

Ayush Exports

Regulatory Opportunities and Challenges in Key Markets



RIS

Research and Information System
for Developing Countries

विकासशील देशों की अनुसंधान एवं सूचना प्रणाली

AYUSH Exports: Regulatory Opportunities and Challenges in Key Markets

Namrata Pathak

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Preface

Professor Sachin Chaturvedi

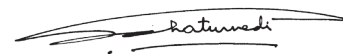
Director General, RIS

Traditional herbal medicine is increasingly finding global acceptance. Today regulations for herbal medicines have been formulated in most countries. Ayush products themselves have been witnessing a steady growth in exports with new markets. However, even as India's exports grow, the regulatory landscape for each market varies and unlike modern pharmaceutical industry, the ease of navigation of regulatory requirements for Ayush in these international markets has not been uniform. Drug registration for Ayush pharmaceuticals is still a major challenge. Nevertheless, Indian exporters have adapted well and have managed to evolve export strategies within the available legal pathways.

An understanding of the regulatory landscape of export destinations with their associated challenges and opportunities is extremely relevant for all stakeholders, including the Ministry of Ayush. On the one hand it unlocks doors to the possibilities of export expansion through the understanding of regulatory windows open for such products, on the other; it highlights the bottlenecks that need to be addressed for market entry or expansion.

Major exports of Ayush include medicinal plants/ herbs, extracts, pharmaceuticals, and health/ dietary supplements. USA, EU and UAE constitute major export destinations for Ayush. The study provides an overview of the regulatory landscape with reference to the above mentioned commodities and the pathways adopted by exporters for easiest access to market and distribution channels. It highlights the tariff and non-tariff barriers to exports. Services and service providers of traditional medicine are important channels of drug distribution and hence regulatory landscape for the same is also explored .

I am sure that the study will serve as a valuable reference for policy makers, industry, academia and practitioners associated with understanding and promoting global expansion of Ayush industry. I take this opportunity to thank the FITM team Dr Namrata Pathak and Ms Sanjna Agarwal for bringing out this important study.



Sachin Chaturvedi

List of Abbreviations

Central Council for Research in Ayurvedic Sciences	CCRAS
Certificate of pharmaceutical product	CoPP
Code of Federal Regulations	CFR
Compounded Annual Growth Rate	CAGR
Complementary and Alternative Medicine	CAM
Cost, Insurance and Freight	CIF
Directorate General for Commercial Intelligence and Services, Ministry of commerce	DGCIS
Dietary Supplement Health and Education Act	DSHEA
European Directorate for the Quality of Medicines and Health Care	EDQM
European Food Safety Authority	EFSA
European Medicines Agency	EMA
European Union	EU
Food and Drug Administration	FDA
Food, Drug and Cosmetics Act	FD&C Act
Good Manufacturing Practices	GMP
Global Value Chain	GVC
Hazard Analysis of Critical Control Points	HACCP
Harmonized System of Codes	HS
Investigational New Drugs	IND
Letter of Credit	L/C
Maximum Residue Levels	MRLs
New Drug Applications	NDA

Non-Communicable diseases	NCD
Non-Tariff Measures	NTM
Non-Tariff Barriers	NTB
Natural Health Products	NHP
Health Canada Natural Health Products Directorate	NHPD
Marketing Authorisation	MA
Medicinal and Aromatic Plants	MAPs
Most Favored Nation	MFN
European Pharmacopoeia	Ph Eur
Reference Member State	RMS
Research and Development	R&D
Standard International Trade Classification	SITC
Sanitary and phytosanitary measures	SPS
Technical barriers to trade	TBT
Traditional Chinese Medicines	TCM
Traditional, Complementary and alternative medicine	TCAM
Therapeutic Goods Administration of Australia	TGA
Traditional Medicines	TM
Trade Analysis and Information System	TRAINS
United Nations Conference on Trade and Development	UNCTAD
United States Pharmacopoeia - National Formulary	USP-NF
United Arab Emirates	UAE
United States of America	USA
United States Pharmacopoeia	USP
World Health Organization	WHO
World Integrated Trading Solutions	WITS

Executive Summary

Steady regulatory development in traditional, herbal, complementary and alternative medicines and allied services globally has been aiding the herbal industry. USA, EU and UAE constitute major export destinations for Ayush products. The ease of navigation of regulatory requirements for Ayush in these international markets has not been uniform. Drug registration for Ayush pharmaceuticals is still a major challenge. However, Indian exporters have adapted well with the available pathways and have managed access and expansion in these markets.

Barring UAE, Ayush pharmaceuticals are being marketed and distributed as herbal dietary supplements in countries/regions under study (USA, EU). UAE allows for Ayush pharmaceuticals to be marketed as drugs. In US and EU Ayush pharmaceuticals, herbs and extracts are often being exported and distributed as dietary supplements owing to the comparatively limited regulatory requirements although health claims are not permitted for labelling of dietary supplements. While EU provides a framework within which the food supplements and ingredients sector operates, regulatory differences at the national level exist.

In USA drug registration under the Botanical Drug category can be a market authorisation pathway for Ayush, although no Ayush drug is registered as yet. Single herb botanical drug substances (e.g., Psyllium and Senna)

are included in the OTC drug review. Single herb Ayush drugs could be strategized for botanical drug registration in USA. For India, the relevance of products like Psyllium is demonstrated by the fact that Psyllium (husk and seeds) constitutes the highest per centage (86.26 per cent in 2021) of India's total MAPs export to USA. Registration strategies for single herb botanical drugs, may help increase exports of products similar to psyllium.

In EU, the Herbal Directive provides for drug registration of traditional herbal medicines. No Ayush pharmaceutical is registered as a herbal medicinal product in EU yet. Based on survey of herbal medicinal products that have been successfully registered by simplified registration procedure in the EU by countries like China it was found that the establishment of a TCM Working Party at the European Directorate for the Quality of Medicines and Health Care (EDQM) has been an important strategy. In EU, the European Pharmacopeia (Eur Ph) and the EDQM are important as a first point of reference for traditional medicines registration process. Ayush may initiate setting up a similar Working Party for Ayurveda at the EDQM for enabling understanding and inclusion of Ayurveda monographs

Tariff barriers to export are negligible in all three countries. 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 and the least number of tariff and NTBS. Comparatively, EU imposes a larger number of NTMs especially for MAPs and extracts, especially SPS and TBT. UAE imposes the highest number of NTBs for all three categories of commodities among all the markets under study.

