sites/default/files/Majorpercent20Itempercent20wisepercent20Exportpercent202019.pdf)*

#*: Consolidated Organic Agricultural Statistics for the Year 2020-21 (Agricultural and Processed Food Products Export Development Authority, Min. of Comm., GoI. URL: [https://apeda.gov.in/apedawebsite/organic/data.htm#certification\\_process\\_5](https://apeda.gov.in/apedawebsite/organic/data.htm#certification_process_5))*

Forest essentials, Lotus herbals and the multinationals like Colgate Palmolive or Proctor and Gamble have picked up the trend to develop products with herbs like *Glycyrrhiza glabra*, *Aloe vera* or Amla (*Phyllanthus emblica*), which is reflected in the increase of export size of this category. Good quality products, attractive packaging, all time availability and impetus on advertising in print and audiovisual media have contributed to the success of this sector in both domestic and international markets.

On the other hand, horticulture sector,

which is 10 times bigger than AYUSH shows stagnation (Table 5). The reason is that horticulture did not reinvent itself to meet the stringent EU regulations, and remained happy with its focus on Middle East, where regulation is weaker than Europe or America.

## Major Importers of AYUSH Products

In the import sector of AYUSH products, USA is the top importer country, comprising of \$88m/ year (25 percent of total AYUSH exports of India) (see

**Table 4: AYUSH and Related Sectors Export Size (2018)**

Value \$ Billion/ year

SECTOR	Value \$ Billion/yr
Pharma	17
TCM	3.7
AYUSH	1
Organic	1
Spice	3
Horticulture	5
Beauty-PC	10

Source: [http://www.dgcisanalytics.in/dgcis/EXIM-Analytics#/home?\\_g=\(\)](http://www.dgcisanalytics.in/dgcis/EXIM-Analytics#/home?_g=())

**Table 5: Horticulture Export Trend**

YEAR	Vol. M t/yr#	Export '000 t	Value Export Rs. '000 Crore
2000	145	1.5	1.2
2005	182	2	1.5
2010	240	35	10
2015	295	40	14
2018	311	25	10

Source: Jha et al, 2019

Table 6). Most of it is imported as health supplements and not medicines, Turmeric powder, Sandalwood, Psyllium husk powder, Sandalwood oil, Neem capsules, Tulsi tea sachets, are sold in grocery shops and are used in home remedies by NRIs.

USA does not accord AYUSH full medical system status. Insurance cover for Ayurveda therapy and products is not provided because it is not recognized as a system of medicine. The organizations of physicians like AAPANA and NAMA are working to create a structure for practice of Ayurveda which is suitable in the respective states. Recent efforts by Govt.

of India to promote Yoga and AYUSH therapy through collaborations with universities like MIT may also gradually change the situation.

Other 5 subsequently ranked countries (no. 2 to 6- Germany, UAE, Pakistan, Italy and Nepal) have lent official recognition to Ayurveda (Pakistan and Nepal) or associated systems under the category of Natural Medicine(Germany , Italy, UAE) and comprise another 25 percent of the AYUSH export basket. Homeopathy, in fact, was born in Germany and is actively promoted in Europe, and also produces most of the ingredient herbs, except a

**Table 6: AYUSH Products- Importing Country Ranking**

RANK	Country	YEAR	2013-14	2014-15	2015-16	2013-14	2014-15	2015-16	
		Status	Qty t	Qty t	Qty t	USD M	USD M	USD M	percent
1	U.S.A	+	18290	18560	20601	99	86	88	24.3
2	GERMANY	++	5664	8003	8336	19	32	28	7.7
3	U ARAB EMTS	+++	3029	3504	3080	20	17	19	5.3
4	PAKISTAN	+++	6438	7409	3761	19	19	19	5.1
5	ITALY	++	1481	1534	2124	8	11	14	3.9
6	Sub-total		34902	39010	37902	165	165	168	
7	Others				19773			60	
8	TOTAL				<b>57675</b>			<b>228</b>	

Status (legal)- +: nominal , ++: partial, +++: full (many physicians, colleges); percent- of Total value- '15-16

Note- 1) Malaysia and China are ranked no. 11 and 12 with \$ 7 Million value each, the later growing fast.

2) Countries ranked 2 to 5 have higher recognition to Ayurveda, so its easy to market drugs there.

Source: Govt. of India. URL: [https://data.gov.in/sites/default/files/dataurl05012018/rs\\_session-242\\_au2880\\_1.2.csv](https://data.gov.in/sites/default/files/dataurl05012018/rs_session-242_au2880_1.2.csv)

**Table 7: Top Countries with NRI Population and AYUSH Export Share**

S.No.	Country	Population Million	percent of Total	AYUSH export percent	Remark
1	USA	4.5	15.0	24	
2	Saudi Arabia	4.1	13.7	0.9	Can grow 13 times#
3	UAE	3	10.0	5	Can grow 2 times here#
4	Gulf- other*	2.4	8.0	1	Can grow 8 times#
5	Malaysia	1	3.3	2	
	Sub-total	15	50	32.9	
13	Others	10.7	35.7	0.45	Can grow 6 times#
	TOTAL	25.7	85.7		
Total NRI/ PIO		30			(Gulf total- SN 2 to 4- 9.5= 30percent)

\*Kuwait- 1, Qatar and Oman- 0.7 million each;

#- if all NRI/PIO medicine market is tapped

PIO- persons of Indian origin.

Source: Ministry of External Affairs (2018) Population of Overseas Indians

few such as Kuchla (*Strychnos nux vomica*) which is imported from Asia.

Japan and South East Asian countries such as Vietnam or Malaysia also have acknowledged Ayurveda and it comprises of 2-3percent of AYUSH exports each. China imports a lower share of AYUSH materials, but its volume and value is growing for items such as the raw drug Kalmegh- *Andrographis paniculata*. China or any other country may be capable of cultivating such other annual/ biennial species in near future successfully, but perhaps not forest trees like Amala, *Terminalia Chebula* and *Terminalia bellirica* (together, the famous “Triphala” i.e. 3 fruits) as they need specific agro-climatic conditions and also take years to start fruiting. These should be identified for export oriented cultivation practices with long term approach. Dry, hot zone herbs such as Ashwagandha, may also grow in India better than China and India would

benefit by promoting it as alternative to Ginseng<sup>7</sup>. *Gingko biloba* and *Panax Ginseng* are China’s top herbal exports and India can edge it with Ashwagandha, Turmeric, Ginger and few others. Psyllium, a top Indian herbal export is in demand simply as a digestive due to its high fiber content which is generally less in western food habits. AYUSH exports comprise 0.75 percent of India’s total pharmaceutical export<sup>8</sup>.

