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In the backdrop of recent positive projections for growth and development of the traditional medicine sector, debates on institutionalisation and expansion beyond health related domains have emerged. Utilising systems like Ayurveda for Sustainable Development Goals (SDGs) such as nutrition is one such emerging prospect for policy makers that requires concerted integration of several institutions and disciplines. At the same time, while there is a steady progress in research on growth of the traditional medicine manufacturing sector, research on backend and forward linkages and sustainable supply chains remain policy and governance challenges. This includes understanding the traditional herbal medicine industry with its various manifestations of raw material sourcing and supply chain activities and the dynamics of forest and agriculture sector governance at the local, state and national levels. Further, as Indian traditional medicine sector moves from a unitary national identity towards a global political and commercial sphere of influence, manoeuvring reforms in global governance institutions such as World Health Organisation (WHO), non-tariff regulatory barriers in foreign trade and addressing safety concerns with pharamcovigilance are pertinent issues that warrant observation and analysis.

This issue brings together contributions from the academia and policy makers for analysis on the wide spectrum of issues outlined above. Tanuja Nesari, Chandra Shekhar Sanwal, Chinmay Rath and Saurabh Sharma review the need for a medicinal plant policy for India in the backdrop of the strategic significance of medicinal plant sector for the fast growing herbal industry. Deepak Jagannath Londhe, Shobhit Kumar, Sumeet Goel and Ashwin C. Chiluveri highlight the scope and potential of Ayurveda in addressing India's nutritional challenges by reviewing existing policies for malnutrition. Ayurveda's dietetic principles, evidences on efficiency of Ayush products in malnutrition and anaemia along with physical and social Ayush health infrastructure are some issues that have been analysed. Namrata Pathak provides a comparative analysis of the non-tariff barriers (NTBs) faced by India's traditional medicine sector comprising of medicinal plants, extracts and pharmaceuticals in key export markets of USA, EU and UAE. G. Geetha Krishnan provides a historical narrative of Ministry of Ayush's collaboration with World Health Organisation (WHO) for global standardisation of reference material and terminologies of Indian systems of medicine Further, in the backdrop of much debated safety concerns of traditional herbal medicines, Preet Amol Singh discusses historical developments, national and international regulatory provisions, and challenges in pharmacovigilance of

herbal medicines. Finally, Amit Kumar reviews Nirmal Sengupta's book Traditional Knowledge in Modern India.

I hope this issue of Traditional Medicine Review will broaden the knowledge and understanding of readers on the scope, expansion and challenges that underlie India's traditional medicine sector at present.

Sachin Cahturvedi

Prospects and Challenges in the Medicinal Plants Sector: A Review

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Abstract: Medicinal plants are one of the most important components of the non-timber forest products sector and the production, consumption, and domestic and international trade in medicinal plant-based products are poised to grow at a significant rate. India, with approximately 8 per cent of the world's biodiversity including plant genetic diversity with medicinal properties, has the potential to become a major global player in the market for medicinal plants based herbal (formulations) and products. This article reviews the current status of the medicinal plant sector in India, their prospects and challenges. It discusses these in relation to the resource base; use of medicinal plants at the local level; marketing channels and coordination efforts; and information. There are extremely diverse stakeholders spanning the formal sectors of agriculture, forestry, health care, and industry (as well as actors outside of these formal sectors). A major task for all stakeholders, including the policy planners, is the identification and guided development of integration all ministries and departments working on medicinal plants, which can then facilitate the promotion of herbal products.

Introduction

Medicinal plants are one of the most important components of the non-wood forest products sector, and contribute to significant proportion of India's net forest export earnings annually. According to WHO, the international market of herbal products

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is estimated to be US $ 62 billion, which is poised to grow to US $ 5 trillion by the year 2050, but India's share in the global export market of medicinal plants related trade is just 0.5 per cent (Kumar and Janagam, 2011). This indicates that production, consumption and domestic and international trade in medicinal plant-based products is going to grow at a significant rate. For making full use of this potential, India must develop scientific cultivation, post-harvest technology, processing, manufacturing, research and extension, patenting, and marketing for medicinal plants.

With the exception of a limited number of plant species, the production base relies mainly on materials harvested from the wild. Current practices are unsustainable, and many studies have emphasized the rapid depletion of the natural resource base. This problem is further compounded by the inequitable nature of the harvesting and marketing of the plants, thereby perpetuating impoverishment for those charged with stewarding and gathering the resource. Nonetheless, India, known to be a storehouse of biological diversity, has to focus on sustaining the resource base of medicinal plants. Efforts to relieve pressure on wild plants through cultivation have made a good start but have a long way to go. This is a complex issue by virtue of the sheer number of plant species and the needs for sustainable propagation, suitable agronomic practices, the selection of superior genotypes, and linking production to people. Constraints exist at all levels especially in relation to the documentation of the sector. There are extremely diverse stakeholders spanning the formal sectors of agriculture, forestry, health care and industry (as well as actors outside of these formal sectors). Medicinal plants fall into segments of these formal sectors and receive more or less attention depending on policy. Most of the available data regarding the formal sectors is in aggregate form, and such statistics supply little information about how the market actually works; they rely solely on market price as an indicator of value. Much more attention therefore needs to be given to the socio-institutional context of the market. With this backdrop the objectives of this paper are the following:

- To explore the nature of problems in realizing the potential of medicinal plants sector.
- To understand the required initiatives for growth of the medicinal plants sector.

Present Status: Problems and Challenges in Medicinal Plants Sector

Developing appropriate technologies for the cultivation of medicinal plants is a critical factor in ensuring a continuous and uniform supply of raw materials for the herbal industry and halting the degradation of natural resource base.

It is reported that public-sector research institutions in India have standardised practices for the propagation and cultivation of a total of nearly 40 species. But information on the actual level of adoption of these agro-technologies at the farm level is not available.

The present focus of medicinal plant research is mainly on developing agro-technologies for the mandated crops. Even where suitable plant varieties and agro-technologies for medicinal plants are available, their adoption by farmers needs further encouragement.

One of the major constraints in encouraging cultivation of medicinal plants is the absence of formal marketing linkages. Thus, the lack of assured marketing is one of the biggest hurdles in medicinal plant

sector. Some of the major problems in the field cultivation of medicinal plants identified by the authors are:

- Non-availability of verifiable data on availability and consumption of medicinal plants;
- Absence/ignorance of cultivation technology;
- Ignorance of cultivation economics (medicinal plants as pure crop may be uneconomical);
- Land availability due to land ceiling act and Indian Forest Act 1927;
- Inadequate irrigation facilities;
- Non-availability of planting materials;
- Lack of knowledge and training in post-harvest handling of medicinal plants;
- Lack of quality assurance and standardization of medicinal plants; and
- Inadequate marketing set-up for selling cultivated medicinal plants.

The domestic trade in medicinal plants in India is extremely complex, secretive, traditional, confusing, badly organized, highly under-estimated and unregulated. Also, there is no systematic local, regional, or national-level data regarding the number of species traded, volumes, prices etc. with any one agency. Most of the data is disjointed, scattered, grossly inadequate, and incomparable. The following factors make medicinal plant trade difficult:

- There are no inventories of medicinal plants at all-India basis.
- No reliable system of matching domestic trade names to botanical names exists. In the trade, a species is known by its local name, which can change from one market to another or from one region to another. For instance, for the trade name Ashok there are two botanically different species, Saraca Indica and Polyalthia longifolia. Similarly, for the trade name Chirayata the two botanical species are Andrographis paniculata and Swertia chirata.
- Medicinal plants are harvested and traded in their raw form, whether as leaves, fruit, flower, seeds, gum/resin, roots, rhizomes, stems, bark or the whole plant. Since most raw drugs are traded in dried forms, long after their harvest, only the most experienced people in the trade are able to recognize the species by their parts used.
- Price fluctuation, competition from synthetics, exporters' non-compliance with rules and regulations of importing countries and consequent refusal;
- Quality constraints, asymmetric information with suppliers about the total world-trade in medicinal plants, limited number of botanical suppliers and traders who have a very strong bargaining power vis-à-vis the growers, irregular supply; and
- Inappropriate methods of collection and storage leading to sub-optimal levels of active constituents and consequent increase in price of their derivatives are some of the major constraints faced by this sector.

R&D in medicinal plants at various stages in the value addition chain is being done by research and development organizations in Government of India, but according to Scientific Advisory Committee to the Cabinet, R&D in medicinal plants is beset with the following problems:

- There is no focus on a few numbers of plants at one time, which should be determined at the national level. Too many plants are taken up for research and focus is lost.
- Poor intra-institutional linkages lead to non-availability of data on past and current research and therefore there is duplication of work.

- Nature of priorities assigned in mandate of these organizations is different and hence the focus is diffuse.
- There is no interaction between these research institutions and growers on one hand and industry on the other hand. Therefore, research conducted by institutions does not reach farmers and research institutions do not come to know about needs of industry.
- The loss of traditional knowledge is being increasingly felt. Traditionally communities cultivate (even today) selected medicinal plants for personal use. The microniches and ideal growth conditions for these species are known by the communities. If large scale cultivation is to be planned, then there is a lot to learn from the communities. It thus becomes extremely important to document ethnobotanical knowledge and also provide incentives to the communities to keep this living tradition alive.

Possible Strategies for Medicinal Plants Sector

Medicinal plants have always been of interest to the local communities since these plants are used on daily basis by them. They also have a commercial value for the communities which procure them at considerably lower than the market price because they are sold in the 'raw' form. To increase the communities' stake in conservation there could be considerable value addition to medicinal plants through simple techniques such as drying, cleaning, crushing, powdering, grading and packaging. Not many efforts are being made in this direction as yet.

Of late, cultivation of medical plants is being promoted as the solution to guarding against the depletion of the plants and degradation of habitats. However cultivation of these plants is not so easy. There is an unavailability of quality planting materials as also a lack of standardised agronomic practices. Today, out of some 400 species used by the Ayurvedic, Unani, Siddha and Tibetan medicine, less than 20 species are under commercial plantation.((Foundation for the Revitalisation of Local Health Traditions or FRLHT, 1997)

Urgent action is needed for addressing the problem of marketing. Though contract farming may be one of the viable options for giving a boost to cultivation of medicinal plants, effective legislative measures are needed to enforce the contracts. In the past, there have been certain cases when the contracting party (buyer) backed out at the last moment putting the supplier (farmer) in trouble.

It was also noted that forest officials do not allow even collection of germplasm by the scientists from the reserve forest areas. At the same time, local people collect medicinal plants from the forests and sell in the market at cheaper rates. Though this is an illegal practice but this goes on unabated.

A SWOT analysis of Indian medicinal plants has established that this sector has several strengths such as enormous biodiversity, all types of soil and climate, a rich heritage of Indian System of Medicine (ISM), a strong base of R&D laboratories, skilled manpower, lower production and manpower costs and a well-developed pharmaceutical industry.

With its vast wealth of knowledge on medicinal plants and herbs, India is the most suitable country for conducting fundamental and application oriented research in this field. In fact, next to information technology and biotechnology, research in medicinal plants, which combined the best of both these technologies, should emerge as the most sustainable growth sector in the years to come.

Therefore, the need of the hour is an integrated approach which addresses

various issues in the supply chain right from farm to firm and consumer.

Need for a Medicinal Plant Policy

With growing interest in medicinal plants, there is a need to integrate a long term strategy to conserve and sustainably harvest these plant products. The use of medicinal plants in India and many other developing countries can be considered a living tradition. The traditional systems of medicine largely depend on natural resources of medicinal plants form the bulk of the medicine. The Natural Products Alert (NAPRALERT) databases at the University of Illinois document the ethnomedicinal uses for more than 9,000 species (Farnsworth and Soejarto, 1991).

The All India Ethnobiology Survey carried out by the Ministry of Environment and Forests estimates that over 7,500 species of plants are estimated to be used by 4,635 ethnic communities for human and veterinary health care across the country (Foundation for the Revitalisation of Local Health Traditions or FRLHT, 1997). A study of the codified medical texts of Ayurveda reveal that approximately 1,700 species of plants are documented for their medicinal properties and mode of action and over 10,000 herbal drug formulations are recorded. (FRLHT, 1997). Rigorous inventories from the Unani, Siddha or the Tibetan medical systems also would yield more information on plant use.

Medicinal plants like many other natural resources are doomed to extinction unless fire-fighting measures are deployed. In a complete turn around, modern medicine is getting more interested in medicinal plant therapies and as a result the demand for medicinal plant products globally is on the rise (RIS, 2021). Drug laboratories are today analysing more and more plant products as remedies for the ever growing list of diseases. Some of the existing major life saving drugs is plant derived. Take the example of reserpine - a drug commonly used to control high blood pressure and as an effective tranquiliser. Reserpine was isolated from the raw plant *Rauvolfia* extract and used in western medicine in 1952. Interestingly, the powdered root of *Rauvolfia* has been in use in India for at least 2,000 years to treat mental illness (Srivastava et al, 1996). This root, 35 years since it gave the world its first tranquiliser, has become both medically and economically extremely important. The US alone dispenses over 22 million prescriptions for reserpine (Srivastava *et al*, 1996)

Another threat medicinal plants face is that of habitat destruction. Under the Forest (Conservation) Act , 1980[1] and the Wildlife (Protection) Act, 1972[2], medicinal plants do get some amount of protection. But a lot of medicinal plants grow away from the protected areas domain and since there is no consolidated strategy for medicinal plants, a lot of them just disappear without even the knowledge of it. Within protected areas also, the lack of a focused conservation strategy could cause a depletion of this valuable resource. Over 70 per cent of the plant collections involve the use of roots, bark, wood, and stem and in some areas the whole plant, leading to destructive harvesting. (Farnsworth and Soejarto, 1991). If not carefully monitored, this practice could lead to the depletion of genetic stocks and ultimately to the diversity of medicinal plants.

The loss of ethnobotanical knowledge in particular has also accelerated the depletion of plants of medicinal value. Indigenous communities, because of their intimate knowledge of the ecosystem and elements therein, knew how to harvest plants while the species could maintain its population at natural or near natural levels and ensure that the level of harvest will

not change the species composition. With this loss of traditional knowledge, we are fast losing the ethical means which ensure a sustainable harvest.

Efforts to conserve medicinal plants are being made throughout the country, but are scattered. The ideal conservation strategy for any species is one of in situ conservation. For medicinal plants this is being done to some extent in the current protected area management regime. Simultaneously, it is also important to look at the *ex-situ* conservation of medicinal plants through set ups like medical plant gardens and gene banks. The All India Health Network, Lok Swasthya Parampara Samvardhan Samiti, Coimbatore, has established 50 such gardens in the country.[1] The FRLHT has also established 15 such gardens in the three southern states of Kerala, Tamil Nadu and Karnataka.[2] The Department of Biotechnology, Government of India, has taken the initiative to establish three gene banks in the country.

More urgent than conservation for plants is to ensure the availability of plants and planting material to the various user groups and this is possible if enough nurseries are established throughout the country. In southern India, FRLHT has recently set up a network of 53 supply nurseries. Besides this, no organized nursery network or supply of quality planting material of medicinal plants exists.

Discussion

The importance of the medicinal plant sector can be gauged from the fact that medicinal plants serve the healthcare needs of about 80 per cent of the world's population. According to the World Health Organization (WHO), the goal of 'Health for All' cannot be achieved without herbal medicinal plants (Nahla *et al*,. 2011). But the lack of national legislation or effective international agreements on conservation of biodiversity has resulted unsustainable use of medicinal plants resources. Given the extent of biodiversity in India, a major task of all the concerned including the policy planners has to be the identification and guided development of new products with large export potential. India has set a vision regarding its medicinal plants sector and some major policy initiatives have been taken in this direction. Still, strategic actions based on research on the issues identified above will be needed to realize the vision. However, the fact that not all medicinal plants are amenable to cultivation should not be ignored. Hence, conservation and cultivation must go together with prioritization for development of the medicinal plants sector as a whole. To harness the potential of this sector, we should have an economic outlook, realistic policy and effective planning strategy. Since available evidences are inadequate to fully capture the complex issues of this sector, three is a dire need to undertake in-depth socio-economic and policy research analysis to fill the gaps in understanding the dynamics of medicinal plants sector.