Given that in most cases TM is marketed as raw herbs, herbal/dietary supplements and active nutraceutical ingredient, strict quality and SPS requirements in the US, UAE and European markets are particularly difficult to surmount. The market for MAPs places great importance on quality and on freedom from microbial contamination. In most cases MAPs exports encounter maximum NTBs specially pertaining to SPS. Conformity Assessment including traceability in regions like EU are a major challenge as EU increasingly looks at more strict mandatory compliance of several standards. Indian exporters would have to intensify efforts at meeting global standards for conformity assessment requirements which in turn would meet the SPS requirements.

Till date many of the significant Indian 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 and may be addressed by the Ayush Export Promotion Council. Recognition of TM as a health service is likely to push sales of Ayush

pharmaceuticals hence efforts on quality Ayush health professionals is relevant in global markets. In US while Ayush systems are not yet recognised as medical systems, the emerging scenario whereby eleven US states have enacted laws for complementary and alternative medicine practice is expected to open more opportunities for Ayurveda drugs exports in future. It is tough to draw a direct linkage with health service law and regulations to exports of Ayush drugs in EU. While France has no specific law on Ayurveda practice, it still constitutes the biggest per centage of Ayurveda drugs to EU. At the same time while Germany has a long history of Ayurveda related practice, exports of Ayurveda pharmaceuticals constitutes a small per centage as compared to MAPs and extracts. In UAE the regulatory framework for Ayush services is made easy by regulatory provisions for medical care under Traditional Complementary and Alternative Medicine with professional licence for Ayurveda, Homeopathy and Unani medicine practitioners.

Distribution channels of Ayush products from India to all three countries/regions include five major pathways i.e. wholesale distribution companies servicing retail stores; wholesale distribution companies servicing practitioners (Doctors of TCM, Ayurveda, Naturopathy, among others); mail order companies servicing consumers; online e-commerce platforms and Company Outlets (health stores, clinics, daycare centres and spas); Based on interviews with industry representatives, the marketing channel adopted by most exporters is through the B2B for all categories -herbs, extracts and Ayush pharmaceuticals. Barring countries like UAE with regulatory norms inhibiting direct sale of goods, it is possible to manage the supply chain integration by reducing the number of middlemen from the producer to the consumer. Stronger market linkage, market information and quality processing with standards subscriptions adhering to conformity assessment requirements can enable B2C exports of Ayush.

Section: 1

Introduction

1.1 Background

Traditional Medicine is increasingly finding global acceptance. 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. Countries with laws or regulations increased from 45 to 109 and countries with a national programme for T&CM more than tripled from 23 to 79. Regulations for herbal medicines have been formulated in most countries, with number growing from 65 to 124 countries between 1999 and 2018. Ayush products themselves have been witnessing a steady growth in exports. However, even as India's exports grow, the regulatory landscape for each market varies. Contrary to the perception that Ayush pharmaceuticals are imported and marketed as per regulations governing herbal/traditional/complementary medicine/products in the respective country, interviews with stakeholders, especially major exporters have highlighted that subsectors of Ayush goods have taken to diverse regulatory pathways to gain market access. Literature on these pathways has been inadequate. In addition to adequacy of

laws/regulations on traditional medicines sale and practice, imports into many markets are affected by several factors. 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.

1.2 Focus of Study and Data Sources

The objective of this study is to highlight the regulations on traditional medicine, herbal and allied products in key Ayush markets. The major goods and allied products of Ayush include medicinal plants/ herbs, extracts, pharmaceuticals, health/dietary supplements. The study provides an overview of the major markets and their requirements with reference to the above mentioned Ayush goods in order to highlight both the opportunities that exist for India and to indicate what needs to be done in order to expand these opportunities further. It analyses the navigation of regulations by exporters for easiest access to market and distribution channels. It also explores the tariff and non-tariff barriers to exports. Services and service providers of traditional medicine are important channels of drug distribution and hence regulatory landscape for the same

are also studied. The study focuses on broad trends or tendencies, in countries/regions that make up the bulk of India's exports across all Ayush product components (50 per cent) viz, USA, EU and UAE, as it is not possible to discuss each individual product, country or situation. It draws out some conclusions and recommendation that are general in application and are unique to some markets. However, it is important to appreciate that the specifics of individual trade situations vary significantly with the product and the country being considered.

The study has been prepared on the basis of reference to primary sources, including analysis of laws/regulations of respective countries, interviews with exporters and trade and tariff data. Available literature on herbal medicine legislations, regulations, and practice includes (Ajazuddin, 2012) (WHO, 2001, 2005, 2019), (Alostad et al, 2018). Brinckmann (2006) also documents regulatory environment for herbal medicines in several countries. CCRAS (2009) has brought out a compendium of drug registration formats of select countries.

Medicinal plants being an important export component of Ayush, FAO (2006) studies the medicinal plant market features of select markets. However, given the dynamic nature of the herbal industry, laws and regulations in all countries are constantly evolving. This study studies the latest laws, regulations, tariff and non-tariff barriers, opportunities and challenges for manufacturers/exporters in major export destinations. Based on interviews with industry representatives, the study of existing legislations/ regulations for drug registration, the alternative regulatory pathways, sales/ distribution channels being adopted, this study suggests policy strategies for growth of Ayush pharmaceuticals export. The India export data is drawn from DGCIS (Directorate General for Commercial Intelligence and Services, Ministry of commerce) and global trade data is drawn from UN ComTrade, WITS database. The tariff and non- tariff measure data is drawn from UNCTAD's TRAINS database from WITS. Harmonised System (HS) Chapters 9, 12, 13 and 30 are used for analysis.

Section: 2

Global Trade, Trade Barriers and India's Ayush Export Markets

The usage of traditional medicine systems is expanding beyond the countries of origin. Of particular significance are the herbal medicinal products derived from plants or natural sources. Increasing attention to policy support for global outreach by countries of origin like India and China, influx of significant investments in R&D and acknowledgement of efficacy of these systems in addressing increasing challenges of NCDs are providing impetus to the global market. These factors explain the expansion of the herbal medicinal sector at the rate of 7.6 per cent during 2014-19 despite continuation of recession for nearly one and half decades (RIS, 2021). As the sector is expanding fast across the globe, there are numerous opportunities existing in number of sub sectors within the industry. Herbal medicine industry being a part of the health and food industry, market access however is highly dependent on the importing countries' regulatory requirements for market authorisation, quality and safety. These vary considerably. Despite increasing efforts at the national and multilateral level, the legislative acceptance of traditional medicines as pharmaceuticals outside the countries of origin is still evolving. This section provides an overview of global trade (although in the absence of specific HS lines for herbal medicines, analysis has been made only on raw herbs/medicinal plants and extracts under chapter 9, 12 and 30), the tariff and

non-tariff landscape. It provides highlights of India's exports (MAPs, extracts and pharmaceuticals), major destinations, sales and distribution channels. The objective is to throw light on the trade trends and potential of commodities and markets.