It is generally seen that the imports of AYUSH herbs are proportional to the strength of Indians in different countries. It could be due to consumption and local promotion of Indian herbs or spice items by the NRIs. Table 7, presents the number of NRI/ PIO (people of Indian origin) in the top 15 countries that comprise 85 percent (25 million) of the 30 million total population. USA tops with 4.5 million (15 percent of total) and it contributes to nearly 1/4<sup>th</sup> of all AYUSH exports.



## Reasons for Plateau of Exports of AYUSH Products

In the last decade, due to THMPD regulations in EU and USA, added with requirement of phytosanitary standards and restrictions on list of herbs permitted in healthcare, exports have not been on the rise as it could have been. The European herbal regulation of 2001 enforced from 2007 permits use of species with 15 years safety experience in the Europe and/or 30 years outside Europe preferably in the country of origin<sup>6</sup>. However, the traditional physicians maintained little record of clinical practice for a particular drug for a particular disease or condition and also modern biochemical, radiological or pathological parameters.

The phyto/sanitary standards imply strong limits for (a) heavy metals, (b) pesticide residues, (c) microbial contamination which is cost intensive for traditional manufacturers. In Australia, for instance, the Therapeutic Goods Administration (TGA) keeps a close eye on Ayurvedic products landing in Australian territory. The import batches are discarded if they fail to comply with standards.

## Policy Initiatives and Recommended Growth Strategies for AYUSH

The Ministry of AYUSH has been taking various measures to improve the domestic and global sales of AYUSH products. Image building of AYUSH as an integral part of national health agenda has also been fruiting well. The efforts have been more prominent since the birth of the Ministry in 2014. Internationally, Federation of Indian chamber of Commerce and Industries (FICCI, 2012) and Confederation of Indian Industry (CII) have started focusing on

AYUSH in their trade fares and since past 4-5 years, they have been conducting exclusive sessions for the promotion of this sector<sup>4</sup>. Since 2017, AYUSH has also become prominently functional at the WHO headquarter, Geneva, with a permanent representative from Govt. of India since 2018<sup>13</sup>. Inclusion and concurrence of AYUSH disease conditions in the 11<sup>th</sup> edition of International Statistical Classification of Diseases and Related Conditions (ICD 11) and Benchmark document for Practice of Ayurveda and Panchakarma for member states have paved the way for official and formal global functioning.

However, there is no specific policy for export of AYUSH products except the schemes to support manufacturers who wish to promote their products overseas. The AYUSH premium mark by Quality Council of India (QCI) is availed by about 60 companies like Maharishi Ayurveda, Multani Herbals, Divya pharmacy.

The main issue that needs to be addressed is whether the medicinal herbs and products should be exported as drugs or spices or nutraceuticals or food supplements. No doubt that the traditional practitioners of AYUSH systems practicing abroad sincerely wish to prescribe and sell the finished products as medicines but they are well aware of the legal requirements to do so. The policy makers are also aware of the facts regarding quality requirements for registration of a product as drug: shortcomings in pharmacopeia standards of AYUSH products, green-compliance and environmental barriers, phytosanitary standards, concerns regarding presence of heavy metals and pesticide residue exceeding national standards, technical barriers like patents, etc.

AYUSH ministry can promote export of a handful selected value added products with branding for mainly western chronic ailments such as piles, diabetes, hypertension, heart ailments as safe and effective treatment by branding the drug contents and action, with the aforesaid standards in association with Ministry of Commerce and Ministry of External Affairs through Ayush Guidance Cells existing at about 50 odd consulates. Then the impact of AYUSH may be visible as seen today with the “brand India” campaign in the past decade.

### Permitted Herbs/Spices Focus

Europe, USA, Australia, amongst other developed nations prohibits use of many main ingredient species of AYUSH drugs, because their safety and efficacy is not proven using the modern scientific methods where results are reproducible. The list is also not uniform for all the countries in Europe. This may be due to the bio-safety concerns or Convention on Biological Diversity paradigm. Alteration in the amount of active principles or biomarkers after cultivation in a different country or using other approaches like tissue culture is some of the constraints. Hence, a smart approach will be to develop drugs from spices and herbs that are permitted in those countries because there is growing recognition of their healing power<sup>14</sup>.

Already some researchers or companies have started tapping this permitted herbs list to develop healthcare products by emphasizing on the health benefit. For example Ashwagandha is promoted as a stress buster and also in Parkinson’s disease as tested in animal model<sup>15</sup>. Certain herbs can also be used to treat Dementia<sup>16</sup>. Other spices such as

Coriander, Cumin, Black Pepper, Turmeric etc. are routinely used as food supplements in Europe and America and has been designated Generally Recognized As Safe (GRAS) by the US-FDA. American Herbal Pharmacopeia has included Triphala very recently<sup>17</sup>. Focus on spice based permitted drugs can avoid the problem of drug adulteration or drug with disputed identity<sup>18</sup>, e.g. Shankhapushpi (*Evolvulus alsinoides/ Convolvulus pluricaulis*). Spices are also known to contain salicylic acid and are responsible for aspirin like medical effect<sup>19</sup>. This may explain the efficacy of drinking spice decoction resulting in much lower intensity of COVID-19 in India than the western countries<sup>20</sup>. Clinical research on most potent AYUSH herbs needs to be shared with western pharmacopeia authorities for recognition e.g. Arjuna (*Terminalia arjuna*), is found to be useful in many clinical trials in relieving heart disease compared to the standard treatment of isosorbide mononitrate (ISMN)<sup>21</sup>.

### Wellness Focus

The wellness segment which comprises of personal care products (soap, toothpaste, beauty, cosmetics, toiletry etc.) and health tourism, is growing. Many corporate companies such as Himalaya, Dabur and Emami have focused on it for revenue generation. It is also the main component of export growth of AYUSH products especially to countries such as USA where AYUSH products are permitted only as health supplement. Table 8 below depicts the different segments of the wellness business globally and AYUSH is relevant here and needs branding.

About half of Himalaya Drug Co. revenue is from export, as they customized medicines to the rules in the

**Table 8: Wellness Sector- Global**

Segment	Value \$ Billion	Percent Share
Personal care	1082	25
Nutrition	707	15
ACM	359	10
Preventive	574	15
Fitness	595	13
Tourism	639	13
Resorts/ pools	250	9

ACM- alternative/ complimentary medicines, Source: Wang (2019).

country of import and promoted single herbal formulations such as Brahmi or Ashwagandha tablets. Their Liv -52 is a famous example and is a multi-million dollar drug.