The Indian government has no doubt taken certain policy measures to protect the country's invaluable biodiversity as well as meet international obligations under the post-WTO regime. Though these initiatives are appreciable, there is enough scope for making them more focused and effective. We may begin with conservation and on-farm cultivation of priority species as reported by various high-level expert committees. At the same time, the industry estimates for raw material demand should be available well in advance so as to regulate the demand-supply scenario optimally. This is important if we have to ensure development of this sector in a sustainable manner.

Effective policymaking for this sector calls for awareness raising, coordination and engagement of all the stakeholders.

One of the immediate tasks for conserving medicinal plants diversity is to effectively implement the provisions on conservation and sustainable use of biodiversity (Biological Diversity Act, 2002)[3] and the Patents (Amendment) Act, 2005.[4] Capacity building is another important area which would be a major source for harnessing the potential of medicinal plant sector. A national policy on utilizing medicinal plants for herbal formulations needs to be developed soon which should ensure that all herbal formulations in the market are safe, effective, of good quality, reasonably priced and are prescribed and utilized rationally. It is equally important that the interests of the growers are well protected by the supply of modern technologies, services and credit supplies and above all, by a good marketing system. The national policy should have effective provisions for ensuring equitable benefit sharing for all stakeholders. This would go a long way towards fulfilling traditional healthcare needs and ensuring the conservation and sustained utilization of medicinal plant resources in the country.

Conclusion

The need to conserve medicinal plants is now widely recognised and several measures suggested. However, as mentioned earlier, no consolidated strategy to address issues discussed exists, neither is there a defined policy for the conservation of medicinal plants. Three Acts cover medicinal plant issues in India i.e. the Indian Forest Act (IFA)[5], the Forest (Conservation) Act, 1980[6], and the Wildlife (Protection) Act, 1972 (WLPA).[7] The Indian Forest Act applies only to material brought from the forest. The Forest (Conservation) Act, 1980, and the Wildlife (Protection) Act, 1972, facilitate only the in situ conservation of medicinal plants. Outside protected areas the Wildlife (Protection) Act, 1972, provides a regulatory mechanism of six endangered plant species under its Schedule VI. Out of these only one is of medicinal value. The export import policy of India looks at the export as well as import of plants and plant parts on the basis of the Convention of International Trade in Endangered Species of Wild Fauna and Flora (CITES), Appendix 1, which essentially lists the same six species of plants that are under schedule VI of WLPA (Jha, 1995).

A national policy need to integrate all policies within its framework should have several points:

- The policy must be formulated keeping in mind the various user groups of medicinal plants. It must recognise the fact that there is a much larger population of non-commercial users, as opposed to commercial users.
- The policy framework should advocate conservation *in-situ* and *ex-situ* as well as cultivation. This is needed, considering the long term availability of medicinal plants and the immediate needs of user groups. The policy would have to look at means to raise financial resources and incentives for encouraging conservation actions.
- To facilitate implementation, the policy should review existing institutions working in the field, encourage their strengthening and, where necessary, also review the possibility of building new institutions.
- Most importantly, the policy needs to take into account the legal and regulatory mechanisms related to medicinal plants.

Endnotes

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Convergence of Ayush in National Nutrition Policy of India: Situational Analysis and Way Forward

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Abstract: Malnutrition, in all its forms, is a serious global public health problem that presents a significant nutritional challenge for current society. In order to achieve sustainable and better nutritional outcomes, it is more important than ever to reinforce nutritional policies and increase the coherence of diverse sectors. Global nutrition strategies such as the Rome Declaration of Nutrition1 2014 have recognised that 'nutrition improvement requires healthy, balanced, diversified diets, including traditional diets where appropriate, meeting nutrient requirements of all age groups.' The Government of India has also been moving towards holistic programme to address malnutrition, undernutrition, and other such nutrition-related chronic diseases. In this article, attempt has been made to highlight the scope and potential of Ayurveda in addressing the nutritional challenge. Data on existing policies for malnutrition; Ayush dietetic principles, evidences on efficiency of Ayush products in malnutrition and anaemia; protocol for the management of malnutrition and Ayush institutes and human resources has been reviewed.

Introduction

Malnutrition, in all its forms, resulting from poor diets, is a critical global public health problem, creating an immense nutritional challenge for the current society. The need has never been greater for strengthening nutritional policies, increasing the

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coherence of various sectors that go beyond the nutritional community to achieve sustained and better coordinated operational actions and outcomes. Further, post-COVID 19 pandemic, the strong links between poor metabolic health and worse COVID-19 outcomes have highlighted the importance of improving nutrition towards the resilience of the population to such shocks in the future. Worldwide, 149.2 million children under five years of age are stunted, 45.4 million are wasted, and 38.9 million are overweight (World Health Organization, 2021). India has made progress in its social, economic, and global platforms; however, there is still a lot to be accomplished on the nutritional status of its citizens. Various five-year plans have placed it at the forefront of their agenda. Over the years, the issue of malnutrition has been presented in various ways, such as a health issue (1950-65), a food shortage issue (1965-75), a multidimensional poverty challenge (1975-97), or a nutrition and food security challenge (after 1997). After adoption of the National Nutrition Policy in 1993, under the umbrella of the Department of Women and Child Development, the Government of India has introduced many schemes and programs to address malnutrition, undernutrition, and other such nutrition-related chronic diseases. The recent launch of the Prime Minister's Overarching Scheme for Holistic Nutrition or POSHAN Abhiyaan[2] by the Government of India shows its priority towards fighting against the issue of malnutrition. When accounting for the vast and interconnected health, economic, and environmental burdens, the present nutrition crisis is a reality that no longer can be ignored. Hence, convergent action from different fronts is needed to effectively address the crisis, which is in alignment with the vision of National Health Policy[3] (NHP-2017) and leverage the pluralistic health care legacy for mainstreaming the different health systems.

Laws/Policies Regarding Nutrition at Global and National Level

United Nations (General Assembly and World Health Assembly) and WHO have initiated various policies on Nutrition, Non-communicable diseases (NCDs), elimination of malnutrition. Further, under Sustainable Development Goals (SDG2), it has targeted to end hunger, achieve food security and improved nutrition, and promote sustainable agriculture (World Health Organization, 2018).

The Government of India (GoI) over the years has initiated several large-scale supplementary feeding programmes and programmes aimed at overcoming specific deficiency diseases to address malnutrition like National Nutrition Policy of 1993, National Food Security Act 2013, Integrated Child Development Services (ICDS), the mid-day meal scheme, and the POSHAN Abhiyaan (Table 01).

An Overview of Recent Initiatives for Sustainable Nutrition Outcomes in India

Synergistic Action: Inter-Ministerial Convergence under POSHAN Abhiyaan

With an aim to achieve improvement in the nutritional status of children under six years, adolescent girls, pregnant women and lactating mothers in a time bound manner, the novelty of the *Abhiyaan* is twofold: at the consumer level, it aims to foster behavioural change among individuals, especially parents, and amalgamate knowledge about healthy dietary practises. The Abhiyan also seeks to improve linkages between communities and health and wellness, thus paving the

way for a mass movement to promote transformative change, also referred to as '*Jan Andolan'*. Under the *Abhiyaan*, *Poshan Maah*, *Poshan Pakhwada* and Community Based Events (CBEs) have served as significant strategies for changing nutrition practises. The gatherings serve as a platform for disseminating essential messages and to counsel pregnant and lactating women, and their influencers (husbands/ mothers-in-law) on appropriate nutrition and health behaviour.

The Abhiyaan introduces a convergence platform where different ministries and departments working with common goals impacting nutrition outcomes come together to achieve a synergy of all interventions to target under nutrition effectively. Since inception of POSHAN Abhiyaan, Ministry of Ayush has been the knowledge partner of Ministry of Women and Child Development and actively participates in the various activities with the help of State Ayush Departments and National Institutes/ Research Councils under the Ministry. For integration of Ayush systems with the ongoing nutrition interventions, Ministry of Ayush and Ministry of Women and Child Development have also entered a Memorandum of Understanding (MoU) in 2020[9].

Table 1: Chronology of Nutrition Programmes in India

Sr. No	Programme/policy	Highlights
1	**National Nutrition Monitoring Bureau, 1972[4]**	The Bureau was established in the year 1972 under the guidance of the Indian Council of Medical Research to create a dynamic database on the diet and nutritional status of various communities. It also recommended corrective measures in the Central Nutritional Policies.
2	**National Nutrition Policy, (NNP)1993[5]**	The NNP adopted by the GO1 in 1993, advocates a "comprehensive, integrated and inter-sectoral strategy for alleviating the multifaceted problem of malnutrition and achieving the optimal state of nutrition for the people ".
3	**Mid-Day Meal Scheme, 1995[6]**	To ensure better nutrition amongst the school-going children the scheme covered all the children of primary schools run by the government or aided by the government to receive a fully prepared mid-day meal.
4	**National Food Security Act, 2013[7]**	The Act's provisions include: A. Food security by providing grains at subsidized prices B. Nutritional support to pregnant women and lactating mothers X. Nutritional support to children. Δ. Prevention and management of child malnutrition.

Table 1 continued...

Table 1 continued...

5	**National Nutrition Mission or POSHAN Abhiyaan, 2018[2]**	The Prime Minister's Overarching Scheme for Holistic Nutrition or POSHAN Abhiyaan or National Nutrition Mission, is GoI's flagship programme to improve nutritional outcomes for children, pregnant women and lactating mothers. Strategy/pillars of the mission: • Inter-sectoral convergence for better service delivery • Use of technology (ICT) for real time growth monitoring and tracking of women and children • Intensified health and nutrition services for the first 1000 days of life including pregnancy and 2 years after birth. • *Jan Andolan*-effective outreach and implementation of programme throughcommunity mobilisation and large scale participation for increasing awareness and behaviour communication change.
Other major nutrition programs include[8]:		
6	**National Vitamin A Prophylaxis Programme, 1970**	This plan sought to administer about 2,00,000 International Units (IU) of vitamin A to such children every six months.
7	**Special Nutrition Programme, 1970**	This program has provision for supplementary feeding of around 300 calories and 10 grams of protein to preschool children. It also covers nursing mothers and feeds them with 500 calories and 25 grams of protein.
8	**Balwadi Nutrition Programme, 1970**	This program was started in 1970 under the department of social welfare through voluntary organizations. It focuses both on healthcare as well as education. It is meant for children who belong to the age group 3–6 years.
9	**Integrated Child Development Services (ICDS), 1975**	It is package of integrated services. It provides food, preschool education, primary healthcare, immunization, health check-up, and referral services to children under 6 years of age and their mothers.
10	**National Iodine Deficiency Disorder Control Programme, 1992**	This program started as the National Goiter Control Programme (NGCP). It was later renamed to National Iodine Deficiency Disorders Control Programme (NIDDCP) in August 1992. This was to broaden the spectrum of iodine deficiency disorders like mental and physical retardation, deaf-mutism, cretinism, stillbirths, etc.

Aligning National Education Policy (NEP) 2020 and Indian Traditional Knowledge

As per NEP 2020, 2.9 "Children are unable to learn optimally when they are undernourished or unwell. Hence, the nutrition and health (including mental health) of children will be addressed, through healthy meals and the introduction of well-trained social workers, counsellors, and community involvement into the schooling system." Further, the policy emphasised on holistic and multidisciplinary ecosystem wherein the rich legacies of Indian Traditional Knowledge need to be optimally utilized through our education system.[10]

Recognizing schools as useful platform, Government of India has launched "School Health Program" under Ayushman Bharat [11]to strengthen health promotion and disease prevention intervention. It is a joint collaborative programme between the Ministry of Health and Family Welfare and Ministry of Human Resource and Development. Major objectives of the School Health Programme are -to provide age appropriate information about health and nutrition to the children in schools, to promote healthy behaviors among the children that they will inculcate for life and to promote yoga and meditation through Health and Wellness Ambassadors.

Ayush Dietetic Principles, Products, Practices, Infrastructure and Human Resources to Strengthen Nutritional Health

The science of nutrition at the present times evolved as an elaborate and organised subject of study. Contemporary perspective mull over gross components of diet like carbohydrates, fats, proteins, minerals, water etc. Ayurveda accentuates basic dietary guidelines in terms of appropriate food, combinations of food, cooking methods, storage, eating atmosphere, hygiene, and etiquette (*Ashta Ahara Vidhi Visheshayatana*), which are pivotal in the preservation and promotion of health and prevention of disease (Sharma, 2004).Various classical Ayurveda texts (Bhojankutuhalam, Nighantu Ratnakar)[12-13] cover an array of themes on food ranging from the diversity of natural sources, recipes, properties in relation to seasons and places, food safety and measures for the same and their health benefits. It offers extensive insights about food and health based on certain unique conceptual as well as theoretical positions.

In this age of globalisation, modern food systems have resulted in the loss of knowledge and consumption of traditional and local nutrient rich foods and increase in the industrialised and processed food products leading to various nutrition issues. The inclusion of Ayush dietary principles, products, and practices in India's nutritional Programme can help raise the nutritional Status of the population, health promotion, and prevention of various nutritional deficiency diseases and diet-related NCDs.

Ayush Dietetic Principles

Principles of Proper Metabolism for Good Health

It is not just the amount of nutrients, but their bioavailability, absorption, and assimilation are equally important aspects to ensure the proper nutritional status of a person (Schönfeldt, Pretorius and Hall, 2016). Therefore, for effective interventions it is necessary to consider the nutrient bioavailability and nutrient content of foods, while planning nutrition related policies and nutritional interventions. The dominant focus within the ICDS programme is on food/nutrient supplementation.

The digestive/metabolic factor (*Agni*) is a core principle entity of Ayurveda on which the whole process of digestion, metabolism, immunity, and in fact, the life force depends (Agrawal, Yadav and Meena, 2010). Various herbs have been mentioned under the categories of *Deepan* (digestion and metabolism enhancing) and *Pachan* (digestion) for improving an individual's appetite and digestion (Kesarwani and Gupta, 2013).

Comprehensive review of Pharmaco-therapeutics of *deepan* and *pachan*herbs (digestion/metabolism enhancing herbs) has reported that herbal bio enhancers like- trikatu-combination of *maricha* (Piper nigrum Linn.), *pippali* (Piper longum Linn.), and *Sonth* (Zingiberofficinale Rosc.), *Jeeraka* (Cuminumcyminum), *Yashtimadhu* (Glycyrrhizin), *Sahjan* (Moringaoleifera)) Curcumin (principal curcuminoid of spice haldi (Curcuma longa), etc. improved oral absorption of nutraceuticals like vitamins, minerals, amino acids, etc. (Dudhatra *et al*., 2012). Research studies have evaluated the influence of dietary spices–black pepper, red pepper, ginger on the membrane fluidity in intestinal brush border membrane (BBM) in rats. Intestinal villi from these spice/spice-agent-fed animals revealed an increased microvilli length, which would mean an increased absorptive surface of the small intestine, providing for an increased bioavailability of micronutrients (Prakash and Srinivasan, 2010).

Further, herbs mentioned for managing malnutrition cases as per Ayurvedic classical texts have reported numerous benefits in scientific studies. For instance, Punarnava (Boerhaviadiffusa Linn.) has reported to have good source of nutritional supplements, i.e. 15 amino acids (six essential) in the whole plant and 14 amino acids (seven essential) in the roots along with isopalmitate acetate, behenic acid, arachidic acid (6.3 per cent), and saturated fatty acids (38 per cent). Various animal studies and trials have reported immunomodulation, hepatoprotection, and diuresis activities (Mishra *et al*., 2014). It has been used in management of anaemia in traditional medicine as well.