2.1 Global Herbal Medicine Market

RIS (2021) has estimated the global market size of the herbal sector at USD 657.5 Bn in 2020, likely to touch USD 746.9 Bn by 2022. The global herbal market comprises of medicinal and aromatic plants (MAPs) herbal medicines, herbal extracts, plant derivatives and supplements. Growth performances of these sub-sectors differ significantly although the aggregate sector grew at the rate of 7.4 per cent per annum during 2014-2020. Various sub-sectors, particularly, herbal pharmaceutical sector expanded at the rate of 18.5 per cent during the same period with the market share of 14.1 per cent in 2020 (RIS, 2021). From the pattern of growth of the industry, it is evident that higher value-added sub-sectors are growing faster than primary sectors and the industry is expected to witness expansion of value chain based on trade among the trading economies.

COVID 19 has further enabled a surge in global demand for biodiversity based goods and services, including phytopharmaceuticals (UNCTAD, 2022). Herbal medicines have witnessed higher than anticipated demand

across all regions as compared to pre pandemic levels. Several reports have revised estimates the size of the herbal medicine market albeit using different methodologies. According to Fortune Business Insights (2022) the global herbal medicine market is projected to grow from USD 165.66 Bn in 2022 to USD 347.50 Bn by 2029, at a CAGR of 11.16 per cent. Zion Market Research study (2022), estimated global herbal medicine market size around USD 166 Bn in 2021 growing at CAGR approximately 11.2 per cent between 2022 and 2028.

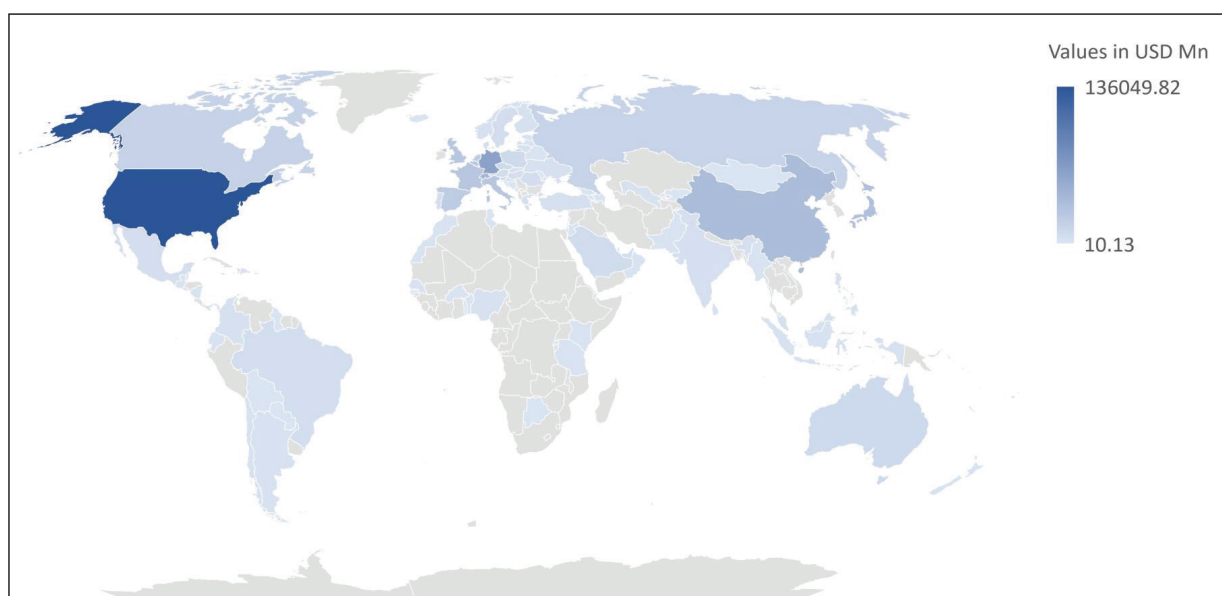
2.2 Major Suppliers and Importers

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. In this industry, MAPs segments can be estimated accurately and to a large extent for the plant extracts segment of the industry. The global trade in the MAPs and extracts could be a reflection on the size of the industry (RIS, 2021). 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 per cent of total exported value of MAPs in 2021, respectively. While China registered a CAGR of -0.36 per cent in the export of MAPs for 2017-21, India recorded a CAGR of 6.14 per cent. The existing trade pattern demonstrates a clear difference between trade structure of India and China with respect to MAPs sector. Shorter trade distances reveal that exports from China are mainly concentrated in nearby countries, like Japan, Hong Kong, South Korea, etc. whereas the average trade distance for India is high, indicating high trade with distant countries, like the US and EU region particularly Germany, than the partners in the immediate neighbour. It may also be noted that the market of MAPs is more competitive than plant extracts. The global trade pattern reveals that major net exporters and importers procure their products from diverse range of countries. Over the period 2017-2021 some countries have shown substantial growth in export of MAPs and extracts. These include Luxembourg

Figure 2.1: Importing Countries (MAPs and Extracts) in 2021



Source: Authors' compilation based on UN ComTrade, WITS database

(CAGR 68 per cent), Iceland (61 per cent), Norway (40.76 per cent) Burkina Faso (36.62 per cent) Lebanon (34 per cent) and Tanzania (30 per cent).

USA, EU Countries (Germany, Italy, Spain, Belgium, France and Netherlands), Switzerland, China and Japan are major importers of MAPs and extracts. The net positive demand from the developed countries could be a major driver of herbal medicines and supplements in the global market. 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.