The other strategy is to promote medical tourism as famously done by state of Kerala, branding itself as “God’s own country” where Ayurveda resorts are common. Some companies in Tamil nadu have also been successful at doing it such as Arya Vaidya Nilayam (AVN) Group, Coimbatore. Such hospitals also manufacture and market Ayurvedic/ herbal products innovatively, focusing on kidney, heart, brain health etc.

AYUSH sector has about 75 percent share in products and only 25 percent in the services (hospitals, tourism, insurance etc.)<sup>4</sup>. This can be reversed, for better growth just like the Indian economy boomed after the growth of service sector that comprises 60 percent of the economy today with agriculture and industry comprising only 15 percent and 25 percent respectively<sup>22</sup>. Earnings in the service segment are much higher than farming or production; so, promoting AYSUH services will benefit India manifold.

### Customized Focus for Particular Diseases

To improve the domestic sales classical products should come out with more scientific data, translated in layperson’s language. The large middle class is curious about Ayurveda and all the good things that it has to offer. While having surplus resources, the westernized young population demands or questions for proofs of claims and debates on better options. Attempts at presentation of Ayurvedic concepts and OTC products on social media platforms like Charak Pharma are being made and has promising scope.

To promote export in the different regions of the world, innovative products based on biomarkers rather than classical and its branding for specific effect either therapeutic or wellness are required. Perinatal diseases, malnutrition and diarrhoea comprise 23 percent of the disease burden in India<sup>23</sup>; while Cancer, respiratory disease and bronchitis comprise 3 of the top 4 ailments, causing 33percentof the disease burden in USA<sup>24</sup>. In Europe Musculo-skeletal diseases, hypertension and digestive ailments top the chart, comprising 61percent of the disease burden<sup>25</sup>. Heart disease is a

leading ailment causing 9 to 20 percent of the disease burden in these 3 regions, and the proportion is double in USA than India or EU, possibly due to higher red meat consumption<sup>26</sup>.

Customization of the products depending on country or region for their disease profile is needed. To register a product as medicine in the pharmacopoeia of developed countries demands huge and accurate data which is cost intensive for Indian companies. Hence, the health promoting and wellness sector which works with the terms 'beneficial', health promoting, food supplements, nutraceuticals may have to be used till the time indigenous industry equips itself with quality data for therapeutic purposes. The name of the product should be clear, understandable and attractive for the end user, unlike the classical pharmacopoeial names which are beyond comprehension for a non-Indian buyer. Himalaya Drug Co. has successfully done it with Liv-52 for liver ailments, "Dybogen" for diabetes, or "Renalka" for burning micturition. Others like Sharangdhar pharma have used similar approach while naming the products, for example "Pylowin" to treat piles; "Pentacid" for acidity, "Harto" for heart care or Solumik's "myostaal" for joint disorders, or Charak pharma's "Kofol" immunity kit, PCOD management kit etc.

Unlike the developed countries, there exists a brighter export opportunity in the Gulf. It is already the leading buyer of Indian horti-exports, for instance, 2/3<sup>rd</sup> of mangoes and 15 percent of grapes are exported to GCC countries<sup>27</sup>. Also, the Gulf region is home to nearly 1/3<sup>rd</sup> of NRIs plus it has a lot of floating population of westerners for treatment and wellness purposes. In spite of these opportunities,

only 7 percent of the AYUSH exports are consumed within the region. It has the potential to grow to about 5 times if targeted properly. The regulatory environment is friendlier in the Gulf than Australia, Europe and USA. Secondly, people from Middle East countries already flock to Ayurved resorts in Kerala and having the biggest Malayali emigrant community working there, may make it easy to penetrate.

### Tapping New Herbs for Newer Health Benefits

It is important to know and tap the fact that some Indian herbs may be famous abroad by other names, e.g. Vidari- *Pueraria tuberosa*, is widely known as (Indian) "Kudzu", a tonic. It can be studied and branded as a superfood. Some new herbs are being vigorously exported recently to USA or Europe. Indian Hemp is popular in central European countries. *Phyllanthus amarus* used in the USA to treat hepatitis B<sup>28</sup> which was patented (no. US3636191A) by Dr. Baruch Lumberg of University of Pennsylvania.

Drumstick (*Moringa olifera*) is rich in Calcium, iron and other micronutrients, besides polyphenols and provides relief in Arthritis pain that affects about 1/3<sup>rd</sup> of the elderly population<sup>29</sup> (see Box 1). The global market of drumstick leaf powder is Rs. 27,000 crore (\$ 4 billion/ year), but India exported only worth Rs. 14 crore in 2015. It is now cultivated on over 5,000 (five thousand) ha in Tamil Nadu alone. However, the product quality must be high and price should be competitive to Africa which is the main exporting region. Below are key medicinal plants used in India and neighboring countries and their potential in healing as proposed earlier<sup>30</sup>. Turmeric

and Curcumin product from it is a globally famous case today<sup>31</sup>.

Akkarkara (*Anacyclus pyrethrum*)

Drumstick (*Moringa olifera*)

Hing (*Ferula asafetida*)

Mint (*Mentha* spp.)

Salai (*Boswellia serrata*)

Guggul (*Commiphora wightii*)

Gamboge (*Garcinia cambogia*)

Licorice (*Glycyrrhiza glabra*)

Roselle (*Hibiscus subdariffa*)

Gamboge (*Garcinia cambogia*) is a small forest tree popular globally as anti-obesity drug due to Hydroxycitric acid in it but it is mostly wild, not cultivated in India, and needs promotion. Roselle/ Mesta (*Hibiscus subdariffa*)- the jute cousin, is another species with the same ingredient used as rose tea in Europe and Africa. Akkarkara (*Anacyclus pyrethrum*), Guggul (*Commiphora wightii*), Asafetida (*Ferula narthex*), Licorice (*Glycyrrhiza glabra*), Salai (*Boswellia serrata*) are some others which can be grown and exported. Only Guggul, Licorice and Asafetida are supported in the subsidy scheme of National Medicinal Plants Board (NMPB) in the above list. These are in shortage and so, improving their production can help export and "Make in India" mission. The other 7 species among the 9 mentioned here may be added to the NMPB subsidy scheme.

Further, recent research has clarified the misconception on risk in heavy metals such as Mercury in Ayurvedic drugs and ascertained their safety as well as higher efficacy due to the traditional nanotechnology said to be used<sup>32,33</sup>. Traditional medicine can tap to capitalize the newfound evidences such as dairy products and ghee (clarified butter, an

important adjuvant of Ayurvedic drugs) being healthy<sup>26,34,35</sup>. More schemes or coverage such as ADB (Asian Development Bank)- Bombay Chambers Of Commerce incubation course for herbal/ AYUSH enterprises/ startups can also boost exports<sup>36</sup>.