The status of nutrition can improve if *deepaniya* products (bioavailability enhancers) from the traditional age old system of Ayurveda by using modern food technology are coupled with the Supplementary Nutrition Programme as an adjuvant to existing THR.

Principle of *Balya* and *Rasayana Dravyas*: In community-based management of acute malnutrition (CMAM), take-home food rations (THR) and routine basic treatment is provided to children with moderate malnutrition without medical complications. Children with severe acute malnutrition and without medical complications are provided home-based treatment and rehabilitation using Ready-to-use Therapeutic Food (RUTF) (World Health Organization, 2012). RUTF is a high-calorie, nutrient dense, viscous paste made out of micronutrients, vitamins, peanuts, milk solids and vegetable oils (Lenters, Wazny and Bhutta, 2016).

Acceptance of RUTF at community level, high cost, and concerns about replacing family foods and best practices for optimal nutrition, RUTF is not sanctioned for use by the Government of India (Ministry of Women and Child Development, 2017).[14] Therefore, it is imperative to explore the alternative cost-effective local products for the management of acute malnutrition.

Health Promoter formulations mentioned under *Balya, Poshak* and *Rasayan* category in the Drugs and Cosmetics Act, 1940 are recommended for promotional and preventive health (Department Of Health, Ministry of Health and Family Welfare, n.d.).[15] Ayush products under this

food category are having high nutritional value. They can be included in current Take Home Rations and can be explored for possible use as RUTF with the use of appropriate food technology.

Malnutrition and poor immunity is interlinked and forms a vicious cycle. A malnourished child has low immunity level and is prone to infectious diseases such as diarrhoea, due to which they lose weight and again fall into the trap of malnutrition (Bourke, Berkley and Prendergast, 2016). Therefore, for prevention and management of malnutrition, along with nutritional supplements, -based Ayush products for optimising immunity need to be considered in a programme focused on malnourished children.

Principle of galactodepurant (*Stanyashodhan*) and galactagogue (*stanyajananam*) for optimum quality milk Production

Mother's milk is the best food for new-borns and infants. To have good nutritional status, the lactating woman has to have optimal nutrient intake. The nutrients in milk come from the diet of the mother or from her nutrient reserves. The World Health Organization (WHO) recommends that all infants be exclusively breastfed until 6 months of age and that breastfeeding continue as an important element of their diet until two years of age. Many factors contribute to a ceasing breastfeeding early, with the most commonly reported reason being perceived insufficient breast milk supply.

In National Food Security Act 2013, there is a provision of Nutritional support to pregnant women and lactating mothers by providing meal/THR, free of charge, during pregnancy and six months after the child birth.[7]

Therefore, besides current nutritional support which is being provided through Anganwadi services, evidence based Ayush products having galactagogue and galactodepurant properties can be included in the current programme for optimal quality milk production (Bazzano et al., 2016). This may ensure optimum milk quality and quantity for children optimising their growth and development.

Ayush Products for Prevention of Anaemia

Iron Deficiency Anaemia (IDA) is most prevalent and the most neglected nutrient deficiency in the world, particularly among adolescent girls and pregnant women (Stevens *et al.*, 2013). Persistence of high prevalence of anaemia across all age groups in India is shown in National Family Health Surveys (NFHS) 2 to 5[16] (NFHS 2: 1998-99; NFHS 3: 2005-6; NFHS 4: 2015-16 and NFHS 5: 2019-21). It is managed with the supplementation of external iron containing one or the other types of iron salts under the Anaemia Mukt Bharat (AMB) strategy with a multi-pronged approach and a more robust operational and accountability framework through the 6X6 strategy (Ministry of Health and Family Welfare, Government of India, 2018).

The strategy involves six Categories of beneficiaries (5-59 months children; 5-9 yrs children; 10-19 yrs old adolescent boys and girls, pregnant women, lactating mothers, women in reproductive age); six interventions (Prophylactic Iron and Folic Acid Supplementation, Deworming, Intensified year-round Behaviour Change Communication (BCC) Campaign and delayed cord clamping, Testing of anaemia using digital methods and point of care treatment, Mandatory provision of Iron and Folic Acid fortified foods in Government funded health programmes and Addressing non-nutritional causes of anaemia in endemic pockets with special focus on malaria, hemoglobinopathies and

fluorosis; and 6 institutional mechanisms (Inter-ministerial coordination, National Anaemia Mukt Bharat Unit, National Centre of Excellence and Advanced research on Anaemia Control i.e. NCEAR, Convergence with other ministries, Strengthening supply chain and logistics, Anaemia Mukt Bharat Dashboard and Digital Portal- one-stop shop for Anaemia.

No decline in the prevalence of anaemia among pregnant women despite various efforts including increased Iron Folic Acid (IFA) intake, indicates the lack of effective outcomes from the ongoing anaemia control programme. Further, it has been also reported that the long-term treatment of IDA with these drugs is mostly associated with constipation, heartburn, nausea, gastric discomfort, etc. (Nguyen and Tadi, 2020). Thus points to the need to review the interventions, etiological factors and pathophysiology of anaemia and to explore midcourse corrections in the ongoing anaemia control programme in the country.

Systematic review on "Ayurvedic preparations for the management of Iron Deficiency Anaemia" has reported that use of Ayush medicines like *Punarnavadi Mandura*, *Dhatri Lauha*, *Dadimadi Ghrita*, *drakshavleh,* etc. have significant results in both subjective and haematological parametersin the nutritional deficiency anaemia (Samal, 2016).The response of most of the Ayurvedic formulations was better than Allopathic formulations and there was no untoward effect as observed with iron salts. Therefore, for prevention and management of mild to moderate cases Ayush dietary principles along with clinically studied Ayush medicines can be considered under Anaemia Mukt Bharat Programme.

Practices

Garbhini Paricharya in Ante Natal Care Programme: The World Health Organization recently made a recommendation about supporting 'culturally-appropriate' maternity care services to improve maternal and newborn health (World Health Organization, 2003). Ayush systems of medicines, especially Ayurveda is traditionally practiced over long period in India. *Garbhini Paricharya* explained in Ayurveda brings a unique perspective on care of the mother during this pivotal time. It emphasizes on preparing the body for pregnancy prior to a planned pregnancy as a way to prevent complications, to maximize health of the mother, and even enhance the future health of the child.[17] Further, it includes a holistically planned regimen of thoughts, action, education, dietary modifications, lifestyle modification, and medical management of pregnant lady. This regimen aims to ensure a healthy and smooth childbirth and at the same time sustain the overall health, nutrition and wellbeing of both the woman and the baby. The measures are simple, easy to follow by women and families at the household level and emphasizes on the use of locally available resources.

Appropriate and evidence based components of *garbhiniparicharya* need to be incorporated in various National Health Programmes for Maternal and Child Health as a part of ante natal care.[18]

Therapeutic Massage (*Abhyanga* practice): Sound sleep is one of the important factors for appropriate secretion of Growth hormone. Simple practices like Abhyanga (oil massage) of infant by mother have a positive effect on successful breastfeeding and have numerous health benefits to children like better circulation of blood, prevention from hypothermia, sound sleep, and reduced stress. *Abhyanga* is mentioned as a part of daily regimen in Ayurveda classics and practiced traditionally in most of the households. This procedure can be

considered for inclusion in the treatment protocol for Severe Acute Malnutrition (SAM) children[19] after developing the Standard Operating Procedure (SOP).

Seasonal and Regional Food Practices: Overreliance on a few staple crops and monotonous dietary practises are leading causes of low dietary diversity, micronutrient deficiency, and persistent malnutrition. The World Health Organization has recommended dietary diversity in order to maintain proper child growth and development (World Health Organisation, 2008). In various studies, it was found that greater dietary diversity was significantly associated with increased HAZ among children and reduced stunting (Khamis *et al.*, 2019).

As per the provisions made in the NFSA 2013, food rich in calories is provided to a specific section of society through the archaic PDS (public distribution system) Further, additional nutrition is provided in the form of a take-home ration (THR) to specific beneficiaries including pregnant women, lactating mothers, children from 0-6 years of age. At present, the THR programme's recipe and formulation are very less diverse and typically composed of wheat, maize, rice, lentils, soy, groundnut, and sugar (Beesabathuni, Kumari and Bajoria, 2020) (World Food Programme, 2020).

There is a need to look beyond calories and effort may be directed toward improving dietary diversity by providing diverse food articles including millets like Jowar (sorghum), Bajra (pearl millet), ragi (finger millet), Jhangora (barnyard millet), Barri (Proso or common millet), Kangni (foxtail/ Italian millet), Kodra (Kodo millet) etcand pulses/legumes like-Arhar/ Masoor/ Mung/ Chana/ Masoor/ Moth/ Urad etc.

Staple crops, including cereals, roots, nuts, pulses, and vegetables, are adapted to local land, resilient to environmental challenges and rich in micronutrients. Use of region- and season-specific cereals, millets, pulses, vegetables, nuts and regional oil in Hot Cooked Meal (HCM) need to be considered. Keeping this view, guidelines for HCM may be provided in Schedule II of the NFSA. This will help reduce food miles and thereby help provide nutrient-rich, fresh food to the people. It can also contribute to rural development and a sense of community.

Use of Ayush Infrastructure and Human Resources

Community management of Acute Malnutrition (CMAM) is an integrated public-health approach to address acute malnutrition, emphasising treating uncomplicated SAM patients solely on an outpatient basis (World Health Organization, 2013). For sustainable management of uncomplicated SAM and MAM children, the Ayush infrastructure of more than 780 educational institutes, 12500 HWCs planned under Ayushman Bharat, 29951 Ayush dispensaries and 3859 Ayush hospitals and its human resources[20] can be roped in for OPD services after an appropriate training programme. Further, pilot studies can be considered by integrating Ayush products into CMAM protocols.

To address the issue of SAM children, particularly among those with medical complication, the World Health Organization (WHO) recommends the concept of Nutrition Rehabilitation Centre (NRC) wherein inpatient treatment regimens of intensive medical and nutritional protocols are provided.[21]

The services and care provided for the inpatient management of SAM children include:

- 24-hour care and monitoring of the child.
- Treatment of medical complications.
- Therapeutic feeding.

- Providing sensory stimulation and emotional care.
- Social assessment of the family to identify and address contributing factors.
- Counselling on appropriate feeding, care and hygiene.
- Demonstration and practise - by - doing on the preparation of energy dense child foods using locally available, culturally acceptable and affordable food items.
- Follow up of children discharged from the facility.

There are 1151 Nutritional Rehabilitation Centres (NRCs) in 25 States/ UTs in the country functioning under the National Health Mission, at public health facilities.[22] It is estimated that in proportion to number of SAM children, there is limited inpatient capacity and the NRCs are overcrowded with patients; hence, it is necessary to increase the bed capacity. Ayush institutions imparting postgraduate studies in Ayurveda Paediatrics can be considered for setting up of NRC in Ayush facilities after appropriate capacity building.

Ayush-Based Behaviour Communication Change (BCC) Strategy for the Double Burden of Malnutrition

To date, much of the debate on malnutrition in India has, of course, focused on malnutrition, particularly in children, or inadequate food intake, manifested as poor anthropometric outcomes. But quite recently, it has been observed that overnutrition and overweight/obesity have significantly increased in the country. Interestingly, this trend is no longer primarily an urban phenomenon but is also characteristic of many rural populations. Thus, India appears to be experiencing a nutritional transition, a term that refers to changes in the food environment, physical activity, and lifestyle that lead to an increase in overnutrition over time. A recent National Family Health Survey[23] (NFHS-5, 2019-21) suggests that obesity is increasing in most States and Union Territories. The problem is more worrying for children. Obesity among children under the age of 5 has increased, and the number of overweight youngsters has increased in 33 states and union territories. The proportion of obese children increased from 2.1 per cent in NFHS-4[24] to 3 per cent in NFHS-5. By gender, obesity in India has increased by 4 per cent in both men and women over the past five years. In NFHS-5 (2019-21), the percentage of women who are overweight or obese is 24 per cent, while in NFHS-4 (2015-16) it was 20.6 percent. Among men, the prevalence increased from 18.9 percent (NFHS-4) to 22.9 per cent (NFHS-5). Being overweight or obese poses a significant risk for non-communicable diseases, including heart disease, diabetes, etc. and is a continuing public health concern.

Whilst nutrient deficiencies may be curbed by providing supplementary nutrition and poverty reduction measures, for obesity prevention, nutrition education; behaviour communication change strategies; promotion of physical activity; encouragement of local and seasonal food practices and may be instrumental.

Standard modules based on the principles of the Ayush diet, *Dinacharya* (daily regimen), *Ritucharya* (seasonal care), *Panchakarma* (bio-purification therapy), etc. must be developed for nutrition education and behavioral communication. These modules can be used for training, communication, and community sensitization for the nutritional wellbeing of the people.

Conclusion

The health of citizens is of paramount importance to maximising their potential for growth and development of the nation. India has committed to Universal Health Coverage (UHC) in order to provide health services to all without any discrimination at an affordable cost, ensuring equitable access to achieve the United Nations' Sustainable Development Goals (SDG's). Promotion of proper nutrition is one of the eight essential components of primary health care and it is a critical part of health and development. Better nutrition is related to improved infant, child, and maternal health; stronger immune systems, safer pregnancy and childbirth, a lower risk of NCDs; and longer longevity. Over the last few years, governments have been attempting to address the problem of malnutrition head-on, with a rise in active conversations on nutrition and many positive advances made by the Indian Government.

Malnutrition is a cross-cutting issue, and it needs support from multiple sectors to ensure improvements in food security and nutrition for individuals, households, and communities.

Integration of the evidence-based principles, practices, and products of Ayush systems of medicine in existing Health and Nutrition policies may help combat the issue of malnutrition and improv national nutrition parameters.

Endnotes

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12 This scheme is typically categorized into two components i.e. Pradhan Mantri Jan Arogya Yojana and Health and Wellness Centres. While the first component of Ayushman Bharat, the Pradhan Mantri

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19 Government of India is currently implementing various programmes/ schemes aimed at improving maternal and child health as mentioned below:

i) National Health Mission (NHM): NHM's focus on maternal and child health through the component of 'Reproductive-Maternal- Neonatal-Child and Adolescent Health (RMNCH + A)' includes increased public health spending; decentralizing village and district-level health planning and management; employing community health workers (known as ASHAs); providing cash transfer. Women and child specific components of the NHM are-Janani Suraksha Yojana (JSY) and Janani Shishu Suraksha Karyakaram (JSSK)

[i]i) Pradhan Mantri Surakshit Matritva Yojana Abhiyan for antenatal Care

iii) Pradhan Mantri Matru Vandana Yojana for pregnant women and lactating mothers.

iv) DAKSHATA for enhanced competency of the health care providers to strengthen the intra-partum and immediate postpartum care. Health care providers are trained by designated trainers in small batches.

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Role of Non-Tariff Trade Barriers in Ayush Exports

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Abstract: India's exports in traditional medicines have shown impressive growth although regulatory barriers imposed by importing countries both in the form of non-tariff measures pose a significant challenge to exports. Key Non-tariff barriers (NTBs) for traditional medicine exports such as medicinal plants, extracts and pharmaceuticals from India include Sanitary and Phytosanitary measures (SPS), technical Barriers to trade (TBTs), pre-shipment and other formalities, non-automatic import licensing, quotas, prohibitions and price control measures. This Article analyses broad trends in NTBs for Ayush exports to countries/regions that make up the bulk of India's exports across all components, viz. USA, UAE and EU.

Introduction

Traditional Medicine is witnessing a resurgence as global attitudes change and move from the hitherto marginalisation by bio-medicine dominated healthcare towards a more integrative approach. The Traditional and Complementary Medicine 2019 report (WHO, 2019) which evaluates reporting at four time points from 1999 to 2018, reported that the number of member states with a national policy on traditional and complementary medicine (T&CM) had between 1999 and 2018, increased from 25 countries to 98 countries. Ayush India's traditional medicine themselves have been witnessing a steady growth in exports. However, even as India's exports grow, the regulatory landscape for each market varies. In addition to adequacy of laws/ regulations on traditional medicines sale and practice, imports into many markets are affected by several factors.