2.3 Trade Related Regulatory Barriers for MAPs, Extracts and Pharmaceuticals

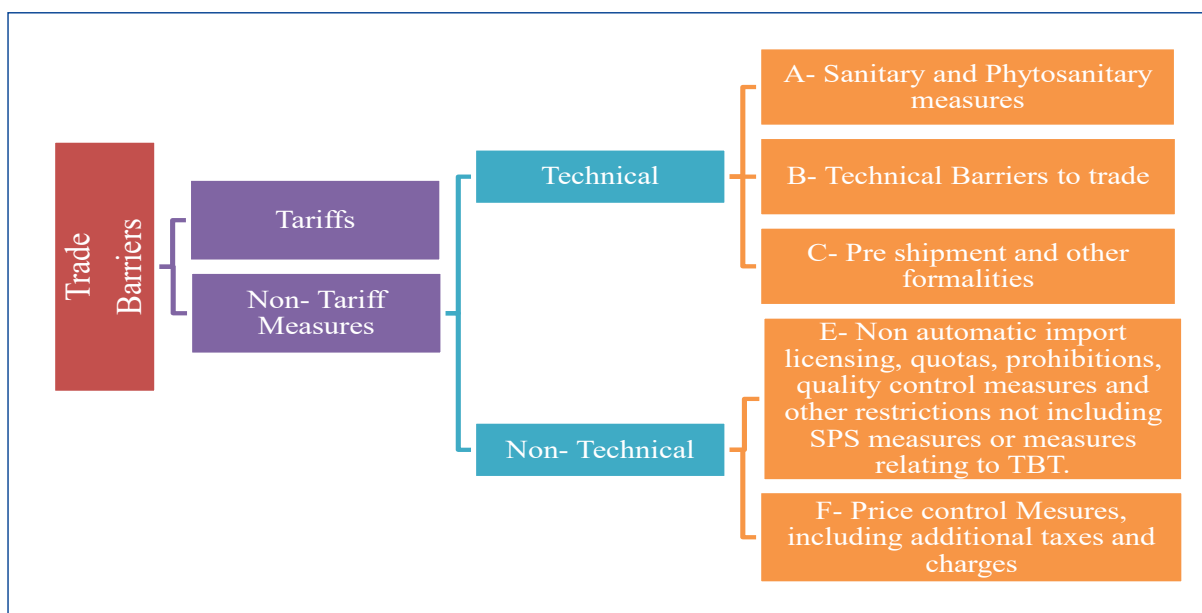
Both tariff as well as non-tariff measures (NTMs) are applicable to international trade in herbal medicines. Tariffs are customs duties or taxes imposed by governments when goods enter a country. While tariff rates can be measured, a major challenge with NTMs is that they are difficult to measure and 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 NTMs¹, five apply to commodities under study. 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 licencing, quotas, prohibitions, quality control measures, and other restrictions not including SPS and TBT and (F) price control measures.

Tariff Rates

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 2.1 indicates

Figure 2.2: Tariff and Non- Tariff Barriers in Herbal Exports



tariff rates for medicinal plants, extracts and medicines for a number of markets. In general, rates on most materials into developed countries are zero or low. Those on a number of products into developing countries which have a local industry they wish to protect are substantially higher.

This includes countries like India, Thailand, Bangladesh, Nepal, Vietnam and Pakistan. This level of tariff makes exporting to these markets extremely difficult. On the other hand, tariffs into the EU, USA Australia and Japan are zero or very low.

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. Our intention is to outline their prevalence and the

Table 2.1: 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: UNCTAD, TRAINS database

need for detailed assessments of the costs and benefits of different regulatory options.

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 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 to 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.

2.4 India's Exports: Major Markets, Sale and Distribution Channels

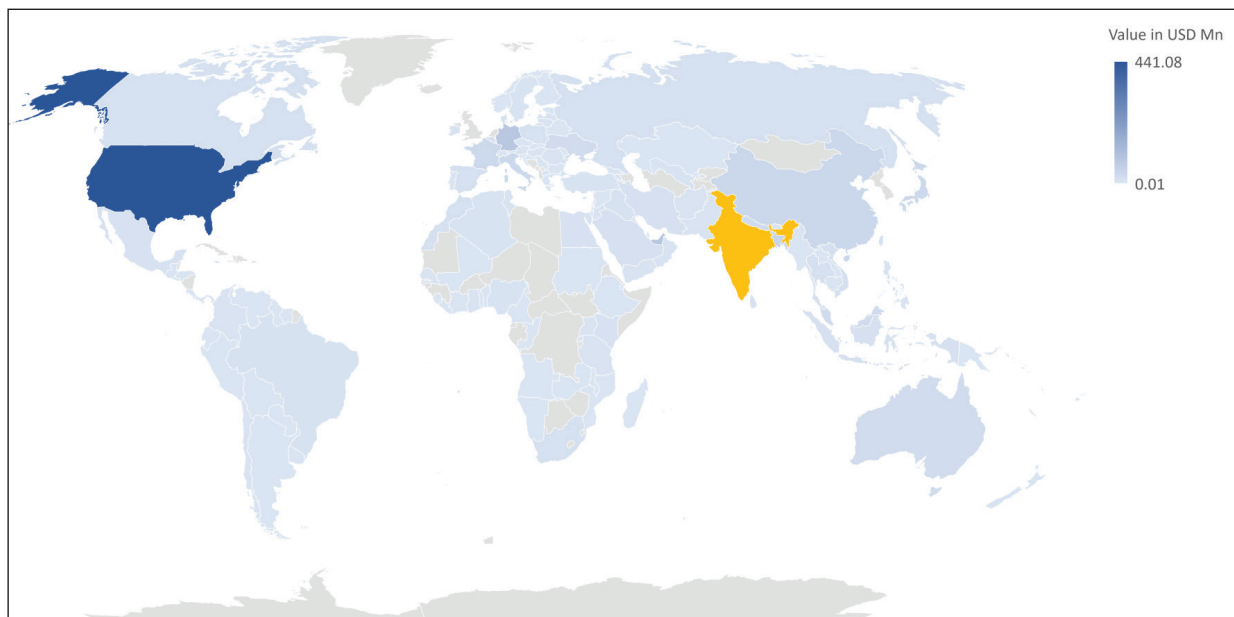
India has steadily increased its presence in the global trade of the herbal medicinal sector. Exports in the sector expanded from USD 0.86 Bn in 2017 to USD 1.26 Bn in 2021, registering a robust growth of 7.82 per cent, though the estimated statistics for the export sector was still underestimated in the absence of authentic statistics for the plant derivative sector. The strength of the AYUSH sector exports is that it has been catching up in line with the vertical value chain process and finished goods including supplements, medicants/medicaments/pharmaceuticals would steer the export performance of Ayush exports in the coming years. Despite its accomplishments in recent years, AYUSH exports have been an untapped sector with tremendous prospects

for growth. There are a variety of products that constitute the AYUSH export basket, ranging from drugs, plants, plant parts, extracts, cosmetics and nutraceuticals. Being associated with several industries including food and cosmetics without specific HS lines allocated to each makes accurate estimation of export volumes a challenge. Among other factors, exports of goods are being facilitated with the growing traditional, complementary and alternative medicine healthcare services globally. Although still in the process of institutionalisation, major systems of medicine originating from countries like India and China are increasingly being accorded regulatory status in other countries.