## Conclusion

The WHO shows seven regulatory categories for herbal products viz. prescription medicines, non-prescription OTC, herbal supplements, dietary supplements, health food, functional foods, and general foods and others<sup>2</sup>. To put products in these categories; product innovation, AYUSH concept innovation, pharmacopoeia quality standards by following Good Agricultural Practices to grow medicinal plants, followed by GMP, added with strong database of consistent usage using newer big data platforms, will be essential for domestic and export growth. The most promising sectors of nutraceuticals, therapeutic foods, natural products, wellness products are the low hanging fruits. There should be a mechanism to establish legal status of products and practitioners in the overseas countries for a smooth market entry and sustainable development. Based on the available export data, reaching out to countries in a phase-wise manner would be feasible and rewarding.

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# Innovation in the Indian Systems of Medicine: Rationale and Means

T. C. James\*



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## Introduction

The World Health Organisation (WHO) refers to the ancient medical systems of China, India and many other Asian and African countries as traditional medicine (TM) which it defines as “the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness”<sup>1</sup>. The definition, as such, does not exclude innovation, the stress being on ‘indigenous’. At the same time, innovation is not taken as an essential characteristic of TM. They need not even be rationally explainable. This becomes more apparent when one reads the definition of modern medicine as “a general term for conventional healthcare based on the “Western model” of evidence-based practice for diagnosing and treating disease”<sup>2</sup>. As per these definitions, one is based on theories, beliefs and experiences and the other is on evidence. The term evidence seems to have been used in a narrow sense of documentary proof based on clinical trials (CTs)<sup>3</sup>. The practice of CTs in western medicine is not that old, having seriously begun in 1943-44 only, although James Lind of Scotland is credited with having conducted a clinical trial for the treatment of scurvy in 1747. It was in the 1940s only the British Medical Research Council officially recognised its importance. It was still a long process, with the development of the Nuremberg Code of ethical guidelines in 1948 after details about the

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trials conducted in Nazi Germany came to light and the World Medical Association coming out with the Helsinki Declaration in 1964 after the thalidomide tragedy (Bhatt: 2010). Currently, double-blind, randomized, placebo-controlled clinical trials which are required to follow a strict protocol are in vogue in modern medicine and drug approvals for new ones are granted on the basis of the positive results, statistically, of the CTs on safety and efficacy. The disasters caused by the kind of unregulated trials of new drugs of Western Medicine on humans, not only led to the introduction of various guidelines and regulations for such trials but also the spread of the perception that 'medicines' that have not undergone such rigorous procedures should not be considered as medicines and that impression adversely affected all traditional medicine. The medical systems and practices that have been in existence for millennia were pushed back as traditional medicines. Innovations and innovative drugs were not expected to be part of the oeuvre of these systems.

In India, the import, manufacture, distribution and sale of drugs (and also cosmetics) are regulated by the Drugs and Cosmetics Act, 1940. This Act also regulates the Ayurvedic, Siddha or Unani (ASU) drugs also. As per the Act, ASU drugs include "all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the First Schedule"<sup>4</sup> of the Act. This definition in itself does not include innovative drugs

since the drugs have to be manufactured exclusively as per the authoritative ancient texts which have been separately named. There are 59 classical texts of Ayurveda, 31 of Siddha and 14 of Unani Tibb (ASU) are listed in the First Schedule. The requirement of compliance with the listed formulae makes innovation antithetical to the systems. At the same time, being an inclusive definition, it can be argued that the possibilities of innovative drugs in the traditional systems are still there, though this presumption has not yet been tested in a court of law.

The Act, however, provides for a separate category known as 'patent or proprietary medicine' that is defined in relation to ASU as all formulations containing only such ingredients mentioned in the formulae described in the authoritative books in the First Schedule. In relation to any other systems of medicine, it includes a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised by the Central Government<sup>5</sup>. This does not preclude innovation per se but is rather encouraging innovations though for the ASU it has to be keeping the ethos of the system as is clear from the stipulation that the new formulations should contain only such ingredients as described in the classical texts.

The National Commission for Indian System of Medicine Act 2020 defines Indian System of Medicine (ISMs) as "the Ashtang Ayurveda, Unani, Siddha and Sowa-Rigpa Systems of Medicine supplemented by such modern advances, scientific and technological development

as the Commission may, in consultation with the Central Government, declare by notification from time to time”<sup>6</sup>. This definition includes the possibility of innovations in ISMs since it provides for modern advances, scientific and technological development. This is an open approach and does not close the doors for innovation and does not lock ISMs as closed systems of the past. It is more in line with the discussions in the Inter-Governmental Committee of the World Intellectual Property Organisation. The text of a proposed definition under consideration of the Committee reads:

Traditional Knowledge refers to knowledge originating from indigenous [peoples], local communities and/or [other beneficiaries] that may be dynamic and evolving and is the result of intellectual activity, experiences, spiritual means, or insights in or from a traditional context, which may be connected to land and environment, including know-how, skills, innovations, practices, teaching, or learning.<sup>7</sup>

The crucial terms are ‘dynamic’ and ‘evolving’. They are clearly pointing to the possibility of innovations.

Proceeding from the above definitions and descriptions of the ISMs if one is to conclude that they are systems that as a general rule do not question the time-honoured principles and practices and consequently not actively pro-innovative, it will not be much off the truth. In fact, the major selling point of these systems is their ancientness. This was acceptable so long as they remained individual or family practices, but once commercialisation started and pharmaceutical manufacturing firms and hospitals got established, the issue of innovation acquired a new salience.

Apart from the market competition with other ISM firms, they also had to face competition from modern medicine establishments and firms. A major strength of modern medicine is its innovativeness in developing new and more effective drugs for both old diseases and new ones like the coronavirus pandemic. Modern medicine also developed an armoury of vaccines against a number of infectious and other diseases. In this context, ISMs have to establish that they are also innovative and can meet the challenges of previously unheard-of diseases like severe acute respiratory syndrome (SARS) or acquired immunodeficiency syndrome (AIDS). The recent global pandemic of COVID-19 also threw up new challenges and raised issues about innovation. Modern medicine took up the challenge in different ways. There were initial attempts at repurposing existing drugs and then of developing vaccines for the new virus. The new vaccines have been using new technologies like tweaking DNAs, mRNAs, plasmids, viral vectors and so on. Some ISM firms and practitioners also took to the repurposing of existing formulations and developing preventive drug therapy kits. Some considered the pandemic, not as a new disease but a variant of old ones for which, according to them, treatments are available in the systems.