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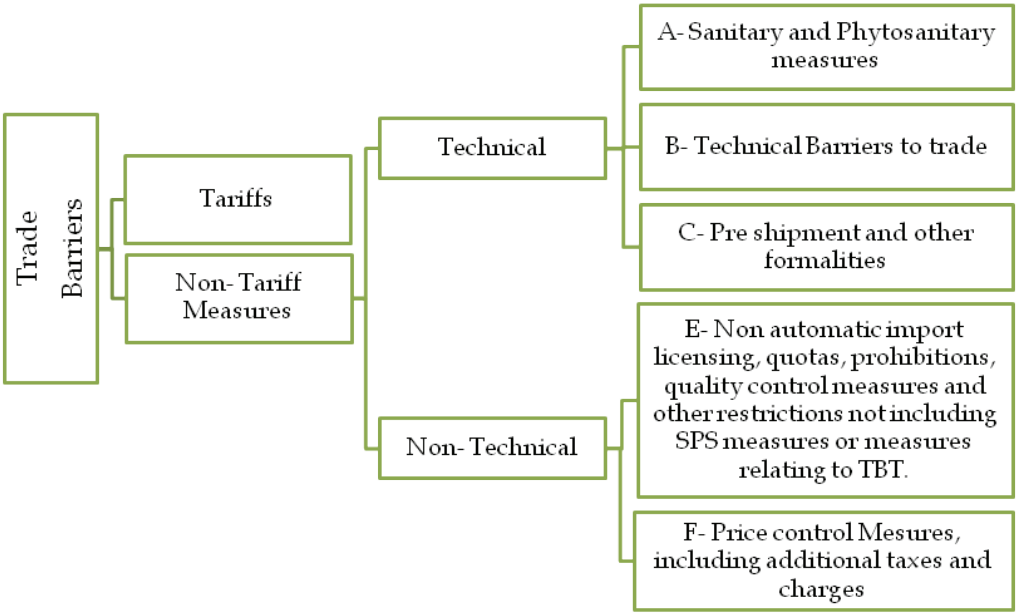
A regulatory import restriction is one such factor. The severity of such restrictions can affect the accessibility of some markets to import Ayush goods. The most obvious of these are tariffs, but others such as market authorisation requirements, quotas, sanitary and phytosanitary standards, packaging and labelling requirements may also exist and impact herbal trade. These are Non-Tariff Measures (NTMs) which have become a determining factor in foreign trade of Ayush. The major goods and allied products of Ayush include medicinal and aromatic plants (MAPs) / herbs, extracts, pharmaceuticals, health/ dietary supplements. This article focuses on broad trends in non-tariff barriers in export to countries/regions that make up the bulk of India's exports across all Ayush product components (50 percent) viz, USA, EU and UAE.

Global Trade: Tariff and Non-Tariff Measures (NTMs) Applicable to Ayush

Trade classification of herbal medicine industry is not universally defined for all segments of the industry in terms of HS or Standard International Trade Classification (SITC) codes and therefore, all segments of the industry cannot be estimated accurately in a transparent manner. For the purpose of analysis, HS chapters 9, 12, 13 have been used to map global trade for MAPs and extracts. China and India are the two major exporters of MAPs across the globe, accounting for around 25.65 and 17.25 percent of total exported value of MAPs in 2021, respectively (Pathak and Agarwal, 2023) While China registered a CAGR of -0.36 percent in the export of MAPs for 2017-21, India recorded a CAGR of 6.14 percent. Over the period 2017-2021 some countries have shown substantial growth in export of MAPs and extracts. These include Luxembourg (CAGR 68 percent), Iceland (61 percent), Norway (40.76 percent) Burkina Faso (36.62) Lebanon (34 percent) and Tanzania (30 percent) (Pathak and Agarwal, 2023). USA, EU Countries (Germany, Italy, Spain, Belgium, France and Netherlands), Switzerland, China and Japan are major importers of MAPs and extracts. USA and EU countries (Germany, Spain, France, Italy and Netherland) have also been exporting MAPs and extracts. USA, Japan, Hong Kong, and Germany are major net importers of MAPs and Extracts.

Both tariff as well as non-tariff measures (NTMs) are applicable to international trade in herbal medicines. Tariffs are customs duties or taxes imposed by governments when goods enter a country. While tariff rates can be measured, a major challenge with NTMs is that they are difficult to measure and quantify (Helble and Shepherd, 2017). Many NTMs are necessary for consumer safety, and environmental, animal, and plant protection. However, these may intentionally or unintentionally act as barriers to trade based on government import restrictions. The severity of such restrictions can affect the accessibility of some markets to imports. NTMs include both technical and non-technical measures. Based on the international classification of sixteen NTMs[1], atleast five apply to Ayush. These include Technical Measures such as (A) Sanitary and Phytosanitary measures (SPS); (B) Technical barriers to trade (TBT); (C) pre- shipment inspection and other formalities, and Non-Technical measures such as (E) Non-automatic import licensing, quotas, prohibitions, quality control measures, and other restrictions not including SPS and TBT; and (F) price control measures. Figure 1 outlines major trade barriers in herbal exports.

Figure 1: Tariff and Non- Tariff Barriers in Herbal Exports



Source: Pathak and Agarwal, 2023.

Tariffs

For tariffs analysis, we source data for Most Favoured Nation (MFN) tariffs, on six-digit sub-categories of HS Chapters as applicable to herbal medicine industry. Table 1 indicates tariff rates for medicinal plants, extracts and medicines for a number of markets. In general, rates on most materials into developed countries negligible. Several countries with protectionist measures for local industries have imposed substantially higher tariffs. These include countries like India, Thailand, Bangladesh, Nepal, Vietnam and Pakistan. On the other hand, tariffs in the EU, USA Australia and Japan are negligible demonstrating limited tariff barriers to Ayush exports in major markets.

Non-Tariff Measures (NTMs)

Despite the overall reduction in tariff levels by several countries, the potential gains may be diminished or eroded by the increased use of non-tariff barriers to trade. Health products are typically subject to numerous NTMs, most prominently product registration and approval, as they have the potential to directly impact health. While NTMs can further important public policy objectives such as ensuring consumer safety and promoting public health these may create challenges in export. Following are the major NTM classifications applicable to Ayush exports.

Sanitary and Phytosanitary (SPS) measures

SPS measures can take many forms. This could include for example requiring products to come from a disease-free area, inspection of products for pests, specific treatment or processing of products, setting of allowable maximum levels of pesticide residues and prohibition of certain additives. Determining whether health and safety import regulations are

Table1: Applied MFN Tariff Rates

Countries	Spices	MAPs	Extracts	Medicants	Medicaments
Argentina	10.00	8.00	5.00	8.92	9.29
Australia	0.00	0.83	0	0	0
Brazil	10.00	8.00	5.00	8.92	9.29
Bangladesh	19.17	29.58	15.00	30.00	26.25
China	12.83	9.96	12.6	0	1.44
European Union	2.24	0.3	0	0	0
India	30.00	18	29.6	10	10
Japan	2.63	1.77	2.12	0	0
Kenya	25.00	9.33	0	0	0
Nepal	9.58	30.00	30.00	35.00	33.75
Pakistan	12.75	9.00	50.00	33.00	42.82
Philippines	9.33	4.14	1	3	4.24
Russian Federation	4.00	5	5	0	3.8
Saudi Arabia	5.00	5	5	0	0
South Africa	5.83	8.08	0	0	0
United Arab Emirates	5.00	5	5	0	0
United States of America	0.71	1.14	0.32	0	0
Viet Nam	15.00	3.92	5	0	2.55

Source: Pathak and Agarwal, 2023.

definitively inappropriate is challenging. Besides the regulations themselves, one of the significant difficulties businesses face is acquiring accurate, timely information about SPS regulations. Not only are requirements often spread across several agencies, regulations can change frequently and without warning in some countries. This slows the certification, scaling, and customs inspection processes. An important SPS measure could be the Negative and Positive Lists of Substances permitted for imports. Many countries publish their own negative and positive lists of substances for use in various classes of goods (cosmetics, dietary supplements, foods, medicines). There is however no comprehensive global listing or database.

Technical Barriers to Trade (TBT)

In principle, governments enact TBT measures to protect consumers and the environment as well as to set conditions for competition. TBTs deal with several aspects of production and supply chains. These could include production equipment and specific processes, labelling and packaging, product performance and quality control, environmental impacts, traceability and product identity, testing and certification. TBTs have several different objectives. They facilitate competition by clearly defining product characteristics and quality assessment. TBTs also advance domestic goals by establishing minimum standards

and safety requirements. However, they can also be used to protect domestic industry and suppress competition. While the WTO encourages members to use existing international standards as far as possible, and includes the concepts of harmonization and equivalence of technical measures, through, for example, mutual recognition of regulations, TBTs can hinder import trade. Labelling and packaging would for example become a challenge when customs have the authority to deny entry not only based on compliance with regulations, but also on whether or not commensurate labels about those checks appear on the packaging. Testing protocols, inaccurate product classification are some other challenges with respect TBT.

Pre-shipment Inspection (PSI) and other Formalities

PSIs are often imposed to streamline import procedures in order to safeguard national financial interests by preventing capital flight, commercial fraud, and customs duty evasion (ITC, 2016). The obligations placed by the WTO on PSI include non-discrimination, transparency, and protection of confidential business information. The application of PSIs by the mandated agencies is viewed by economic operators as causing unnecessary costs and delays as the procedures are often done twice before shipment or at the entry into the destination country. Red tape and corruption are often associated with this practice.

Non-Technical Measures

Non-Technical measures such as non-automatic import licenses are used for controlling imports of restricted goods such as hazardous or dangerous goods, and for administering Tariff rate quotas. Often non-automatic import licensing used for economic purposes have the primary intent of limiting imports to protect domestic producers, thus resulting in potentially substantial barriers to trade for producers in exporting countries.

Major Markets and Key NTBs

Overall, USA (34.95 percent), EU (18.66 percent) and UAE (5.52 percent) are the major markets for all three categories of Ayush exports. They contributed to 59.12 percent of all Ayush exports in 2021.

USA

Exports of Ayush products to US have grown at 8.02 per cent during 2017-21. Extracts constituted the highest proportion of India's export basket in 2021 (57.3 percent) Ayurveda drugs contribute to the highest proportion of Ayush pharmaceuticals exports (96.4 per cent), while Psyllium (74.58 per cent) and turmeric (13 per cent) dominates export of MAPs. Ayush exports to US including herbs, extracts and pharmaceuticals are mostly marketed and distributed as dietary supplements. Given the strong regulatory challenge of herbal medicinal products being registered as drugs, selling such products as food supplement is the legal and most feasible way of marketing them. In the US, the sale of food supplements is governed by the Dietary Supplement Health and Education Act (DSHEA) 1994[2], while labelling requirements are subject to the Nutrition Labelling and Education Act 1990.[3] Section 3 of DHSEA defines supplements quite broadly as "anything that supplements the diet." Supplements include vitamins, minerals, herbs, amino acids, enzymes, organ tissues, metabolites, extracts, or concentrates.

While no pre-market approval requirement for dietary supplement is required several TBTs remain. These include the following:

Premarket Safety Notification for New Dietary Ingredients

Under section 413(a)(2) of the FD&C Act (21 U.S.C. 350b(a)(2)), the manufacturer or distributor of a New Dietary Ingredient (NDI) that has not been present in the food supply as an article used for food, or a dietary supplement that contains the NDI, must submit a premarket safety notification to FDA at least 75 days before introducing the product into interstate commerce. If the required premarket notification is not submitted to FDA, section 413(a) of the FD&C Act (21 U.S.C. 350b(a)) provides that the dietary supplement containing the NDI is deemed to be adulterated under section 402(f) of the FD&C Act (21 U.S.C. 342(f)).

Quality Standards for Herbal Ingredients as per The United States Pharmacopeia – National Formulary (USP-NF)

The quality standards that are applied to natural ingredients and finished products in the US are dependent on the regulatory framework for the product, i.e. whether it is a botanical drug product, herbal dietary supplement product or natural food product. Official monographs published in USP-NF designate that the article has an FDA-approved or USP-accepted use. USP-NF botanical monographs are FDA-enforceable and include descriptions, requirements, tests, analytical procedures, and acceptance criteria[4].

No Health Claims for Labelling of Dietary Supplements

Given that all Ayush drugs are marketed as supplements, health claim restrictions are a challenge inhibiting sales potential of these drugs. Section 6, DSHEA lists the kinds of claims that supplement manufacturers can put on product labels or promotional materials. Acceptable statements are ones which: 1. Claim a "benefit related to a classical nutrient deficiency disease and disclos(e) the prevalence of such disease in the United States"; 2. "Describe (e) the role of a nutrient or dietary ingredient intended to affect the structure or function in humans;" 3. "Characteriz(e) the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function;" or 4. "describe (e) general well-being from consumption of a nutrient or dietary ingredient. While Section 6 does not provide for any kind of FDA review of these statements prior to their use, or any FDA review of the evidence supporting the statements, it does, however, require the manufacturer to include a disclaimer that the statement has not been evaluated by the FDA.[5] Section 6 also provides that manufacturers cannot make statements that suggest the supplement can "diagnose, mitigate, treat, cure or prevent" disease.[6] Claims like these can only legitimately be made for drugs, not dietary supplements.

European Union

Germany, Italy, France and Netherlands are major markets across categories. Total exports of Ayush products to EU have grown at 8.36 per cent during 2017-21 (Pathak and Agarwal, 2023) . MAPs exports to Netherlands have seen a growth of 11.81 per cent during 2017-21. During the same period extracts exports to France has grown by 28 per cent. Poland is emerging as an important Ayush pharmaceuticals market with an impressive at 54.57 per cent (Ibid). For traditional medicines, including Ayush, under the EU Directive 2001/83/EC, amended in 2004, Directive 2004/24/EC (the Herbal Directive), registration can be undertaken under three regulatory pathways, i.e. Traditional use registration[7], Well-established use registration[8] and Stand-alone or mixed application[9] although all three pathways come with their unique set of challenges.

Till date no Ayush pharmaceutical has been registered as a medicine in EU. Herbs, extracts and finished goods are exported as food/dietary supplements, natural ingredients, food additives, spices and herbs (Pathak and Agrawal, 2023). Food supplements can be placed in the market by notifying the competent authority, as per the EU food supplements legislation[10], Directive 2002/46/EC. The claims made for ingredients such as vitamins and minerals are organised under the European Food Safety Authority.[11]

Registration Procedures for Medicines

For registration of a Ayush herbal medicinal product with the simplified registration procedure/traditional use registration, supporting evidence of traditional use in the EU is always an unavoidable challenge, which must be demonstrated with bibliographic or expert evidence For well-established use is applicable to a medicinal product having published scientific literature or studied data with an acceptable level of efficacy and safety, as well as having at least 10 years of medicinal use history in the EU. For this category, it is very likely that most of Ayush pharmaceuticals are not suitable.

Rules Concerning Nutrients as Ingredients of Food Supplements

The EU food supplements legislation[12], i.e. Directive 2002/46/EC only lays down rules applicable to the use of vitamins and minerals in the manufacture of food supplements. This is a challenge for herbal supplements, although rules concerning nutrients or other substances with nutritional or physiological effects used as ingredients of food supplements are defined at the national level.

Marketing Approvals for Novel Food

Natural ingredients not sold in Europe before 1997 are described as Novel Foods and must be authorised/ registered by competent authorities before being allowed in the EU market after a safety evaluation by the European Food Safety Authority (EFSA). The new Regulation (EU) 2015/2283 on Novel Food came into force in January 2018.[13] Natural ingredients are to be registered for use if they are not listed in the EU Novel Food Catalogue.[14] This Catalogue serves as an important reference for medicinal herbs, although most Ayush herbs are neither listed as being sold before 1997 or after including common herbs like *Emblica officinalis* or Amla.