Key Markets

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

Figure 2.3: India's Export of Ayush product to the World in 2021



Source: Based on Directorate General of Commercial Intelligence and Statistics (DGCI&S). Accessed on Dec 28, 2022

Pharmaceuticals

During 2017-2021, the export of AYUSH pharmaceuticals rose from USD 136.9 Mn to USD 193.6 Mn, registering a CAGR of 7.18 per cent. In 2021, top destinations included EU (17.08 per cent), USA (11 per cent) UAE (10.9 per cent) and Nepal (10.4 per cent). Other destinations include Russia, South Africa, Kenya and Malaysia. Exports to some countries have grown significantly. Russia and Poland registered a CAGR of 31.19 and 54.57 per cent respectively during 2017-21.

Medicinal and Aromatic Plants (MAPs)

Major MAPs exports are covered under HS Chapter 12 although Ayush commodities like turmeric and saffron are also covered in HS chapter 09. The exports of MAPs from India increased from USD 476.09 Mn in 2017 to USD 630.05 Mn in 2021, registering a CAGR of 5.76 per cent in the period. In absence of HS lines for all MAPs exported and based on the available lines for identified commodities Psyllium (48.42 per cent), Turmeric (32.66 per cent), Zedovary Roots (3.37 per cent), and senna leaves (2.53 per cent) constitute major MAPs exported.

Extracts

The exports of extracts has increased from

USD 253.24 Mn in 2017 to USD 438.47 Mn in 2021, registering a CAGR of 11.60 per cent. EU countries such as Ireland (64.14 per cent), Denmark (37.74 per cent), Poland (28.83 per cent) Sweden (112.09 per cent) and France (27.97 per cent) have registered significant growth in the imports of extracts from India. Other attractive destinations with encouraging growth in exports from India during 2017-21 are NewZeland (33.39 per cent), Indonesia (30.05 per cent) and China (24.43 per cent)

Sale and Distribution Channels

Some enterprises provided typical export flows for their exported finished goods. Business to Business (B2B) appeared to be the most common channel which entails export to a single exclusive master distributor who in turn re-distributes into five different channels:

- Wholesale Distribution Companies servicing retail stores
- Wholesale Distribution Companies servicing practitioners (Doctors of TCM, Ayurveda, Naturopathy, among others)
- Mail Order Companies servicing consumers
- Online e-commerce platforms
- Own Company Outlets (health stores, clinics, daycare centres and spas).

Section: 3

USA

3.1 Market Profile

USA constitutes the highest shares of India's Ayush exports. The herbal medicines market in the USA is USD 24.5 Bn in the year 2022 and the country currently accounts for 18.4 per cent share in the global market (Fortune Business Insights, 2022). High per capita spending enables access to high value products. Limited pricing restrictions allowing for higher pricing along with direct-to-consumer advertising provides additional advantage to exporters. At the same time high operating costs and limited public health finance limit potential for exports. Of major interest to Ayush besides the market size is the favourable epidemiological trends. The epidemiological profile is that of a developed country with high prevalence of non-communicable diseases (NCDs). Cardiovascular diseases (38 per cent), cancer (25 per cent), respiratory diseases (9 per cent), and diabetes (6 per cent) are the four leading causes of NCD deaths² NCDs are responsible for nearly four of every five deaths

(79 per cent)³. This figure is only expected to increase in the coming decades as a consequence of population growth and aging, urbanization, and exposure to risk factors. Ayush industry's strengths in NCDs offers a fertile consumer base that is showing growing interest in alternative healthcare solutions. Moreover, the wellness trend is fast catching up and could further drive demand for Ayush products and services. Laws permitting practice of CAM in eleven states in US could further catalyse Ayush drug sales in the market. At present, most Ayush goods including MAPs and pharmaceuticals are sold as dietary/food supplements.

3.2 Exports to USA: Emerging Trends and Patterns

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 per cent) (Table 3.1). Ayurveda drugs contribute to the highest proportion of Ayush pharmaceuticals exports (96.4 per cent),

Table 3.1: India's Ayush Export to USA

Category	Value exported in 2021(USD Mn)	CAGR (%) (2017-21)	Share as a % of total Ayush exports (2021)
MAPs	167.24	5.40	37.92
Extracts	252.52	9.95	57.25
Medicants and Medicaments	21.32	8.46	4.83

Source: Based on Directorate General of Commercial Intelligence and Statistics (DGCI&S). Accessed on December 28, 2022

while Psyllium (74.58 per cent) and turmeric (13 per cent) dominates export of MAPs. Exports of some MAPs and extracts have grown over the last five years. Between 2017-21 the CAGR in exports of some commodities reflect the prospects for expansion. This includes Neem leaves (20.58 per cent), Sarsaparilla (24.54 per cent), Tukmaria (30.14 per cent), Garcenia (37.97 per cent), Gum Arabic Extract (109 per cent) and Belladonna extracts (86.4 per cent).

3.3 Botanical Drugs: Registration Requirements

All drugs (including traditional medicines) have to undergo a series of tests and clinical studies to prove their efficacy, safety, quality and dosage standard, as well as go through an approval process before being introduced to the market. Three types of new drug registration applications are permitted:

- INDs: Investigational New Drugs
- NDAs: New Drug Applications
- ANDAs: Abbreviated New Drug Applications for Generic Drug products

While the Federal Food, Drug and Cosmetics Act 1938 (FD&C Act) is the basic food and drug law of US, Code of Federal Regulations (CFR)⁴ regulates the law, Food and Drug administration (FDA)⁵ enforces the law.

For Ayush pharmaceuticals, the most possible beneficial regulatory pathway would be registration as 'botanical drugs'⁶. The term botanicals have been described by FDA as products that include, among others plant materials, algae, macroscopic fungi, and combinations thereof. It does not include: products that contain animals or animal parts (e.g., insects and annelids) and/or minerals, except when these are a minor component in a traditional botanical preparation (e.g., traditional Chinese medicine, Ayurvedic medicine)⁷.

A botanical product may be classified as a food (including a dietary supplement), drug

(including a biological drug), medical device, or cosmetic under the FD&C Act. Whether an article is a food, drug, medical device, or cosmetic depends in large part on its intended use⁸ though for some product types, other factors must also be considered⁹. Intended use is established by, among other things, the product's labelling, advertising, and the circumstances surrounding its distribution¹⁰.