There are different and sometimes divergent approaches to innovations in ISMs. The orthodox view is that the formulations and prescriptions in the established texts have stood the test of time and do not require any modification. The proponents of this view do not favour changing the ingredients and procedures laid down in these texts for drugs and practices. They are for maintaining the

'purity' of the system and do not favour modernization. Some, of course, go for limited modernisation in the sense that they use more 'consumer-friendly dosage forms.

A predominant view among many traditionalists is that the concepts on which these systems are built are timeless and no relook is warranted. While admitting that environmental and lifestyle changes may cause modifications of a disease or the appearance of a new disease, the reactions of the body to the disease would be the same as those of our ancestors, and, therefore, no basic change in therapy is required, but only in the methods adopted for the cure. (Narayanaswamy, 1981). In other words, in this approach, the exact methods of treatment will vary from patient to patient according to their unique needs and what herbs are available, but the basic and essential concepts of how to heal will stay the same: like attracts like and opposite bring balance.<sup>8</sup>

The other view is that innovations are required since times have changed. In their view innovations are necessitated by various reasons such as non-availability of the exact raw materials as prescribed in the ancient texts for many drugs, changes brought about by climate change and environmental factors, depletion of forests and resultant reduced availability of medicinal plants from the forests and increasing dependence on cultivated plants, and so on. These groups are also making improvements and adaptations in the old formulae to meet with the demands of a modern competitive market. While the orthodox may be happy with serving the people within the country, though many like to make foray outside but without diluting the medicines, the others want to

reach out to the world, to be a competitive system to the modern medical system in health care everywhere in the world.

International organisations like the WHO have taken a positive attitude towards innovation in TM. The WHO's TM Strategy (2014-2022) contains measures to promote innovation. It admits the dearth of research and innovation into the various forms of Traditional and Complementary Medicine (T&CM). WHO includes a broad spectrum of healthcare practices that are not part of a country's own tradition or conventional medicine and are not fully integrated into the dominant healthcare system.<sup>9</sup> The strategy, which makes out a case for integrating T&CM in the formal health care argues for greater innovation that will be able to supplement evidence for the efficacy of the T&CM. It also talks about fostering an innovation culture among TM practitioner communities.

Innovation is not strictly new to Ayurveda. Even classical Ayurveda is not based on a single text. We have the three great classics (the Brhatrayi, namely, Charaka Samhita, Susurtua Samhita and Ashtangahrdaya of Vagbhata, and the three lesser classics, namely, Sharnghadhara Samhita, Bhava Prakasha of Bhavamisra and Madhava Nidanam, While Charaka Samhita and Susruta Samhita are believed to have been composed around 400 - 200 BC, Madhava Nidhanam is dated around 700 AD and Bhava Prakasam in the 16th century. That means during this long period from around 400 BC to 1600 AD, innovations and new developments were taking place in Ayurveda. Ashtangahrdaya, while based on Charaka Samhita, recommends procedures not found in the old classic<sup>10</sup>. A presumption that one makes is that the Ayurveda

texts do not rule out innovation. Charaka himself was not dogmatic. He was of the view that “textual instructions were not the final word for a competent physician who should apply his mind to the whole patient, the state of illness, time and place and all other circumstances before settling on a course of action. He had to be liberal in outlook, ready to accept that his was not the sole line of effective treatment and that many styles of living could be conducive to good health”<sup>11</sup> .

## Reaching Out to the World

In the world of international trade, ISM products and services fall under the group known as herbal medicine. According to the WHO, “herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations” form herbal medicine. The global market for herbal products is estimated at USD 657.5 billion in 2020 (RIS:2021). However, the ISM sector is quite small. An issue that arises in international trade is that of standardization and classification of products. These relate to contents and packaging as well as drugs themselves. They have to follow the approved formulary and pharmacopoeia. The products have to ensure biochemical consistency. These prescriptions, of course, are based on the trade practices of modern pharmaceuticals. Even the definition that WHO uses for herbal medicine follows the language of modern pharmaceuticals by talking about active ingredients, whereas in most TM formulations the whole plant or a whole part is used without separating the active chemical ingredient. For example, in Ayurveda turmeric is used and not

curcumin separated from it and it does not call for an active pharmaceutical ingredient (API) as is the case with allopathic drugs. The issue in global trade, however, is not a definitional one, but of acceptance and trade practices that insist upon certain standardisation of formats, etc. In order to make ISMs exportable items, it is necessary to introduce standardisation and good manufacturing practices. These necessarily call for research-based innovation and ISMs cannot ignore that.

## Evidence-based Medicine: Research and Development

Acceptability of ISM products and services in other countries is an issue because of the perception that the systems are closed ones and do not encourage innovation. There are very few countries like countries in South Asia that have an understanding of the ISMs and accept them as medicines. Regulatory agencies in most foreign countries insist upon clinical study-based data on the efficacy and safety of the drugs in these systems. It is a fact that the discussions on innovation in pharmaceutical products are heavily tilted in favour of modern medicine. This may be because of the way innovation methodology is perceived. Dr Ram Harsh Singh, Professor Emeritus, Ayurveda, Banaras Hindu University, in a 2011 paper argues for a new exploration in place of a new innovative approach in the area of the classical traditional knowledge base. According to him, new product development in the AYUSH sector should follow the path of reverse pharmacology, observational studies and case records, while ensuring basic safety and therapeutic efficacy and cost-effectiveness<sup>12</sup>.



## Innovations in Products and Processes

Many scholars think that innovation is antithetical to Ayurveda like systems. While the methods and practices may differ from those of modern science, Ayurveda has its own scientific investigation methodology. The nature of empiricism in allopathy and Ayurveda differs. That is how some of the classical formulations of Ayurveda like Triphala are still widely used and are effective even though their formulae are hundreds of years old. Compared to them, many modern medicines become obsolete very fast like antibiotics and the pharmaceutical companies come out with new versions or 'new generation'.

Modern lifestyles may have influenced and rather caused many innovations in the ISM sector. In the urban setting, and even in rural areas with people having to go out for work in offices, shops, etc, the traditional ways of preparing and taking ISM medicines at home are not practicable. That leads to innovations resulting in the introduction of newer forms of medicine dispensation like tablets, capsules, syrups and so on. While the basic ingredients remain the same as per the classical formulae, the new forms are convenient to carry and take. New drug delivery forms and dosages are the results of innovation.