Traceability Requirements as an Important Part of Conformity Assessment

Ethical sourcing is becoming important in the export of natural ingredients to the European market. Subscribing to Good Agricultural and Collection Practices (GACP) guidelines[15] is one such mechanism. Many finished product manufacturers also need to provide information related to ingredient authenticity, raw material origins and social risks in supply chains. Buyers often choose suppliers with transparent supply chains as they need to be able to trace ingredients back to their source. Besides, Regulation (EC) No 178/2002 on the general legal framework and requirements of food law and the procedures applicable in the area of food safety[16] through Article 18 on the obligation of food business operators to put in place a product traceability system. A high proportion of India's MAPs and extracts are sourced from the wild. For exporters of MAPs from India, the unorganised nature of the sector makes compliance with traceability requirements a challenge. The General Food Law 2002 includes tracking requirements to trace ingredients through the value chain. However, as the law does not require a control on quality of food supplements before their marketing, product compliance

lies only with the manufacturer.[17] All food business operators need to implement the Hazard Analysis of Critical Control Points (HACCP)[18] system in their daily operations. Conformity assessments are comparatively stricter for supplements in EU which mandates all food business operators with mandatory HACCP compliance whereas in USA, HACCP would be voluntary for dietary supplements.

Different Regulatory Requirements for Known/Accepted and New Ingredient for Food Supplements

Depending on a product whether a known and accepted or new ingredient for food supplements, regulatory path into the EU market varies. Known and accepted botanicals are those that are allowed as food supplements. These are often specified at a national level on so-called 'positive lists', such as, for example, in Germany which has plant list.[19] These positive lists are only specific about the plants (and the parts of those plants) that are allowed. They do not say which claims manufacturers can make for these ingredients or in what form a plant can be sold on the market.

If the ingredient is new to the food and food supplement market, approval is required as per the Novel Food Law.[20] Ingredients that were not consumed in the European market before 1997 fall under Novel Food law. Such products require documentation and approval before being placed in the market. Data on toxicological, microbiological and allergenic properties required as a part of this process can be complicated and costly to exporters.

Positive/Negative List of Plants Permitted for Import: No EU-wide List

There is no EU-wide positive list of plant parts. Member States have, either jointly or individually, drawn up their own national plant lists stating which plants or plant parts are allowed in food or food supplements. Some European countries, viz, Belgian, French and Italian authorities are signatories to harmonised lists of natural ingredients for food supplements such as BELFRIT and other European countries follow these lists despite not being signatories. Lack of information on list of plants permitted for imports is a challenge for exporters.

UAE

Despite the size and population, UAE has come to claim a high proportion of India's Ayush exports (5.52 per cent in 2021) (Pathak and Agarwal, 2023) . Total exports of Ayush products to UAE have grown at 14.23 per cent during 2017-21. Ayush pharmaceuticals constitute 30 percent of all Ayush exports to UAE and Ayurveda occupies 98 per cent of all Ayush drugs exports. Similar to EU, MAPs constitute the highest proportion of exports) in UAE, although extracts exports have grown at an impressive 28.9 per cent over the period 2017-21.

UAE has adopted traditional medicine as an important part of disease management with a regulatory system in place for registration and import as drugs. As per Article 1 UAE Federal Law No. 4 of 1983, medicines are defined as "any medicine that contains one or more element for treatment or protection of human beings and animals".[21] Traditional, herbal, complementary, and alternative medicine all fall under the purview of the aforementioned definition. Market authorisation for herbal medicines such as Ayurveda is taken through registration of 'Pharmaceutical Product Derived from Natural Sources'.[22] As per Article 65 , Federal Law No.4, 1983 all pharmaceutical products imported into the UAE, need to be mandatorily registered with the Ministry of Health[23].

Import Requirements with 51 per cent UAE Ownership

It remains difficult to sell products in the UAE without a local agent. It is important to conduct thorough due diligence on prospective commercial agents and to carefully draft agreements to ensure compliance with the provisions of the Commercial Agency Law. An important export barrier to UAE under this law is the import licensing requirements where only UAE-registered companies, with least 51 percent UAE ownership, are permitted to obtain licenses for import of Ayush goods[24]. However, the licensing requirement does not apply to goods imported into free zones[25]. There is one free zone for healthcare in UAE, i.e. the Dubai Healthcare City.

Labelling Requirements

Being an Islamic country, requirements include restrictions on pork materials, declaration of alcohol with specifying of reasons. Further, while labelling requirement do not impose mention as traditional medicines, a distinct feature of labelling regulations include requirement of all labels/stickers to be approved by UAE authorities prior to use.

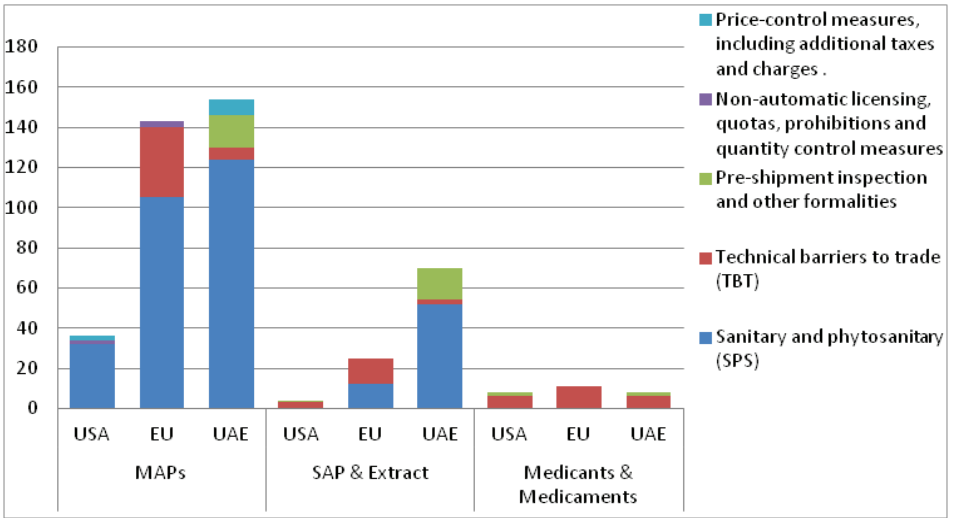
Pre-shipment Inspection and Other Formalities

The importer is to provide a copy of the product's label, packaging, and official certificate from a competent authority in the country of origin to be assessed/ approved in UAE. At the time of registration, a committee at the Ministry of Health undertakes a review of the pharmaceutical product and then determine the "CIF" (cost, insurance, and freight) price for the particular pharmaceutical product.[26]

Comparative Assessment of NTBs in US, EU and UAE

As an export destination, USA has provided the most ease of market access to Ayush. The access to US market is made possible through simple marketing and import regulations. As demonstrated in Table 2 and Figure 2 the tariff and non-tariff barriers are the least in USA. This explains its position as the top export destination for Ayush. Comparatively, EU imposes a larger number of NTMs specially for MAPs and extracts, specially SPS and TBT.

Figure2: NTMs for AYUSH Products in EU, UAE, and USA



Source: UNCTAD, WITS database

Table 6.2: List of NTMs Identified by Countries

MAPs			SAP & Extract			Medicaments		
USA	EU	UAE	USA	EU	UAE	USA	EU	UAE
A12	A12	A13	B33	A13	A13	B33	B31	A14
A14	A13	A14	B42	A15	A14	B42	B33	A15
A85	A14	A15	B83	A21	A19	B83	B81	A64
E32	A15	A19	C9	A22	A21	C9	B82	A81
F61	A19	A21		A31	A22			A83
	A21	A22		A33	A31			A84
	A22	A31		A41	A33			B31
	A31	A33		A42	A49			B42
	A33	A49		A63	A59			B81
	A41	A59		A85	A61			B83
	A42	A61		B31	A64			B84
	A63	A64		B33	A82			B85
	A83	A82		B81	A83			C3
	A84	A83		B82	A84			C4
	A85	A84			A85			C9
	B31	A85			A86			
	B32	A86			B31			
	B33	B31			C1			
	B7	C1			C4			
	B81	C3						
	B82	C4						
	B84	F61						
	E125	F62						
		F65						
		F69						

Source: UNCTAD, WITS database

UAE imposes the highest number of NTBs for all three categories of commodities among all the markets under study. Despite the ease of market authorisation for drug registration of traditional medicines and licence for TM health practitioners, there are high non-tariff barriers especially for medicinal plants and extracts.

SPS are most challenging NTBs specially for MAPs and Extracts. The most common SPS measures for MAPs for example in EU include prohibitions/ restrictions of imports for SPS reasons, such as plants and plant products and their protection in Regulation (EC) No. 1107/2009 of the European Parliament and of the Council (OJ L-309 24/11/2009) (CELEX 32009R1107) or general foodstuffs hygiene rules contained in Regulation (EC) No. 852/2004 of the European Parliament and of the Council. Conformity assessments related to SPS, e.g. Novel Foods (i.e. foods and food ingredients that have not been used for human consumption to a significant degree within the European Union before 15 May 1997) is another barrier. Conformity assessments related to SPS in US include

requirements for quality control which are applicable to dietary supplements (e.g. the US FDA Part 111 CFR Title 21- current Good Manufacturing Practice [GMP] in manufacturing, packaging, labelling or holding operations), or the requirement to establish, keep and make records available. An important Non- Technical Barrier to trade in EU includes the Non-Automatic Licensing as applied to Endangered species to control imports of endangered species listed in Appendices I, II, and III of CITES.

Many of the significant Indian medicinal plants do not find place in the list of importable herbs in many countries. At the same time, exporters often have no information on the list of banned commodities in countries. For example, there is no EU-wide positive list of plant parts. Member states have, either jointly or individually, drawn up their own national plant lists stating which plants or plant parts are allowed in food or food supplements. These lists too are unavailable to exporters. Some European countries, viz. Belgian, French and Italian authorities are signatories to harmonised lists of natural ingredients for food supplements such as BELFRIT; and other European countries follow these lists despite not being signatories. At the country level lack of information on list of plants permitted for imports is a challenge.

Conclusion

Based on data available, UAE imposes high number of NTBs as compared to US and EU. As compared to US and EU, UAE also imposes comparatively higher tariffs for Ayush commodities. In EU and USA, no Ayush pharmaceutical is registered as a drug or herbal medicinal product yet. Ayush drugs, MAPs and extracts are mostly marketed as food/dietary supplements owing to TBTs among other challenges. In EU and UAE MAPs occupy a substantial percentage of exports, while extracts dominate exports to USA. The ratio remains worryingly weighed in favour of export of raw products suggests that factors inhibiting exports of finished products could include issues with market access such as NTBs or non-awareness of target markets for pharmaceuticals. NTBs in the form of SPS remain a challenge for MAPs and extracts exports and Indian exporters would have to intensify efforts at meeting global standards for conformity assessment requirements which in turn would meet the SPS requirements too.

Endnotes

1. International Classification Of Non-Tariff Measures. 2019. *United Nations Conference on Trade and Development (UNCTAD)*. Available at: https://unctad.org/system/files/official-document/ditctab20122_en.pdf
2. The Federal Food, Drug, and Cosmetic Act was amended in 1994 by the Dietary Supplement Health and Education Act (often referred to as DSHEA), which defined "dietary supplement" and set out FDA'S authority regarding such products. Under the Food, Drug, and Cosmetic Act, it is the responsibility of dietary supplement companies to ensure their products meet the safety standards for dietary supplements and are not otherwise in violation of the law.
3. US Food, Drug, and Administration (USFDA). 2014. *Nutrition Labelling and Education Act (NLEA) Requirements-Attachment 1*. Available at: https://www.fda.gov/nutrition-labeling-and-education-act-nlea-requirements-attachment-1
4. Josef Brinckmann. 2008. Support to Sustainable Export Development of Indian Natural Medicinal Products: A Needs Assessment Study (India) , International Trade Center, Geneva.
5. For more detail on this subject, see U.S. Food And Drug Administration Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labelling and Dietary Supplements, claims that can be made for conventional foods and dietary supplements.

[6] While manufacturers are not free to make such claims, third parties are.

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[8] Under Article 10a of Directive 2001/83/ European Commission

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Directions and Progress India's Engagement with WHO on Traditional Medicine

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Abstract: Since its inception in 2014, the Ministry of Ayush, Government of India, has actively engaged with the World Health Organization (WHO) and successfully ensured equitable representation of Ayush systems in the policies, documents, and strategies of the UN body. Collaborations between the Ministry and the WHO have resulted in publications, digital applications, implementation of research studies, the development of data platforms for traditional medicine (TM), and the establishment of a global hub for TM research. This paper explores the initiatives and prospects of this collaboration for global growth of TM.

Introduction

WHO has long recognised Traditional and Complementary Medicine (T&CM) as an excellent health resource be integrated to primary health care to strengthen it and improve health outcomes. T&CM offers an acceptable, accessible, and affordable form of essential care that is available to people across cultures and across economies (including indigenous and remote populations) which integrates the social, environmental, and spiritual elements. This makes it a very valuable health intervention that can support the objective to "leave no one behind", the central, transformative promise of the 2030 Agenda for Sustainable Development and its Sustainable Development Goals (SDGs).[1] Traditional and allopathic systems functionally complementing the needs of a health system would enrich the holistic dimensions of health services. In this respect, the safety, quality, and efficacy of the T&CM interventions

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and the outcome efficiency of integration should form the basis for policy decisions and actions taken by member states of WHO. Lack of systematic data and evidence, insufficient financial support for research, and not enough mechanisms to monitor the safety of traditional medicine practice are the main barriers faced by member states attempting to regulate T&CM. (WHO, 2013) (WHO, 2019c).

Based on its TM strategy, in the past two decades, WHO has undertaken a series of activities to support Member States in regulating, including, and integrating TM systems. These include WHO global goods such as benchmark documents to support member states' regulations in training and practice of TM systems and several publications on herbal products covering a range of related topics from good agricultural practices to communication guidelines on traditional medicine.

India is endowed with both codified and non-codified oral traditions of medicine systems. Both traditions are widely practiced for healthcare delivery across the country. Barriers that impede accessibility to these systems, defined under the formal terminology of Ayush (Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa Rigpa, and Homoeopathy), for citizens of the world residing in several regulatory jurisdictions do exist (Rudra *et al.*, 2017). Realising that concerted efforts are required to effectuate the complementarities of Ayush systems within the frameworks of different health care systems, the Ministry of Ayush, Government of India, has taken several initiatives to overcome them, including engaging with the WHO by supporting the implementation of its Traditional Medicine Strategy with resources and human capital (WHO 2002)(WHO, 2013). It is interesting to note that the contributions of India have been focused in areas identified by member states as the weakest links, such as research, regulations, and integration. And in such engagements, India has directed its attention and actions towards strengthening the safety, quality, efficacy, and regulations of TM products, practices and practitioners. This paper summarises the directions and progress of India's engagement with WHO, since 2014.

Global Benchmarks of Quality to Regulate Practice and Practitioners

Traditional medicine has a long history. WHO defines it as 'the sum 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' (World Health Organization, 2013). The patterns of human migration and globalisation and the subsequent homogenisation of human culture and behaviour have increased the demand for and use of established TM systems across the globe. As documented in the WHO Global Report, the number of countries using TM and *Ayurveda* in 2012 and 2018 has grown significantly (World Health Organization, 2019c).

Of the 179 WHO member states who participated in the global survey, 170, or 88 per cent of all member states acknowledged the use of T&CM. 98 countries, or more than 50 per cent of the 194 member states, had a national policy on T&CM. 109 member states reported the presence of a legal or regulatory framework for T&CM. 107 countries (55 per cent) of all member states reported the presence of a national office for T&CM. 124 member states (64 per cent) responded that they had laws or regulations on herbal medicines. 78 member states reported regulation of T&CM providers (WHO, 2019c).