A botanical product intended for use in diagnosing, curing, mitigating, or treating disease would meet the definition of a drug under section 201(g)(1)(B) of the FD&C Act¹¹. A botanical product intended to prevent disease would also generally meet the definition of a drug under section 201(g)(1)(B) and be regulated as a drug¹². Under certain circumstances, however, an article that meets the definition of a drug would nevertheless be subject to a different regulatory scheme. For example, when a conventional food or dietary supplement bears a health claim about reducing the risk of a disease and the claim is made in accordance with an authorizing regulation issued under section 403(r)(1)(B) of the FD&C Act (21 USC 343(r)(1)(B)), such a product would not be regulated as a drug solely because its labelling contains such a claim.¹³ It may be noted that Section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) requires that a manufacturer of a dietary supplement making a nutritional deficiency, structure/function, or general well-being claim have substantiation that the claim is truthful and not misleading. Hence a botanical product can be a drug or a food supplement depending on its labelling claims and related regulatory subscription.

3.4 Laws on Dietary Supplements: Most Frequently used Pathway by Indian Exporters

Ayush exports to US including herbs, extracts and pharmaceuticals and 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) 1994¹⁴, while labelling requirements are subject to the Nutrition Labelling and Education Act 1990¹⁵. Section 3 of DSHEA defines supplements quite broadly as “anything that supplements the diet.” Supplements include vitamins, minerals, herbs, amino acids, enzymes, organ tissues, metabolites, extracts, or concentrates.

No Pre- market approval requirement for dietary supplement

Under DSHEA, manufacturers of dietary supplements such as herbs are not required to obtain premarket approval by the FDA before making their products available to consumers¹⁶. Instead, the FDA bears the burden for demonstrating that a product is unsafe before it can take action to regulate its use¹⁷. DSHEA includes provisions allowing manufacturers of dietary supplements to make certain statements about the supplement’s effects on the health and overall well-being of the consumer¹⁸. While manufacturers must have substantiation for these statements, they are not required to have them evaluated by the FDA before using them for marketing purposes¹⁹.

However, manufacturers are subject to all of the provisions in DSHEA that govern the

safety and marketing of supplements. Dietary supplements may be liable to legal action under some conditions. Section 4 of DSHEA lists four reasons that a supplement could be considered adulterated and thus subject to FDA regulation. Firstly, the supplement poses a “significant or unreasonable risk of illness or injury” when used according to directions given on the label or, when there are no directions given on the label; secondly, the supplement contains a new ingredient for which there is inadequate information; thirdly, it is declared that the supplement poses an “imminent hazard to public health or safety”; and fourthly, the supplement contains “poisonous or unsanitary” ingredients (Starr, 2015). Even after a product is put on sale, FDA may require the manufacturer to recall or stop the sale of the product if it is proved to cause certain hazards when used under normal conditions. Therefore, unless the FDA can demonstrate that a herbal product is adulterated under one of the four criteria of risks of illness, inadequate information, public health and safety and unsanitary ingredients, the product can remain on the market.

3.5 States with Laws Permitting the Practice of CAM

In US, health services are regulated at the state level and regulated health professional licenses are administered at the State level. All states have medical practice laws that prohibit the practice of medicine without a medical license.

Box 3.1: Authorised prescription and OTC botanical drug products in US

To date, two botanical products have fulfilled the Botanical Guidance definition of a botanical drug product. Both botanical drug products have been approved for marketing as prescription drugs (Sinecatechins, Veregen® and Crofelemer, Mytesi™). There are some botanical drugs, including cascara, psyllium, and senna, that are included in the over-the-counter (OTC) drug review. For a botanical drug substance to be included in an OTC monograph, there must be published data establishing a general recognition of safety and effectiveness, including the results of adequate and well-controlled clinical studies.

Source: USFDA.

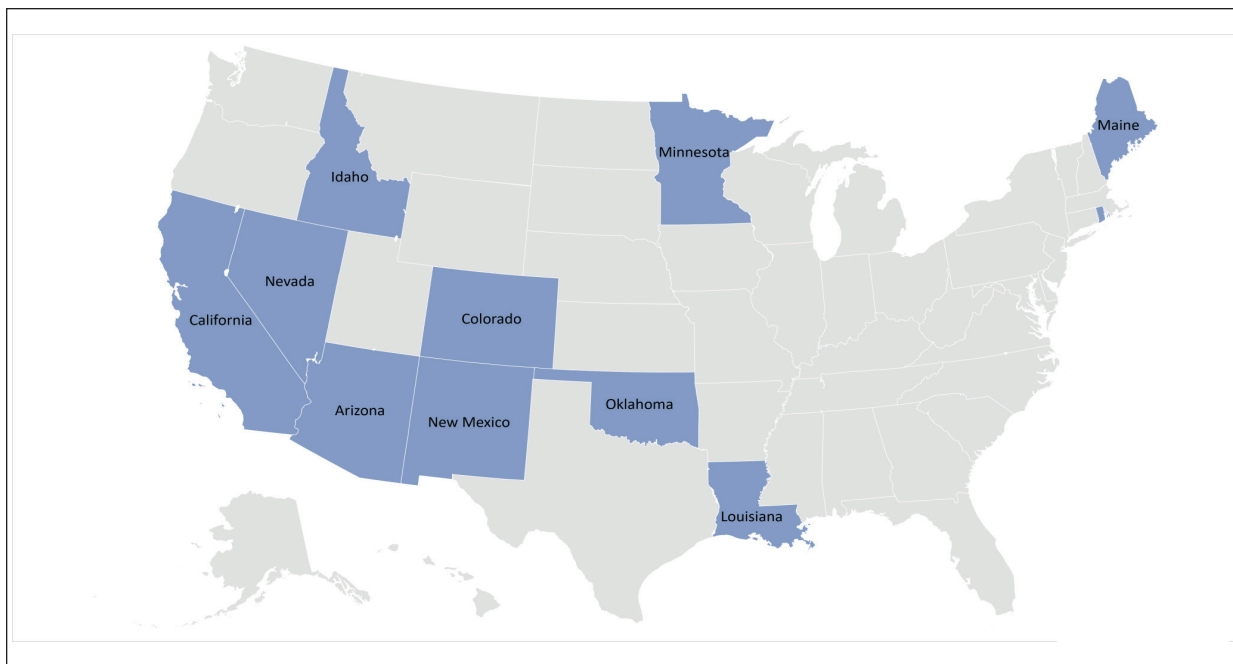
However, States with laws allowing CAM practice have been enacted in eleven states of US and are paving way for broader acceptability of Ayush health systems as a therapeutic option. These include Maine, Nevada, Colorado, New Mexico, Arizona, Louisiana, Rhode Island, California, Minnesota, Oklahoma and Idaho (Figure 3.1). Specific requirements and limitations may vary across states, although laws generally include requirements such as prohibiting such practitioners from performing surgery, including disclaimers and Informed Consent forms or Client Bill of Rights as mandatory information to patients. Ayurveda practitioners can practice as per Ayurveda principles subject to the specifics of the state laws and this could in the future drive the exports and sales of Ayurveda pharmaceuticals to US further.