A basic difference between allopathy and Ayurveda is that while the former separates the active pharmaceutical ingredient in a plant or herb and convert that into the medicine, in the latter such separation does not take place. Modern medicine first identifies the particular deficiency of a protein or vitamin or an excess of any mineral or fat or the particular bacteria or virus that caused an infection, or the microorganism that

makes a cell malfunction and then develop an active pharmaceutical ingredient or protein which targets that condition. Ayurveda and other ISMs approach a disease as one of loss of balance among the tridoshas or panchabhootas and medical intervention is to restore that balance. At the same time, accumulated toxins in the body and visible and invisible microbes are also causes of disease manifestation. While curing the emergent condition its approach is to enhance the general immunity of the body. Since these are generic approaches, the need for particular medicines is less as compared to modern medicine which has to find out the particular cause and develop a new drug or therapy to remove that specific cause. Such treatments might have been already available in the traditional systems as the basic genome structure of the human body has not undergone much change in millennia except minor variations that make the individual personality of every human being. ISM, therefore, to that extent has less compulsion for innovation.

One also has to take note of the financial impact on the healthcare of new innovative products. It is an admitted fact that the allopathy system is making healthcare complex and costly. The cost goes beyond the reach of even the rich (Patwardhan:2014). Diagnosis has become mechanical and without any human touch. Medical devices, which are increasingly being used, are getting costlier day by day and consequently, diagnosis also becomes costly. Medicines are also priced high. Ordinary people look forward to easy access to safe, effective, and affordable, quality healthcare (Patwardhan: 2014). That opens the doors for greater acceptance of ISMs, but at the same time, people have

to get convinced that therapies are safe and effective. There is, of course, the context of a mindset resulting from various adverse drug reactions in modern medicine. Be that as it may, innovations certainly have a role to play in developing greater acceptability of ISMs.

Many consider non-adoption of modern methods, scientific investigation and innovation to explore and enhance the potential of ISM drugs and therapies as blocking the way for ISMs to be full-fledged systems that can meet any situation. This is particularly so in meeting emergencies and shocks. They feel that the basic principles of the systems may have stood the test of time and maybe quite sound. But research for newer applications is needed.

There are other grounds also that impress upon the need for research and innovation in the ISMs. For one, the geoclimatic environment has changed since the times of the ancient texts on which these systems are based. During this time, the medicinal plants which are the raw materials that go into the making of the ISM drugs may also have undergone changes. The common perception of ordinary people is that the nature of diseases has changed, as they hear new names of diseases. These factors necessitate that ISMs also should engage in research and innovation.

It may not be essential that the ISM approach to research and innovation be the same as that of modern medicine. A procedure of systematic documentation of clinical practices and case studies should be able to allay the fears of the general public about the safety of TMs, since the ingredients have been already time-tested. This is, of course, to be insisted upon when innovative drugs, be they repurposed

ones or new dosage forms are introduced. And most innovations are likely to result in such products only and not really a totally new drug. This is so in modern medicine also. For example, out of 1223 new chemical entities commercialized globally between 1975 and 1996, only 379 were real therapeutic innovations or genuine new drugs. That forms less than one third or 30.8 per cent of the total claimed new innovations.<sup>13</sup>

At the same time, ISMs cannot keep a blind eye to the scientific and technological developments taking place around the world. They impact all medical systems and ISMs are no exceptions. What is required of ISMs is to explore how they can and should be employed for the advancement of the systems. "No tradition is a static entity; modernity results from evolving transitions" (Patwardhan:2014). Industrialisation and globalization of the TMs necessitate technological innovations, anyhow. At the same time, the systems should also develop a good scientific evidence base. This, as stated above, can be in its own way and necessarily following the model in modern medicine, which developed the current systems through several errors and misadventures. But that is how scientific advancements take place. Having said that it is also a fact that innovations are happening in medicines, medical equipment, cosmetics, wherein traditional medicine is also a player. Most ISM firms have been claiming that they are innovative, as can be seen from their websites<sup>14</sup>. One important segment where claims of innovations are high is that of herbal cosmetics for these innovations is herbal cosmetics including toothpaste, body and face creams, soaps, hair oils. Innovative nutraceuticals are also plenty



in the market. In herbal cosmetics and nutraceuticals, large foreign firms, who have a predilection towards innovations and IPRs are also very much in reckoning.

## IPR Protection

Any discussion on innovation cannot ignore the question of intellectual property rights (IPRs). In the context of ISMs, the protection of traditional knowledge is also a matter of concern since traditional medicines are clubbed under traditional knowledge in international law. The basic justification of IPRs is that they are required to incentivise innovations and creativity. Of course, they work in an indirect way in that protection ensures that the products of creativity and innovation are not misappropriated by others and the creator or inventor feels confident of sharing the fruits of his/her intellectual efforts. The IP rights which are tradeable makes the investments in industries that engage in making products based on innovations safe and less risky as they will enjoy exclusive rights for a limited period. One of the IPRs is patent which is granted to an invention that can be a new product or process involving an inventive step and capable of industrial application. New product or process means that it has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification, i.e., the subject matter has not fallen in the public domain or that it does not form part of the state of the art. ISM products are further embargoed from patentability by the provision that “a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or process for producing such substances”

is not an invention and hence, not patentable. Further, “an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components” is not an invention as per the Patents Act<sup>15</sup>.

The Patent Office Guidelines<sup>16</sup> with examples from AYUSH systems lay down the following six guiding principles for grant of patents related to these systems:

If the subject matter as claimed relates to extracts/alkaloids and/or isolation of active ingredients of plants, which are naturally/inherently present in plants, such claims cannot be considered as novel and/or inventive when use of such plants is pre-known as part of teachings of Traditional Knowledge

Combination of plants with known-therapeutic effect with further plants with the same known-therapeutic agents wherein all plants are previously known for treating the same disease is considered to be an obvious combination.

In case an ingredient is already known for the treatment of a disease, then it creates a presumption of obviousness that a combination product comprising this known active ingredient would be effective for the treatment of same disease.

Discovering the Optimum or Workable Ranges of Traditionally known ingredients by Routine experimentation is not inventive

In case multiple ingredients are known to have the same therapeutic activity as per traditional knowledge, taking out one single component out of them cannot be considered as inventive

In case individual ingredients are already known for the treatment of a disease

as a part of Traditional Knowledge, then it is obvious that a combination product comprising these known ingredients with further plants with the same known therapeutic effect would be more effective than each of the medicinal plants when applied separately (additive effect).

The provisions clearly rule out the patentability of existing ISM products and processes. The above guidelines are meant to ensure that there is no misappropriation in the case of Traditional Knowledge including Traditional Medicine Knowledge. It is also meant to safeguard against the acquisition of patent rights over existing knowledge, a fundamental criterion of patentability. At the same time in knowledge management and innovation, IPRs play crucial roles. In the past, in traditional societies, secrecy was employed to protect medicinal knowledge from being stolen or misappropriated. But in the case of codified knowledge systems like Ayurveda, this is not possible since the knowledge is already documented and available to the public as well. The case of the patenting of the wound healing properties of turmeric in the USA is an example of misappropriation of the knowledge.