Among the 179 member states surveyed, 93 and 82 of them acknowledge the use of Ayurveda and Unani medicine by their populations, respectively. Of these 32 and 14 member states reports that trained, and certified Ayurveda and Unani providers practice in their jurisdiction. Sixteen member states regulate Ayurveda service providers while eight regulate the service providers of Unani medicine. Further, five member states provides health insurance coverage for Ayurveda, while provide it for Unani (WHO, 2019c). Yoga is a globally accepted health activity, and 175 member states of the UN endorsed it while accepting India's proposal (Resolution 69/131) to declare June 21 as International Yoga Day in 2014[2]. Given that TM practices have developed within different cultures in different regions and there has been no parallel development of standards and methods — either national or international — for evaluating them (WHO, 2002), the rise in demand and use by large sections of their population has heightened the need for member states to regulate them and assure the safety and quality of their products and services. It was acknowledged that a global consensus on what can be defined as reasonable practice in the respective TM system, which is cognisant of patient safety and provides protection to consumers, can offer a reasonable benchmark for comparison and evaluation of such practices in the member states (WHO, 2010).

Identifying this major demand from the member states for standards to benchmark TM services and products, WHO has developed benchmark documents for training and practice of individual TM systems. The benchmark documents describe models of training and practice for trainees and practitioners with different backgrounds and list contraindications identified by the community of practitioners to promote safe practice and minimise the risk of accidents. The most elaborate material to establish benchmarks comes from the countries where the various forms of traditional medicine under consideration originated. These countries have established formal education or national requirements for licensure or qualified practice. Any relevant benchmarks must refer to these national standards and requirements. (WHO, 2010).

The benchmark documents are intended to support countries in establishing systems for the qualification, accreditation, or licensing of practitioners of traditional medicine; assist practitioners in upgrading their knowledge and skills in collaboration with providers of conventional care; allow better communication between providers of conventional and traditional care as well as other health professionals, medical students and relevant researchers through appropriate training programmes; and support the integration of traditional medicine into the national health system. (WHO, 2010)

India has supported WHO with resources to update the benchmarks for the training of *Ayurveda*, and *Unani* medicine and develop the benchmark for the training of *Yoga*. India has also supported the WHO in developing new the benchmark documents for the practice of *Ayurveda* and *Unani* medicine. Of these WHO has published the benchmark document for the training of *Ayurveda*, the benchmark document for the training of Unani medicine, the Benchmark document for the practice of *Unani* medicine and the benchmark document for the practice of Ayurveda, in 2022. (WHO, 2022a) (WHO, 2022b) The number of countries, and regions involved in developing the consensus for each document is an issue that has required concerted coordination efforts. At present, the benchmark document for training in Yoga is in its last

phase of development. These benchmarks are global goods that will serve as tools for establishing international standards in the training and practice of Ayurveda, Unani, and Yoga.

Global Consensus on Definitions of TM Terminologies

A major impediment facing the integration of TM systems in modern health systems are their world views and theoretical constructs, which are different from the allopathic perspectives around which the current health care models and health systems are structured. These differences emanate from their distinct epistemologies, dependent on the scientific world view of the civilisation and culture through which each of them evolved, and are different from the epistemological constructs that serve as the foundation for allopathic medicine. Nonetheless, they also converge in their views in many domains and areas with the allopathic system, as each of them (allopathy and TM systems) is complete by itself in defining and explaining health holistically. Subsequent to this co-existing inherent convergence and foundational divergence, concepts based on which the perspectives of the TM systems understand health and its innumerable domains often converge and more often diverge from the views of allopathic medicine.

Unlike allopathic medicine, which enjoys the patronage of the colonising world and uses the established global order to regularly harmonise its knowledge and practices, TM systems, whose practitioners and knowledge transmitters got separated historically, often find themselves in a disharmonised soup of shared understanding in the usage of terms, understanding of definitions, and application of concepts (Nandy and Visvanathan, 1990).

Thus, to advocate the integration of a specific TM system and to effectuate the same, international organisations like the WHO and member states require globally accepted standard terminologies that define the terms, concepts and knowledge of that TM system, factually, scientifically and consensually. Despite the fact that standard terminologies of TM are an essential tool for working on other standards, guidelines, classifications, and regulations, as well as integrating TM into health systems, not much work had been done on this at the international level (WHO, 2023a).

Supported with resources from India, WHO has published the standard terminologies of three major TM systems – Ayurveda, Unani medicine and Siddha medicine, in 2022. Internationally accepted common terms in Ayurveda, Unani medicine and Siddha medicine will enable to compare, assess, and evaluate the corresponding data internationally. The document will facilitate medicine professionals, policymakers, health workers, service providers, researchers, and the general public to use the same concepts, understandings, and definitions in communications, healthcare services, and medical records. It will support international cooperation in research, information exchange, standards, and classifications in these TM systems. (WHO, 2023a) (WHO, 2023b) (WHO, 2023c)

Global Digital Infrastructure for Collection, Coding, and Analysis of Clinical Data within the ICD Framework

The International Conference on Standardisation of Diagnosis and Terminologies in Ayurveda, Unani, and Siddha Systems of Medicine was organised

jointly by the Ministry of Ayush, Govt. of India and Data, Analytics and Delivery for Impact division of WHO in February 2020.[3] The representatives of the 16 countries (Sri Lanka, Mauritius, Serbia, Curacao, Cuba, Myanmar, Equatorial Guinea, Qatar, Ghana, Bhutan, Uzbekistan, India, Switzerland, Iran, Jamaica, and Japan) who participated in the meeting in principal agreed to the perspective that 'Traditional Medicine does not count, unless we count Traditional Medicine' and in response adopted the New Delhi Declaration on Collection and Classification of Traditional Medicine (TM) Diagnostic Data, which sought the opportunity for including traditional systems of medicine like Ayurveda, Unani, and Siddha in the International Classification of Diseases (ICD) of WHO which is the standard diagnostic tool for health management across the world. Inclusion of Ayurveda, Siddha, and Unani in the TM Chapter of ICD 11 will enable the counting of traditional medicine health services and encounters and measure their form, frequency, effectiveness, safety, quality, outcomes, and cost internationally.[4] Other benefits of ICD would include open TM data for comparability of practice, research and reporting of morbidity at national and international level, improved the quality of communication between patients, service providers and regulators across the continuum of care and improved coverage and scope of TM in the medical insurance and reimbursement systems thereby supporting the WHO objectives related to universal health coverage. Joint use of the ICD-11 TM Chapter and other ICD-11 Chapters can establish strong links for TM with global norms and standards of conventional medicine. It can also enhance adverse-event reporting related to TM. All these will lead to optimal allocation of resources for TM in clinical practices, education, and research and overall global development of TM.[5]

Being of digital format, inclusion of TM chapter in ICD-11 will allow for digitisation of TM diagnoses data and also facilitate integration into Electronic Health Record (EHR) systems. ICD-11's digital form will inherently enable TM classification data to be semantically interoperable across connected systems (across programs, data sources, levels of health system, geographies, and technologies).[6]

India's leadership in initiating the project to include Ayurveda, Siddha and Unani in the ICD-11 classification and its support to WHO with resources to execute the same will bear fruit in early 2024, when WHO will complete the elaborate work it has been doing on this project since 2020 and module 2 of the ICD-TM chapter will be available for all member states of WHO to utilize.

A Tool for the Global Citizens to Safely Learn and Practice Yoga

During the COVID pandemic, with people being mostly confined to their homes, fear of a rise in NCDs instigated by a lack of physical activity and of deteriorating mental health triggered by isolation and a lack of social interactions. This prompted the Ministry of Ayush to work with WHO's 'Be Healthy Be Mobile' initiative and develop a digital mobile application for assisting people to learn safe Yoga and practice it on their own. This app, the WHO mYoga app, was made available to the global public on the International Yoga Day of 2021 by the Indian Prime Minister Shri Narendra Modi himself. Within a short period of time, the multi-lingual WHOmYoga app has become one of the most successful and widely used apps from WHO.[7]

Establishing the Global Hub for Research in TM

Despite being the first port of call for millions of people in every region of the world, the potential use of TM in Primary Healthcare and Universal Healthcare by member states is limited by a lack of evidence, quality data, and appropriately inclusive regulations.[8,9,10] (World Health Organization, 2013), (World Health Organization, 2018), World Health Organization and Human Reproduction Programme, 2019), (World Health Organization and United Nations Children's Fund (UNICEF), 2018). It is also a time when a new dimension in the perspective of global health is emerging that realises the importance of a holistic, integrative approach to the health and wellbeing of people and the planet.[11] Additionally, it is possible that the potential growth of TM in terms of commerce and industry can inherently spell doom for the environment and be detrimental to the interests of deprived communities, who have been the trans-generational knowledge resource for the TM systems. It is also the time when the evolution of new technology and skills and the advent of new vistas of knowledge are changing the perspectives about TM - from being a gathering of human experiences tied together by incoherent logical assumptions to a stream of scientific inquiry that can be studied, understood, and utilized.

It is during this time of change that India has taken global leadership to support WHO in establishing the WHO Global Centre for Traditional Medicine (GCTM).[12] The centre was launched jointly by the Prime Minister of India and the Director General of the WHO on April 19, 2022. India will provide the WHO with resources worth USD 250 million to establish the GCTM at Jamnagar, Gujarat, India, and offer another USD 10 million a year for the next decade to run it and achieve its objectives: to support appropriate use of TM by member states; guide nations to manage and sustainably conserve the environment; advise member states to put in place equitable sharing of benefits with relevant indigenous communities; and enact fair trading practices.[13]

Aiming to achieve its objectives, GCTM will provide leadership, ensure political patronage, and ensure societal buy-in. It will support member states with evidence backed reports and advisories developed based on the best possible science and appropriately integrate technology to improve accessibility to safe and effective TM practice, practitioners, and products. It will create period criteria, assess the biodiversity, and ecological impact of TM and devise context-specific methods for inclusive, sustainable use of TM and support the evolution of fair-trade practices that are globally relevant, working with global bodies such as UNICEF, the WTO, and WIPO. GCTM will contribute to the development of a universal concept of wellbeing that is globally applicable to individuals and societies, but is inclusive and adaptable to the cultural and geographical diversities of human societies. Ensuring and establishing networks of global collaborations that aid the progress of its objectives would be a key functional character of GCTM.

Future Steps

In the future, India should work closely with WHO and other member statess to evolve a globally uniform and acceptable regulatory norm for TM products. Providing leadership and guidance on WHO platforms like the International Regulatory Cooperation for Herbal Medicines (IRCH) is crucial to achieving this goal.[14] Considering

India's vast experience in the field and the diversity of TM systems it has been dealing with, working closely with WHO and playing a leadership role in the development of the International Herbal Pharmacopoeia is an important step that India should pursue India should also take leadership and support WHO in developing a compendium of essential medicines (essential medicine lists) for individual TM systems. India should also consider mooting an international forum in the area of regulation of trade and commerce of TM products and services, under a collaborative body comprising WHO, WTO, and WIPO. Other than developing norms and standards (benchmark) documents for other TM systems (such as the Siddha, Sowa Rigpa and Homeopathy) India should support WHO in developing TM-specific health information systems for its member states. India should also consider to working with WHO and supporting the member states to build their human resources in TM-specific nursing care, and to introduce effective TM interventions in community based palliative care, care of the ageing population, mental health, and maternal and child health.

It is natural and highly probable that India's role in the global growth of TM will be profound in the years to come. Strategically working with global organisations like WHO with long-term vision and clarity of objectives can be of crucial importance in achieving this.

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Herbal Medicine Safety Surveillance in Pharmacovigilance Networks

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Abstract: Over the past few decades, the use of herbal medicines and supplements has grown significantly. The efficacy of a significant number of herbal products has been established, and therapies incorporating these agents have demonstrated promising potential; however, many of these products are still untested or not at all monitored. Most of the herbal medicines are easily accessible in market as Over the Counter (OTC). This has led to widespread self-medication on a global scale, which sometimes causes unfavourable outcomes due to many factors involved. The way that herbal medications are identified, regarded, sourced, and used raises a number of issues. This could be as a result of variations in the use of non-traditional medications (like herbal remedies), which may present unique toxicological issues when used alone or in conjunction with other medications. Since the safety of treatments shall be a top priority, it is also crucial that the appropriate regulatory bodies carry-out the required safeguards utilizing pharmacovigilance as a tool. This paper discusses historical developments, national and international regulatory provisions, and challenges along with recommendations in pharmacovigilance of herbal medicines.

Introduction

The World Health Organization (WHO) defines traditional medicine as a variety of health practices, techniques, knowledge, and beliefs that encompass manual, spiritual, and exercise therapies that can be used to preserve health as well as to treat, identify, or cure diseases (World Health Organization, 2004). Globally, the use of natural remedies is expanding rapidly with the use

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of traditional medications mostly based of herbs for wellness, prophylaxis of illnesses, and prevention in a variety of national health care settings. Many individuals supplement or even substitute allopathic prescribed medications with herbs or other herbal products considering less side effects and good efficacy levels (Singh *et al.*, 2022[1]; Singh *et al.*, 2020[2]; Nortier and Vanherweghem, 2007[3]; Barnes *et al.*, 2004[4]). Although herbal and traditional treatment has historically been seen as safer than allopathic medication, it may not always be possible to completely avoid adverse effects or risks which can arise due to many associated factors involved. Many studies report the Adverse Drug Reactions (ADR) pertaining to herbs and traditional medications calling for a special focus on these. Any ADR that is thought to be caused by a drug/herb that occurs at typical or sub-therapeutically doses used in humans, calls for a dose reduction, or warns against using the same drug again in the future (Shaw, 2010).[5]

Also, sensationalised media accounts of adverse events frequently cast a negative light on the use of herbal medications, which could be related to various problems ((Singh and Bajwa, 2023). Both national health officials and the general public now have serious concerns about the safety of herbal medicines. The ADRs must be documented in order to create safer herbal drugs because they can be caused by side effects, reactions from overdosing, extended use, tolerance, hypersensitivity from allergies, and idiosyncratic reactions. (Shaw *et al.*, 2012). Under the pharmacovigilance protocol, these negative drug reactions are recorded. Currently, incorrect use or subpar product quality can be blamed for the majority of documented negative effects linked to the use of herbal products and herbal medications. Such instances may have been brought on by poor quality assurance processes, ineffective regulatory controls, and totally unregulated distribution methods. (including mail order and online sales). In this article, attempt has been made to provide holistic insights into the various dimensions and discussions pertaining to safety of herbal medicine keeping PV as the central issue.

What is Pharmacovigilance?

The WHO defines Pharmacovigilance as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse drug reactions or any other possible drug-related problems for more patient safety." This definition extends beyond chemical drugs to include herbal, traditional, and complementary medicines, biologicals, vaccines, blood products, and medical equipment (Gossell-Williams *et al.*, 2006).[6] ADR is an unintended reaction to a drug that happens at doses typically used in people for the prevention, diagnosis, or treatment of illness or for the alteration of physiological function. Likewise, unexpected adverse reactions are those whose type or severity do not correspond to domestic labelling, market authorization, or expectations based on the drug's properties. While there are several common operating ADR reporting procedures in Pharmacovigilance systems, most notably spontaneous reporting programmes are used to watch the safety of herbal medicines. Current alternatives to ADR reporting in herbal pharmacovigilance include prescription-event tracking and ADR reporting forms (Shaw *et al.*, 2012). The information required to produce a ADR report is represented in Figure 1.

In addition, PV also examines subpar medications, medication errors, a lack of efficacy data, and the use of medications for conditions for which they have not been approved and for which there is insufficient scientific support, case

Figure 1: Information required for ADR report

Source: Biswas, P. (2013). Pharmacovigilance in Asia. *Journal of Pharmacology and Pharmacotherapeutics, 4(1_ suppl), S7-S19.*

studies of acute and chronic poisoning, estimation of drug-related mortality, and adverse interactions between medications and substances, and foods. With regard to the use of medicines and all other medical and paramedical interventions, PV specifically aims to improve patient care and safety; improve public health and safety; contribute to the assessment of benefit, harm, effectiveness, and risk of medicines; encourage safe, rational, and more effective use of medicines; promote understanding, education, and clinical training in pharmacovigilance; and effectively communicate pharmacovigilance to the general public.