3.6 Key Barriers

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)).

Figure 3.1: States with Laws Permitting Practice of CAM



Source: Authors' compilation from various sources

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 criteria²⁰.

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 FDA²¹. Section 6 also provides that manufacturers cannot make statements that suggest the supplement can “diagnose, mitigate, treat, cure or prevent” disease.²² Claims like these can only legitimately be made for drugs, not dietary supplements.

Section: 4

European Union

4.1 Market Profile

European Union (EU) is a significant importer, producer, exporter and consumer of herbs, extracts and traditional medicines. In 2021, the European market value of herbal medicine as per Fortune Business Insights (2022) was USD 69.20 Bn, although the product segmentation could be in favour of natural ingredients for health and beauty products. Growing demography of ageing population, increasing consumer demand for natural supplements makes Europe a promising market for natural ingredients in health products. European companies are launching new natural health products, and some are replacing synthetic ingredients with natural ones in product formulations. European consumers are also open to trying complementary and alternative medicines, which are stimulating demand for natural ingredients. Western European countries with higher per capita spending are especially receptive although as will be seen later there is a growing demand for herbal products in Eastern European regions as well. Herbal medicinal products and food supplements including drugs, herbs and extracts are governed by a central legislation in EU although an additional set of regulations may be imposed by member states at the national level. Information at the national level may require further information.

4.2 Exports to EU: Emerging Trends and Patterns

Exports of Ayush are heavily tilted towards MAPs and extracts (Table 4.1). Encouragingly, extracts and pharmaceuticals exports have grown faster than MAPs during the last five years reflecting increasing acceptance of Ayush drugs. 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. 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.

4.3 Registration as Drugs: The EU Herbal Directive

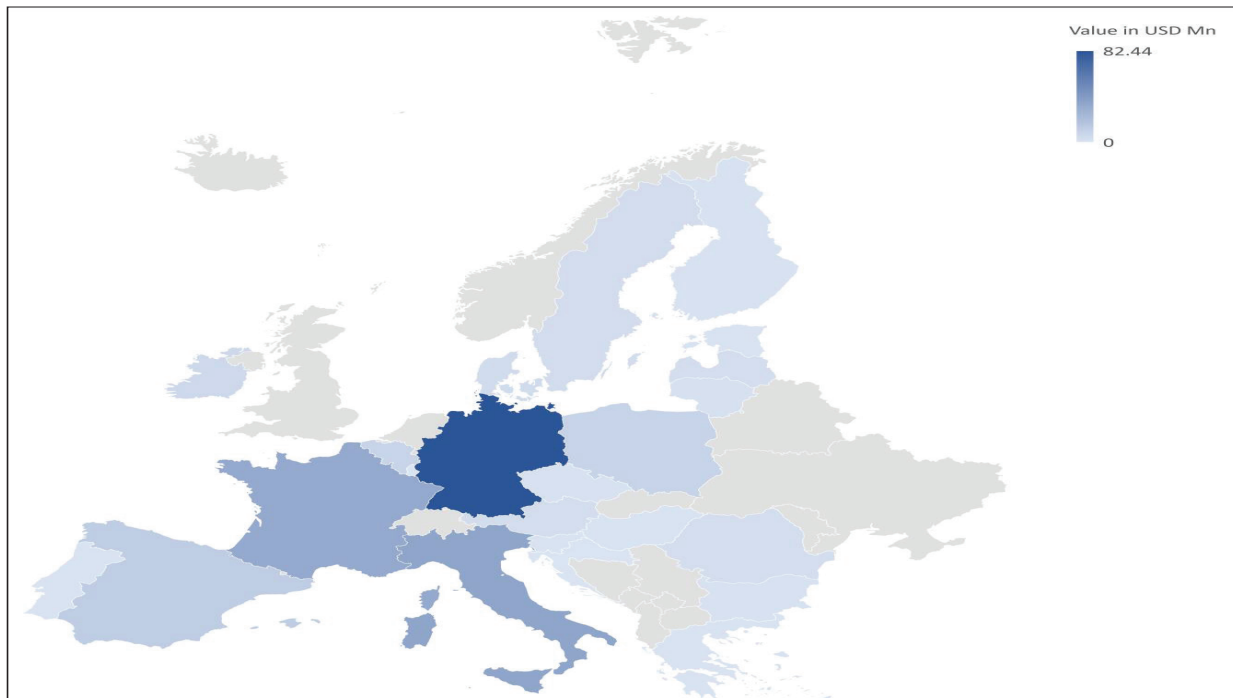
For traditional medicines, including Ayush, under the EU Directive 2001/83/EC, amended in 2004, Directive 2004/24/EC (the Herbal Directive), registration can be undertaken under three regulatory pathways, i.e. Traditional use registration²³, Well-established use registration²⁴ and Stand-alone or mixed application²⁵ although all three pathways come with their unique set of challenges.

Table 4.1: India's Ayush Exports and Major Importing Countries in EU

Categories	Value exported in 2021(USD Mn)	CAGR (%) (2017-2021)	Share as % of total Ayush exports (2021)	Major Importers (2021)
MAPs	138.49	4.64	58.81	Germany (46.06%) Italy (14.56 %) Netherlands (7.88 %) France (7.10 %) Belgium (4.42%)
Extracts	64.26	17.94	27.29	Germany (27.00%) Italy (21.44%) France (19.08%) Netherlands (7.05%) Spain (6.32%)
Medicants and Medicaments	32.72	11.40	13.90	France (33.80%) Netherlands (13.48%) Poland (12.38%) Italy (5.01%) Spain (5.53%)

Source: Authors' compilation based on Directorate General of Commercial Intelligence and Statistics (DGCI&S). Accessed on December 28, 2022

Figure 4.1: Ayush Exports to EU 2021 (Value in USD Mn)



Source: Authors' calculation based on Directorate General of Commercial Intelligence and Statistics (DGCI&S)

Traditional use registration

Traditional use registration, also called simplified registration procedure, was introduced by Directive 2004/24/EC. This registration is designed for herbal medicinal products with a long tradition of medicinal use (at least 30 years, including 15 years in the EU), which can be used without the supervision of a medical practitioner and are administered orally or externally. For registration of a Ayush herbal medicinal product with the simplified registration procedure, supporting evidence of traditional use in the EU is always an unavoidable challenge, which must be demonstrated with bibliographic or expert evidence.