At the same time, as envisaged in the National IP policy 2016 (Government of India:2016), it is necessary to promote research in TK including in TMK. This is further proposed by the Department related Parliamentary Committee (Parliament:2019) also recommended that the Department of Pharmaceuticals should undertake research on Ayush medicine and drugs that would “lead to advancement in the availability of innovative drugs and medicines for the treatment of novel

disease” (para 18.11). In the case of TK, the committee recommended the recognition of informal innovations that embrace TK and indigenous knowledge (para 20.1). This signals that policy-makers and legislators are favouring innovations in ISMs.

Despite the strict provisions in the Act and the Guidelines, there have been many patents in the area of TM. In reply to a question, the Lok Sabha was informed in 2018 that 194 patents have been granted to Indian entities for the inventions based on traditional medicines/herbal related products and 28 patents to various in various foreign entities for formulations/processes based on herbal/plant products. One can say that patentable and other innovations are taking place in ISMs<sup>17</sup>.

## Conclusion

Invention and innovation are the essences of any growing branch of science. The Encyclopaedia Britannica defines science as any system of knowledge that “entails unbiased observations and systematic experimentation”. It is a pursuit of knowledge. Science cannot be a static system. It has to continuously question even well-established principles and theories. The ISMs, if they have to be considered as science have to engage continuously in questioning, experimenting and developing new ideas, new products and new processes. The term Ayurveda means the science of life. To be true to that name, the students and practitioners of Ayurveda and other established systems of medicine in India have to engage in continuous scientific activity leading to innovations.

## Endnotes

- <sup>1</sup> [https://www.who.int/health-topics/traditional-complementary-and-integrative-medicine#tab=tab\\_1](https://www.who.int/health-topics/traditional-complementary-and-integrative-medicine#tab=tab_1)
- <sup>2</sup> S e g e n ' s M e d i c a l Dictionary. © 2012 Farlex, Inc. <https://medical.dictionary.thefreedictionary.com/modern+medicine>
- <sup>3</sup> "A clinical trial is a planned experiment designed to assess the efficacy of a treatment in man by comparing the outcome in a group of patients treated with the test treatment with those observed in a comparable group of patients receiving a control treatment, where patients in both groups are enrolled, treated, and followed over the same time period.". Curtis L. Meinert and Susan Tonascia. *Clinical Trials: Design, Conduct and Analysis*, Oxford University Press. New York. 1986.
- <sup>4</sup> Section 3(a).
- <sup>5</sup> Section 3(h).
- <sup>6</sup> Section 2(h) of the Act
- <sup>7</sup> The text has not yet been finalized. This is the text at the end of the 41st session of the IGC held on Feb-March 2022.
- <sup>8</sup> A Brief History of Ayurveda's Ancient Texts & Why It Matters <https://www.kottakkal.shop/blogs/healing-with-kottakkal-ayurveda/a-brief-history-of-ayurveda-why-it-matters>
- <sup>9</sup> [https://www.who.int/health-topics/traditional-complementary-and-integrative-medicine#tab=tab\\_1](https://www.who.int/health-topics/traditional-complementary-and-integrative-medicine#tab=tab_1)
- <sup>10</sup> M.S. Valiathan. *The Legacy of Vagbhata*. Universities Press. P.xii.
- <sup>11</sup> M.S. Valiathan. *The Legacy of Caraka*. Universities Press. pp.ix-x.
- <sup>12</sup> Ram Harsh Singh. 2011. Perspectives in Innovation in the AYUSH Sector in *Journal of Ayurveda & Integrative Medicine | April-June 2011 | Vol 2 | Issue 2*. Pp. 52-54.
- <sup>13</sup> Drug Development Output from 1975 to 1996: What Proportion for Tropical Diseases? By Patrice Troiller and Piero L. Olliaro Editorial in *International Journal of Infectious Diseases*. Volume 3. Number 2. Winter 1998-1999.
- <sup>14</sup> Some examples: Dabur website claims that it has filed 45 patent applications and has been granted 11 in India. It also claims that it has developed 35 new products for global market ([https://www.dabur.com/](https://www.dabur.com/digital-annual-report/integrated-reports/intellectual-capital)

[digital-annual-report/integrated-reports/intellectual-capital](https://www.dabur.com/digital-annual-report/integrated-reports/intellectual-capital)). Sami-Sabinsa group claims 357 patents including 102 US patents (<https://sami-sabinsagroup.com/about/intellectual-properties>). As per a report in the Times of India, Muniyal Ayurveda in Manipal has claimed that seven US patents were obtained for certain herbomineral products. [<https://timesofindia.indiatimes.com/city/mangaluru/Karnataka-ayurveda-centre-gets-7-us-patents-more-in-the-pipeline/articleshow/79230972.cms>.]

- <sup>15</sup> The Patents Act, 1970 does not use the expression 'innovation'. It deals with inventions. The dictionary meaning of innovation includes a new idea, method, or invention and also the introduction of new things. [Longman Dictionary of Contemporary English. Orient Longman. 1987].
- <sup>16</sup> Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material. Office CGPDTM. Available at [https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1\\_39\\_1\\_5-tk-guidelines.pdf](https://www.ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_39_1_5-tk-guidelines.pdf)
- <sup>17</sup> Lok Sabha Unstarred Question No. 513 answered on 20th July, 2018.

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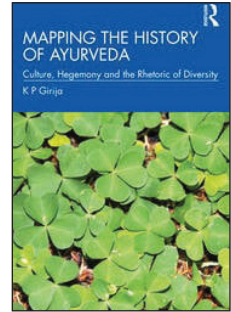
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# Mapping the History of Ayurveda: Culture, Hegemony, and the Rhetoric of Diversity

By: K P Girija



Krishna Ravi Srinivas\*



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Generally, it is assumed that while the dichotomy between modern western medicine and traditional medicine (or AYUSH in the Indian context) is real, traditional medicine itself is unitary without any hierarchical systems within it in theory and practice. It is also assumed that the traditional healing practices that do not come under the rubric of AYUSH can be reduced to and called local traditions or 'minor' traditions but, local healing traditions enriched Ayurveda. According to NCBS "Traditionally, Sanskrit-based Ayurvedic practice was limited to certain segments of society, folk healers came from all levels of society. Although folk practitioners from the lower strata of society lack the scholarly aura, many who specialize in specific healing practices are held in high esteem. Classical Ayurveda has been enriched over centuries through such interactions and exchanges with regional folk practices".<sup>1</sup>

But tradition does not remain static, nor does it remain isolated. In the case of Ayurveda, while it is found in many parts of India, Ayurveda in Kerala is well known and has a unique tradition. It is also the most well-known globally and a major reason for the flourishing of health tourism in Kerala. But what has been the relationship between Ayurveda and local healing traditions of Kerala. To understand this question another question has to be asked is there an 'Ayurveda' that has remained the same over the years. Eric Hobsbawm and Terence Range introduced the concept of 'invented tradition' in the book

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'Invention of Tradition'(1983) . Similarly, in recent scholarship on traditions and the relationship between tradition, modernity on one hand, and, tradition and science on the other hand many ideas have been put forth complicating the traditional understanding of these terms. In 'MAPPING THE HISTORY OF AYURVEDA' K.P. Girija relies on scholarship as well as on the information she gathered from interviews and observations to present a history of Ayurveda in Kerala that enriches our understanding of the development and growth of Ayurveda, making us rethink some of the presumptions and assumptions on Ayurveda.