History and Development of Pharmacovigilance

Post-marketing safety reporting guidelines for herbal medicines were released at the very beginning of the transitional era (1999–2001) from the 20 to the 21 century (World Health Organization, 2007). At the annual meetings in 2000 and 2001, the national pharmacovigilance centres of the international drug monitoring programme sought urgent assistance from WHO in setting up national systems for the safety vigilance of traditional/herbal medicines. At the 2001 WHO meeting, quality control of finished herbal products was also addressed (World Health Organization, 2005). The WHO Joint Committee Meeting on Safety Monitoring and Pharmacovigilance of Herbal Medicines, which took place in Amsterdam, in October 2002, was financially sponsored by the Netherlands Ministry of Health, Welfare, and Sports. Following this, in May 2003, the 56th World Health Assembly adopted resolution WHA56.31 on traditional medicine, urging Member States to create new national drug safety monitoring systems or to enhance those that already exist to keep a watch on herbal remedies and other traditional practises.[7]

A detailed chronological evolution of pharmacovigilance history is mentioned in Table 1.

How Does Pharmacovigilance Operate in Herbal Medicines?

It must be emphasised that the safety monitoring of herbal medicines and other medicines is identical in concept. National pharmacovigilance centres designated by the competent health authorities are in charge of gathering, processing, and analysing case reports of suspected adverse reactions provided by healthcare workers under the WHO International Drug Monitoring Programme. The Program presently consists of a network of more than 70 independent national

Table1: Chronological Evolution of Pharmacovigilance

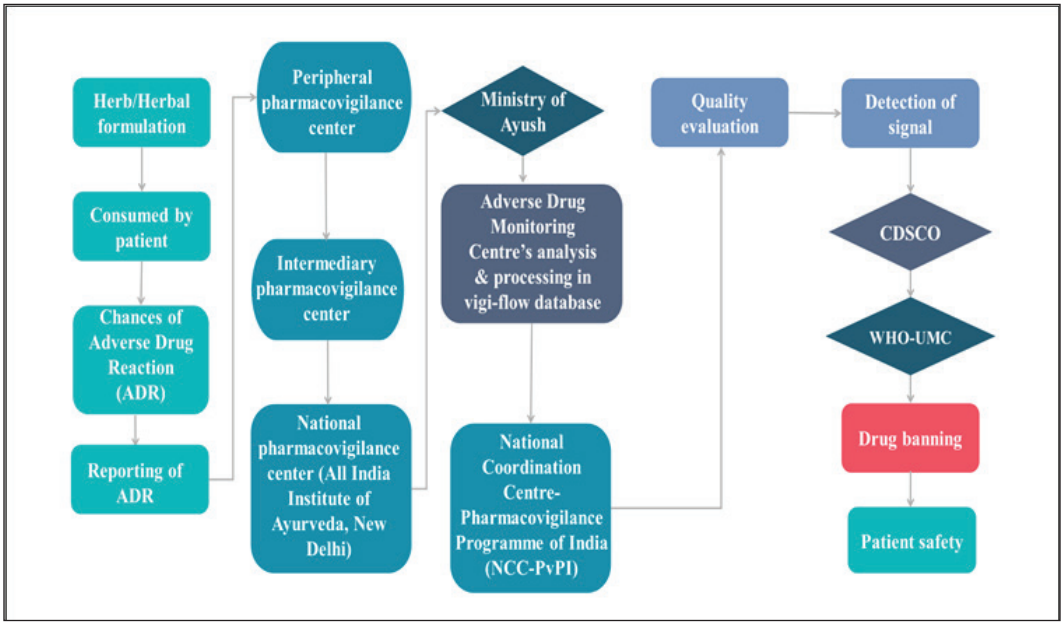
S. No	Year	Advents prompting PV globally	Reference
1	1847	Chloroform- James young Simpson utilized it for the first time as an anesthesia.	(Fornasier *et al.*, 2018)
2	1848	Hannah Greener's death due to chloroform.	(Fornasier *et al.*, 2018)
3	1893	Journal "Lancet" setup a commission for death due to anesthesia.	(Fornasier *et al.*, 2018)
4	1897	Felix Hoffman re-synthesized the compound Diacetylmorphine but went unnoticed.	(Cooper and Deakin, 2016)
5	1906	US FDA was established	(Shorvon, 2009)
6	1910	5 lakhs people were affected due to Diacetylmorphine (Heroine).	(Fornasier *et al.*, 2018)
7	1913	Stopped production of Heroine	(Fornasier *et al.*, 2018)
8	1937	Using Sulphanilamide + Diethyleneglycol patient were suffering from kidney damaging problem. Batch recalled after 105 deaths	(Fornasier *et al.*, 2018)
9	1938	Establishment of the Federal Food, Drug, and Cosmetic Act.	(Fornasier et al., 2018)
10	1954	102 deaths occur used of stallion (diiodo diethyl) with vitamin F for treatment of *Staphylococcal* infection.	(Shorvon, 2009)
11	1959	Reforms in Visa Legislation	(Bonah, 2013)
12	1961	Thalidomide disaster resulting into deformed limbs in infants	(Fornasier *et al.*, 2018)
13	1962	Kefauver Harris Amendment Act passed.	(Greene and Podolsky, 2012)
14	1963	Resolution WHA 16.36	(Pal *et al.*, 2013)
15	1964	UK started the "Yellow card system"	(Evans, 2015)
16	1965	European union issue ec directive 65/65	(Straub, 2002)

Table 1 continued...

Table 1 continued...

17	1968	WHO pilot program started to pool ADR	(World Health Organization, 2004)
18	1970	Work between WHO & UMC for the first programme in PV	(Mandal and Mandal, 2017)
19	1986	Proposed ADR monitoring system for India	(Kalaiselvan *et al.*, 2019)
20	1997	India joined the WHO-ADR programme for monitoring.	(Rehan *et al.*, 2002)
21	1999-2001	Post Marketing Safety Reporting guideline are Issued	(World Health Organization, 2007)
22	2000	In the US, 17 billion dollars was used for herbal products & medicines.	(Hepner *et al.*, 2002)
23	2000-2001	Development of safety vigilance of traditional and herbal medicine by WHO International Drug monitoring programme.	(World Health Organization, 2005)
24	2001	Meeting of WHO (informal) on Quality control of finished herbal products.	(World Health Organization, 2007)
25	2002	Meeting of Working group of WHO on safety vigilance and PV of herbal medications in Netherlands	(World Health Organization, 2007)
26	2003	Traditional medicine resolution WHA 56.31 was approved in the 56th World Health Assembly	(World Health Organization, 2004)
	2003	In India, the Central Drug Standards Control Organization (CDSCO) has launched the National Pharmacovigilance Program.	(Kalaiselvan *et al.*, 2016)
28	2004	Canada hosts a WHO consultation on herbal medicine safety monitoring	(World Health Organization, 2015)
29	2004	Traditional medicines are to be included in the pharmacovigilance system.	(Gromek *et al.*, 2015)
30	2007	FDA Amendment Act	(Momper *et al.*, 2013)
31	2010	Pharmacovigilance programme of India (PvPI)	(Kalaiselvan *et al.*, 2016)
32	2010	UMC collects ADR Reports from more than 100 countries around the world, and in its database of over 4 million Reports, which have 21,000 herbal items are listed	(Gromek *et al.*, 2015)

Figure 2: ADR Reporting System for Herbal Medicines in India[9]



Source: https://itra.ac.in/pharmacovigilance/

pharmacovigilance centres, and WHO and UMC coordinate and support their activities. All case reports collected by the national pharmacovigilance centres are sent to the global WHO database, which is managed by Uppsala Monitoring Centre (UMC) (World Health Orgnization, 2004).

In India, the National Pharmacovigilance Program since its inception in 2003, has been under the governance of the Central Drugs Standard Control Organization (CDSCO) . As the use of Ayurveda, Siddha, Unani and Homeopathy (ASU&H) products and drugs increased globally, so did the relevance of including traditional medicines in pharmacovigilance systems. The majority of adverse events involving the use of herbal or conventional products that have been documented have now been connected to either improper use or subpar product quality (Shaw *et al.*, 2012). In order to develop a system-wise database of adverse drug reactions and make evidence-based recommendations for the clinical safety of ASU and H drugs, the Ministry of AYUSH, New Delhi, has sponsored a national programme under a central sector plan for ASU and H drugs.[8] The project will be managed by *National Pharmacovigilance Coordination Centre* (NPvCC) under the direction of the Ministry of AYUSH, New Delhi. The NPvCC will monitor the programme and also suggest regulatory actions based on the generated ADR data and inappropriate ads. The common reporting system for herbal medicines in India is represented in figure 2.

Current trends of Pharmacovigilance in different countries

The safe use of herbal medications has recently become more widely recognized among numerous stakeholders. Over the past couple of decades, developing countries have been increasingly aware of the necessity to improve the safety

nets around herbal medicines in order to protect patients. More than 140 nations have participated in the WHO Programme for International Drug Monitoring in 2014. The programmes' degrees of success can be seen by taking a larger view from the perspective of developing nations (World Health Organization, 2015). PVP programmes in select countries are presented below.

European Countries

For the European Medicines Agency (EMA), the Committee on Herbal Medicinal Products (HMPC) provides scientific assessments of herbal drugs and preparations as well as details on suggested applications and safe circumstances. As per the directive 2010/84/EU, the EMA also runs the services and procedures that enable pharmacovigilance in the European Union (EU) and coordinates the pharmacovigilance system for the EU[10]. Since herbal medicinal products are considered to be medicinal formulations, they are covered by Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001 on the Community law relating to medicinal products for human use, formerly 65/65/ECC, as revised by Directive 2004/27/EC. This stipulates that in order to market them, an ad hoc authorisation must be given based on the findings of tests and experiments on quality, safety, and efficacy. Similarly, regulation (EU) No 1235/2010 and Commission Implementing Regulation No 520/2012 is mandatory for all EU states on pharmacovigilance including HMPC. In Germany, known and accepted botanicals are often specified on so-called 'positive lists', while Belgium, France and Italy have developed a coordinated list (BELFRIT) for botanicals.[11] Some countries that do not have a national list follow these lists as well (Cousyn *et al.*, 2013). These positive lists are only specific about the plants (and the parts of those plants) that are allowed.

Plants and their formulations are also offered in the food industry as functional foods, innovative foods, dietary foods for specific medical conditions, and foods. Due to industry marketing tactics, these products are perceived by consumers as being more and more drug-like (Regulation 1924/2006 2006). Since 1979, the European Union has operated the Rapid Alert System for Food and Feed (RASFF) to help assure food safety. When dangers to human and animal health are discovered in the food and feed chain, RASFF is a technology that enables the prompt and efficient transmission of information between EU member states and the European commission.

Comparing the regulatory frameworks for foods and medicinal products however, reveals that only pre-market control for medicinal products requires quality proof. In post-market control in the European Union, pharmacovigilance is more important for herbal medicinal products than food products. However, European guidelines and regulations provide significant tools for consumer protection with regard to plants in food. The first stipulates standards for safety evaluations, while the second envisions a list of constituents that are prohibited, limited, or subject to community review (EFSA, 2009; Regulation 1925/2006 2006). Few European nations have an autonomous vigilance system specifically designed for food stuffs. Recently, France started exchanges with 13 EU MS in 2014 to tie up the existing programmes and increase awareness among other nations on "Nutrivigilance".[12]

Belgium

The Kingdom of Belgium adopted its national Traditional Medicine/Complementary and Alternative Medicine

(TM/CAM policy), legislation, and regulations in 1999. Earlier was no national programme in place, and there was no national office. There are now regulations governing herbal treatments that are somewhat similar to those governing traditional drugs. Herbal medicines fall under the same regulations as nutritional supplements, over-the-counter drugs, and prescription drugs. Legal claims about medical benefits and nutrient content are permissible. One of the regulatory requirements for producing herbal medicines includes adhering to the same GMP standards as for contemporary pharmaceuticals as well as the information in pharmacopoeias and monographs (World Health Organization, 2005). The pharmacovigilance centre and routine pharmacy inspections ensure that the same safety standards as for conventional medications are met. Neither a registration system nor a national essential drug list exists for herbal medications. Belgian pharmacists are free to sell herbal medications alongside conventional and OTC medications and herbal medicine side effect monitoring is considered essential in post-marketing surveillance system in the country.

France

In France, which began PV procedure in 1985, herbal medicines are governed by the same laws and regulations that apply to conventional drugs. Herbal drug manufacturing is subject to the same GMP regulations as the production of conventional medications. Inspections are used to make sure that these standards are being followed. In addition to the particular condition of traditional usage without proven negative effects, the safety criteria are the same as for conventional medications. In France, there are 787 herbal medicines registered, but none of them are on the list of absolutely necessary drugs (World Health Organization, 2005).

Romania

The law governing the regulation of conventional pharmaceuticals was amended to include the control of herbal medicines in 2002. The same rules that apply to prescription, over-the-counter, and dietary supplements also apply to herbal medicines. The law allows for medical and health claims to be made concerning herbal remedies. Herbal medicines must adhere to the same GMP standards as conventional pharmaceuticals, and pharmaceutical inspections of the manufacturing and distribution processes confirm that the rules are upheld (World Health Organization, 2005).

Spain

Herbal products fall under the same regulations as nutritional supplements, prescription pharmaceuticals, and over-the-counter medicines. Medical and health claims are permitted by law, but only for goods that are recognized as medicines. One of the regulatory requirements for the production of herbal medicines is the use of both standard GMP guidelines and special GMP recommendations. There are 2277 herbal medicines that have been registered in Spain[13]; however none of them are listed as necessary medications. Herbal medicines are subject to the same post-marketing surveillance system as conventional pharmaceuticals, which were established in 1985 and include monitoring for adverse effects (World Health Organization, 2005).

Asian Countries

Nepal

The Department of Drug Administration (DDA) has been designated as the nation's pharmacovigilance centre for reporting

adverse drug reactions by the Uppsala Monitoring Centre (UMC), located in Sweden. The DDA brought up the issue of significant heavy metal content in herbal products supplied by street vendors in its bulletin "Drug Bulletin of Nepal," however regulation and monitoring are still in their infancy (Shrestha et al., 2020). To control herbal medicines in Nepal, the Ayurveda Health Policy, 1996, created the Department of Ayurveda (DoAy)[14]. There are more than 216 zonal Ayurvedic clinics spread all over the nation and mostly all the hospitals are emphasizing on creating holistic PV mechanism for patient safety (Shrestha *et al.*, 2020).

China

The People's Republic of China published its national TM/CAM policy in 1949, and rules followed in 1963. The ADR Monitoring Centre, which is in charge of regulating both kinds of drugs, was founded by the Chinese Ministry of Health (MOH) in 1989[15]. In 1998, the monitoring Centre became a member of the WHO International Drug Monitoring Program. China's network architecture, administration, and regulation were improved in 1999 by the National ADR Monitoring Centre. The ADR monitoring system is crucial for locating, documenting, and addressing drug safety incidents. More than 9000 herbal medications have been registered, and 1242 of them were on the national essential drug list by the end of 2002 (World Health Organization, 2005).

African Country

Ghana

The Republic of Ghana's national TM/CAM strategy was released in 2002.[16] Through the Food and Drugs Law, which also sets restrictions for conventional medications, Ghana started to regulate herbs in 1992.[17] Herbal medications fall under a different regulatory category and are controlled as OTC medications. Legitimate medical, health, and overall nutritional claims are allowed. The regulatory standards for the production of herbal medicines require the same GMP regulations that apply to traditional pharmaceuticals as well as additional GMP regulations. Herbal drug adverse effect monitoring has been a part of the national post marketing surveillance system since 2000. Herbal remedies are offered in Ghana by licensed practitioners, in specialized stores, and in pharmacies as over-the-counter medications. Hence, PV of herbal medicines is now taking a centre stage for patient guaranteed safety (World Health Organization, 2005).

Challenges in Monitoring the Safety of Herbal Medicines

It is long due that herbal medications were incorporated into pharmacovigilance systems, given the massive global usage. Many difficulties frequently arise when traditional or herbal medicine regulations are developed and put into action in various parts of the world (Salamonsen and Ahlzén, 2018).[18] The difficulties that are frequently encountered and shared by many countries include the regulatory status, assessment of safety monitoring, quality control, safety and efficacy, and inadequate or poor knowledge about traditional, complementary, and herbal medicines within national drug regulatory authorities (Marques et al., 2021).[19] Some of the challenges are mentioned below:

Patient and Physicians Barriers

In India, most of the traditional medications are sold over the counter, and since they are so easily accessible, many people take them. According to medical professionals, modern Ayurvedic treatment differs greatly from that of ancient times. In the past, Vaidya's examined and diagnosed

illnesses for a minimum of an hour, grew herbs in their backyards with known soil and temperature conditions, and created their own medications (Shaw *et al.*, 2012). Today, at least in urban settings, a busy private physician or an Ayurvedic practitioner in a modern hospital like ours may see more than 20 patients in an hour. The majority of the medications doctor gives his patients are already prepared by pharmaceutical corporations, contrary to old writings that state a doctor must create their own medications (Bhardwaj *et al.*, 2018). The country's existing legal framework forbids doctors of modern medicine from recommending Ayurvedic medications and vice versa. This may not always be adhered to, though. Both allopathic and Ayurvedic practitioners concur that concurrent therapy is often well tolerated (Huang et al., 2014).[20] Non-allopathic medical professionals may offer suggestions on whether to continue taking or stop using allopathic medications. Discontinuation can have detrimental effects, especially for conditions including cancer, diabetes, epilepsy, and asthma (Bhardwaj *et al.*, 2018). Low spontaneous reporting of negative events is a problem that exists everywhere. Without any instruction regarding the necessity to recognize, record, and keep track of ADR in their curricula, this has grown to be a significant problem for ayurvedic professionals.

Regulatory Issues

Different countries have different definitions and classifications for herbal medications depending on the rules controlling foods and medicines. A single medicinal plant may be categorised in different countries as a food, a functional food, a dietary supplement, or a herbal medicine. This not only badly muddles the definition of "herbal medicines" for the purposes of national drug regulation, but it also confounds patients and clients (Sloane *et al.*, 2015).[21]

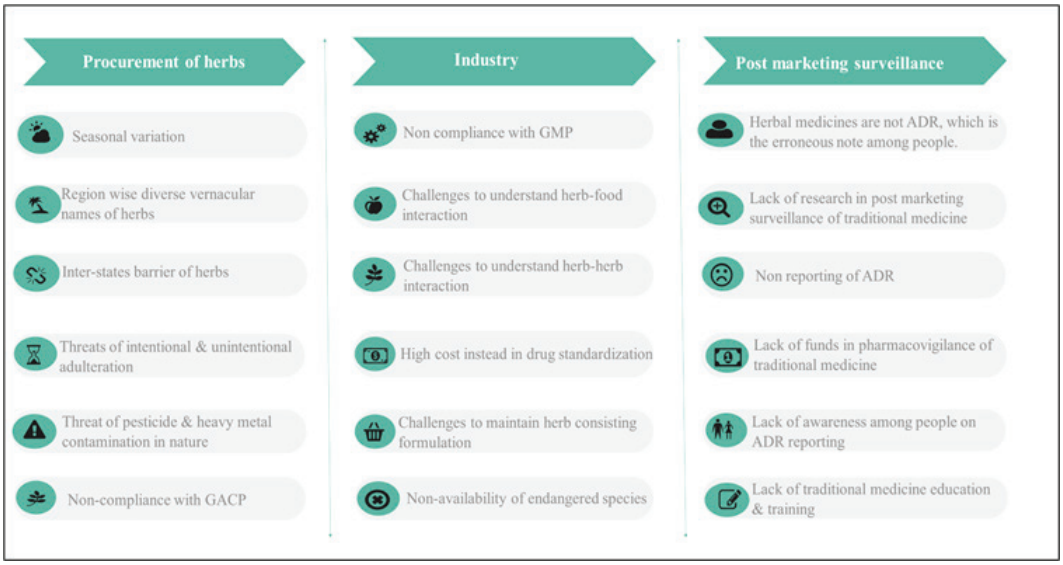
Quality and Purity Issues of Herbal Drug

Today, the most important and challenging problem is quality monitoring of the basic plant materials. The medicinal herb's batch-to-batch differences present the most challenge. The causes are numerous and include pharmacological ecotype variety, diverse taxonomical issues, soil quality, nutritional status, seasonal shifts, and meteorological circumstances. The amount of the active principle can differ across batches and manufacturers due to a lack of quality control. With ginseng, it has been demonstrated that preparations' ginseng content varies greatly and that some do not contain any at all (Ekka et al., 2008).[22] The practitioners employ resources from the market, whereas the manufacturers use the crude (raw) materials, which are frequently grown/cultivated close to their own manufacturing plants. Intestinal enzyme activity was decreased in the Mysuru variety of betel leaf (*Piper betle* Linn.) but intestinal enzyme activity was increased in the Ambadi variety, according to Prabhu *et al*.[23] The drastically varying cost exhibited in the Indian market reflects the disparity in quality (Pandey and Tripathi, 2014).[24] The toxicity of the plant might also result from misidentification. Two incidents of digitalis poisoning in the US have been linked to a dietary supplement for internal cleansing (Tambare *et al.*, 2011).[25] This is caused by several factors, including inadequate recordkeeping, policies, and even study methodologies (Leal *et al.*, 2019[26]; Sahoo *et al.*, 2010[27]).

Education

Two aspects have been noted as crucial in schooling. The first is to guarantee that TM practitioners have sufficient knowledge, credentials, and training. Second, there

Figure 3: Common Challenges in the Pharmacovigilance In Herbal Medicines



Source: Author's compilation based on several sources

is complementarity in the practice and effective communication between TM practitioners (Sen and Chakraborty, 2017).[28] Informal, experiential learning through apprenticing with doctors is still a popular trend in many developing nations. Each of them is dealing with comparable issues on their own (Zhou *et al.*, 2019).[29] Like short-term courses, experiential learning opportunities for students are often insufficient. Although apprenticing with a healer was the traditional method of experiential learning, it is no longer practiced due to an overly formalized system and the lack of respect for people schooled in family traditions (Sen *et al.*, 2011).[30] Some common challenges in pharmacovigilance of herbal medicines in represented in Figure 3.

Way Forward

According to the WHO Traditional medicine strategy, 2002-2005, "If Traditional Medicine/Complementary and Alternative Medicine (TM/CAM) is to be promoted as a source of healthcare, efforts must be made to promote its rational use, and identification of the safest and most effective treatments will be crucial" (World Health Organization, 2002a).

This can be achieved by addressing issues like categorization of herbal drug, evaluation of safety and efficacy, quality assurance, pharmacovigilance, and control of advertisements for herbal medicinal products. The need for educational intervention on various interactions of herbal medicine with other concomitant drugs/foods is critical. It is advised that healthcare practitioners participate in continuing education programmes to expand their knowledge of this rapidly expanding public health issue. Active participation of pharmacists to report ADR is required as majority of pharmacists work in hospitals or pharmacies, where they may encounter situations involving negative medication responses. Hence, their participation in systems for

pharmacovigilance of herbal medicine is essential.

Our herbal regulatory system should strengthen herbal pharmacovigilance database, and authorities should record various aspects of single herbs and/or compound herbal formulations, such as ADR, delayed or acute toxic effects, allergies, etc., on concurrent use with allopathic drugs, in addition to the information already available. Herbal medicine information needs to be specifically requested from the reporter because spontaneous reporting forms are not intended to collect that information. It would be ideal if the reporting form could be changed to more effectively gather details on potential herbal ADRs. The ultimate goal of making safer and more effective treatments available to patients will be accomplished with continued evaluation of their benefit and harm. Regulatory organizations should work to educate herbal doctors, patients, and paramedical staff members on the science of pharmacovigilance.

Conclusion

In the world's health care systems, medicinal herbs have grown to play a vital role for people not only in the diseased condition but also as a possible material for sustaining proper health. The risks involved with using herbal medicine irrationally are also higher, and the legal status and approval process also differ from country to country. In contrast, a holistic PV system shall be designed and factors associated with herbs such as botanical identity, diverse vernacular names of plant species, trade, traceability of herb, GMP, Good Agricultural and Collection Practices shall be focused. Data pertaining to ADR should be made accessible to public. Distinction shall be made for herb recommended for food, nutraceuticals, and medicine. The major difficulty globally continues to be the under-reporting of ADR brought on by herbal formulations, despite efforts to enhance public reporting of ADR. In order to improve the quality of the sector's growth, regulatory standards should be harmonized, voluntary participation encouraged, and community pharmacists and nurses should be included.

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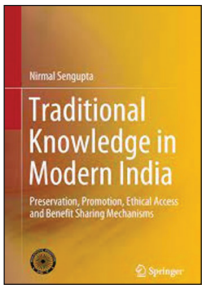

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While there is not yet an accepted definition of Traditional Knowledge (TK) at the global level, the World Intellectual Property Office (WIPO) defines Traditional Knowledge as knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity. According to this definition, TK embraces the content of knowledge itself as well as traditional cultural expressions, including distinctive signs and symbols associated with TK and also refers to knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills, and innovations. It can be found in a wide variety of contexts, including agricultural, scientific, technical, ecological and medicinal knowledge as well as biodiversity-related knowledge. Over a period of time, a lot of literature has come out to discuss various aspects of traditional knowledge, including its documentation, protection and preservation. Lately discussions on its access and benefit sharing have also been intensely debated and discussed at various levels including at the high international Convention level. A lot have also been written on India and its vast and precious traditional knowledge treasure by eminent scholars. However, not often, one finds a book covering such a wide canvass while discussing about modern India's traditional knowledge as has been done by an accomplished researcher and academician Professor Nirmal Sengupta. In this volume, the author has comprehensively captured the idea and concept of traditional knowledge, its evolution, its contestations as well the empirical evidences and successful instances found in India across various sectors.

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The book is structured in eight chapters including the final concluding chapter. Each chapter revolves around a key issue related to the topic and provides an in-depth narrative. The first chapter titled '*The Manufacture of the Traditional*' begins with an interesting insight on '*two worlds of knowledge*', i.e. traditional and modern; and went on to elaborate on various phases on exploration and their historical accounts. One such account has been on indigenous drugs, wherein the author states the pioneering role of Col. R. N. Chopra in undertaking systematic studies of indigenous drugs and in promoting Indian systems of medicine since1920s. The author also went on to cite Tagore's Sriniketan experiment for rural and village development. Thoughts of Gandhi and Nehru on development have also been discussed later in this chapter. The second chapter titled '*Global Mechanisms of Protection and Sharing*' elaborates on the existing international institutional mechanisms and architecture to ensure recognition, protection and sharing of traditional knowledge. Author has provided a detailed account of such key international agencies such as UNESCO, WHO, ILO along with the World Bank and FAO. In the context of norm setting for sharing, the author has discussed the role of UNEP and three key international conventions namely UN Convention on Biological Diversity (CBD); UN Framework Convention on Climate Change (UNFCCC) and UN Convention on Combat Desertification (UNCCD). The author also discusses the role of WIPO as well as WTO. Later in the chapter, author also briefly discusses the significant role of India's TKDL and NIF in facilitating IPR protection of many Indian traditional knowledge products and processes.

The third chapter titled '*Traditional Knowledge for Basic Needs*' deals with four case studies capturing traditional practices prevalent in India in various domains such as healthcare (Indian midwifery system/Dai system), agriculture (surface flow irrigation tanks/ahars), housing and conservation of biodiversity (Niyamgiri hill). All these four case studies have tried to project that national development policy and institutional reforms are gradually changing to accommodate rising awareness about precious traditional knowledge of the country.

The fourth chapter on 'Biodiversity and Genetic Resources' discusses four case studies (Kani tribe's Jeevani, FRLHT, Basmati rice and AYUSH-based cosmetics). These case studies have been selected to demonstrate the challenges, limitations and merit of legal and institutional structures in India for preserving, promoting and ethically sharing the associated traditional knowledge.

In the next chapter on '*Traditional Knowledge in Manufacturing and Industry*', the author elaborates on the four case studies (drug development using Ayurvedic medicinal knowledge, village agro industry from West Bengal, gems from Kerala and toys from Karnataka). These case studies deal with technology development, legal and administrative support, marketing and role of leadership, in promoting the associated traditional knowledge.

Chapter six captures author's take on traditional cultural expressions (TCEs) and expressions of Folklore such as Banarasi saree, music folklore and Yoga. In the penultimate chapter on 'Miscellaneous Other Uses', the author discusses application of traditional knowledge in two additional spheres namely on AI and climate change. Author states that Panini's rule-based Sanskrit grammar is being studies by several leading computational linguists.

In the final concluding chapter, the author argues for robust institutional and legal mechanisms to protect, preserve and

promote vast traditional knowledge and highlight the imperative for developing guidelines for ethical access and sharing of benefits with the traditional knowledge owners.

The author has elaborated on how the division between traditional and modern knowledge was created in late colonial and immediately post-independence period and escalated thereafter. The book through its well-chosen fourteen case studies spanning across various sectors, has attempted to demonstrate the continuing existence of rich traditional knowledge and practices in the modern India, exclusively due to the merit and relevance of such traditional knowledge. Apart from elaborating on the salient features of those selected case studies, what is really commendable is that fact that the author has provided an excellent historical and ethnographical account of their evolution by citing relevant literature. He has quite succinctly captured the international and national policy and institutional discourses, revolving around the issue of presentation, protection and promotion of traditional knowledge. His idea of developing an ethical access and benefit sharing mechanism is quite noteworthy.

Citing many examples, the author has tried to depict how the knowledge capital acquired by marginalised communities over time were under-valued, their applications thwarted, their spread discouraged and how their theft was made easy and possible by denying or ignoring legal protection mechanisms. Lately, several national and international agencies have realised these issues and its consequent losses. They are trying to rectify by enacting several legal provisions. The author rightly argues that the global community stands to benefit by getting access to local traditional knowledge. The current global agenda for respecting, preserving and promoting traditional knowledge, also strives towards ensuring that the knowledge owners too must receive adequate share from the consequent benefit. Unfortunately, fairness in benefit sharing is often understood as sharing a part of the financial benefit. Author argues that it is essential, but not enough. He explains that implicit in such narrow approach is the acceptance that only outsiders can develop local traditional knowledge preserved by the local communities. He, thus, exhorts for soliciting their participation at all levels as a foundation for ethical benefit sharing.

The narration-style of presentation of the case studies makes the reading engaging and lucid. However, at times, the author seems to provide certain unnecessary details about the topics which are not directly related to the theme of the book. Also, he procrastinates on certain points. Such 'de-tours' or digressions could have been avoided. It would have been quite welcoming to find a the final concluding chapter with a clear set of lessons drawn from the detailed case studies the author had undertaken to highlight the prevailing strengthens and weaknesses in the present institutional mechanisms. Such a section could have helped policy makers more in terms of take noting of the gaps for necessary actions or policy interventions.

Nevertheless, as mentioned earlier, this book discusses some of the very relevant traditional knowledge case studies from India and provides a useful and informative account of their evolution. This book would be a good read for scholars/researchers engaged in traditional knowledge research as well as for those who are interested to know India's rich and glorious traditional knowledge products and practices, which are relevant, even in the modern times.

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