The first and introductory chapter sets the tone for the book as the author describes the various questions and theoretical approaches in addressing the issue of Ayurveda as a tradition and the relationship between Ayurveda and other healing traditions. She states, "I use the concept 'indigenous' without placing emphasis on their autochthonic nature." She also takes the position that they are adaptive. In Chapter 2 she discusses how printed materials and print culture transformed the understandings among knowledge holders and helped in modernizing Ayurveda. In the next chapter, she examines the institutionalization and modernization of Ayurveda pointing out how this resulted in Vishavaidyam getting integrated into Ayurveda as a specialized subject. Similarly, marmavaidyam, Netravaidyam, and balavaidyam got integrated, partially or fully. This enlarged the scope of Ayurveda as a practice. In the next chapter, she describes the ideas of bodies or body in nattuvaidyam. In the next chapter (Chapter 5) she describes

how informal knowledge and practices get transformed and absorbed to form modern education or vidyabhasyam. Her analysis reveals how hierarchies in knowledge and practice are developed on one hand, and, on the other hand, the identity of Ayurveda gets crystalized and associated with Kerala. She points out that earlier identities and knowledge claims were fluid but later nattuvaidyam became a separate identity counterposed with nattuvaidyam. While nattuvaidyam was positioned below Ayurveda, Siddhavaidya aka Siddha Medicine was associated with Tamil Nadu as the indigenous medical practice of that state. Ayurveda gained legitimacy and content from practices that were not part of Ayurveda earlier became part of it. The incorporation of such practices and knowledge from nattuvaidyam enriched Ayurveda while the diverse healing practices were 'classified' as folk medicine. In the process, Ayurveda became an erudite tradition and gained legitimacy. In the final chapter, she raises questions for further research and why a gender perspective is important to understand the transformation of Ayurveda.

The book raises many questions and challenges the assumptions about Ayurveda. It also brings forth the assimilation and incorporation of knowledge and practices from other healing traditions into Ayurveda. The book in fact addresses the politics of knowledge in traditional medicine but eschews simple explanations or positing things in black and white. An important finding from this book is that we have to understand that while there is a diversity in knowledge and practices in different healing traditions, classifications like Ayurveda and putting



the rest as nattuvaidyam erase the nuances and diversities. A practical implication of the analysis is that we cannot reduce diverse healing traditions into just one or two categories.

This book can result in informed analysis and debate on what counts as a tradition in traditional health. By deconstructing the development and transformation of Ayurveda the author has pointed out that under the rubric of traditional healing traditions, there is a remarkable diversity but only institutionalized and modernized traditions like Ayurveda often get considered as traditional medicine. One practical implication of this is that only by studying and contextualizing the multiple healing traditions we will understand the importance and role of healing traditions.

This book will be of interest to those interested in and working on traditional medicine, particularly on traditional medicine and society issues.

Marmavaidyam- Massage and treatment for vital points in the body.

Vishavaidyam- Indigenous toxicology.

Netravaidyam- Indigenous treatment for eyes, ophthalmology.

Balavaidyam- Specialised branch of treatment meant for children, paediatrics.

Nattuvaidyam- Indigenous healing practices.

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**Endnote**

<sup>1</sup> <https://www.ncbs.res.in/HistoryScienceSociety/content/overview-indian-healing-traditions>



## Call for Contribution

Traditional Medicine Review (TMR) a multidisciplinary, peer-reviewed journal, aims to capture developments, updates and events on traditional medicine. We invite contributions from interested readers on issues related to traditional medicine, in theory and practice. Reviews of latest publications – research articles, essays, books, monographs, reports – are also welcome. The contributions can be sent to Editor, Forum on Indian Traditional Medicine, Research and Information System for Developing Countries (RIS), Core 4B 4th Floor, India Habitat Centre, Lodhi Road, New Delhi 110003, India (Email: [tjames@ris.org.in](mailto:tjames@ris.org.in); Tel. +91-11-24682177-80; Fax: +91-11-24682173/74).

For soft-copy of TMR, editorial information, contributions, feedback and comments, email: [tmr@ris.org.in](mailto:tmr@ris.org.in) and [dgoffice@ris.org.in](mailto:dgoffice@ris.org.in)

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Submissions should contain institutional affiliation and contact details of author(s), including email address, contact number, etc. Manuscripts should be prepared in MS-Word version, using double spacing. The text of manuscripts, particularly full length articles and essays may range between 4,000- 4,500 words. Whereas, book reviews/ event report shall range between 1,000-15,00 words.

In-text referencing should be embedded in the anthropological style, for example '(Hirschman 1961)' or '(Lakshman 1989:125)' (Note: Page numbers in the text are necessary only if the cited portion is a direct quote). Footnotes are required, as per the discussions in the paper/ article.

Use 's' in '-ise' '-isation' words; e.g., 'civilise', 'organisation'. Use British spellings rather than American spellings. Thus, 'labour' not 'labor'. Use figures (rather than word) for quantities and exact measurements including percentages (2 per cent, 3 km, 36 years old, etc.). In general descriptions, numbers below 10 should be spelt out in words. Use fuller forms for numbers and dates – for example 1980-88, pp. 200-202 and pp. 178-84. Specific dates should be cited in the form June 2, 2004. Decades and centuries may be spelt out, for example 'the eighties', 'the twentieth century', etc.

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## About FITM

The *Forum on Indian Traditional Medicine (FITM)* is a joint initiative by the Ministry of AYUSH and Research and Information Systems for Developing Countries (RIS). The Forum has been established with a broad objective to undertake/commission/promote studies on sociology, economy, political-economy, value chain, trade & investment and international cooperation in traditional medicines; prepare 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; and to facilitate interactions with experts, stakeholders and policy-makers from India and abroad. It facilitates policy discussions/Consultations and talks by national and international subject experts. FITM also provides fellowships and scholarships for studies in the area of traditional medicines.



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*Krishna Ravi Srinivas*

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