Broadly, for traditional use registration, the product:

- Requires no clinical tests and trials on safety and efficacy.
- Requires submission of bibliographic safety and efficacy data.
- Must have been used for at least 30 years, including at least 15 years within the EU.
- Is intended to be used without the supervision of a medical practitioner and are not administered by injection.

Well-established use marketing authorization (MA)

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.

Stand-alone or mixed application for MA

Stand-alone or mixed application is only applicable for novel herbal medicinal products based on own research and development. This application requires a complete dossier of clinical data, and it is not different from western medicine MA application. There is also an option for combination with bibliographic data.

Traditional use registration can be applied in national competent authority of a Member State for national, mutual recognition or decentralized procedures. Well-established use MA and stand-alone or mixed application for MA can be applied not only in national, mutual recognition and decentralized procedures, but also centralized procedure in the European Medicines Agency (EMA). With the national procedure, the traditional use registration can

Box 4.1: Definition of Traditional Herbal Medicines

Under the EU Herbal Directive 2001/83/EC, Traditional Herbal Medicines are defined as 'having indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment; they are exclusively for administration in accordance with a specified strength and posology; they are an oral, external and/or inhalation preparation; the data on the traditional use of the medicinal product are sufficient; in particular the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience; bibliographical or expert evidence to the effect that the medicinal product in question, or a corresponding product has been in medicinal use throughout a period of at least 30 years preceding the date of the application, including at least 15 years within the EU Community'.

Source: EU Herbal Directive 2001/83/EC

be applied for competent authority of a Member State and is only valid in this country. For the mutual recognition procedure, the registration application is based on the recognition of a pre-existing national registration by the Reference Member State (RMS²⁶), and then submitted to another or more EU countries. For the decentralized procedure, the registration application is submitted simultaneously in several EU countries, one being chosen as RMS.

To register an Ayush herbal medicinal product in the EU medicinal market, traditional use registration is easier than the other two regulatory pathways.

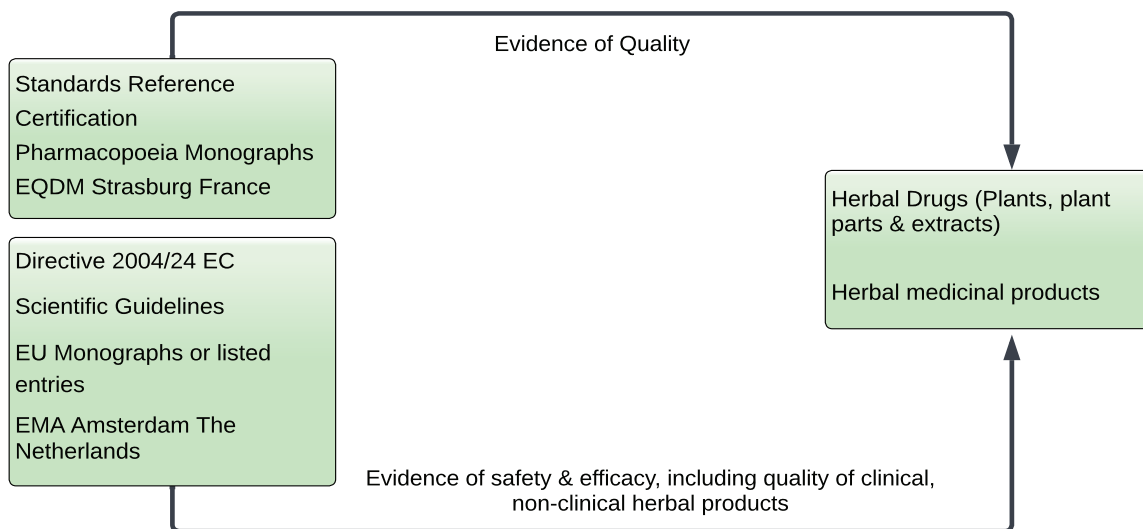
4.4 Network of EU Herbal Medicine Regulatory System: EMA, EDQM and Working Parties

The EU regulatory framework for traditional medicinal products is complex. It is based on a network of the regulatory authorities from the European Economic Area countries, the European Commission, the EMA and the European Directorate for the Quality of Medicines and Health Care (EDQM). The EMA is a decentralized agency and is responsible

for the establishment of scientific guidelines, EU monographs, drafting an EU list of herbal substances, preparations, and combination for use in traditional herbal medicinal products, and the scientific assessment, administration and safety monitoring of medicines on behalf of the European Commission. The EU monographs however are distinct from the monograph of the European Pharmacopoeia (Ph Eur). While the former provides scientific evidence for safety and efficacy for herbal medicinal products, the latter provides scientific evidence for the quality of herbal drugs²⁷.

Medicinal products including herbal medicinal products are authorized / registered by the European Commission/EMA or the regulatory bodies at national level. The EDQM is an organization of the Council of Europe that enables the development, supporting the implementation, and monitoring the application of quality standards for medicines and their safe use²⁸. The EDQM develops the Ph. Eur., which covers the quality requirements for a wide range of substances, including herbal drugs often consisting of whole plants or parts²⁹ and extracts. General quality matters

Figure 4.2: EU Herbal Medicine Regulatory Network



Source: Authors' compilation based on various sources

are also addressed in scientific guidelines issued by the EMA such as the declaration of herbal ingredients in herbal medicinal products, specifications such as test procedures and acceptance criteria for herbal ingredients, preparations and medicinal products. The EMA and the EDQM together regulate medicinal plants, parts, extracts and herbal medicinal products in the market. Therefore, herbal plants, parts or herbal extracts should at least meet these quality standards in the Ph. Eur., monographs, when applying for marketing authorization (MA) or registration of their medicinal products in the EU. (Figure 4.2)

Relevance of working parties in EDQM for Ayush

The Ph. Eur. and consequently the EDQM then becomes important as a first point of reference for traditional medicines. At the EDQM elaboration and revision of methods and texts is carried out by the Ph. Eur. *Groups of Experts* and *Working Parties*. *Groups of Experts* cover the main scientific topics relevant for the quality control of medicinal products and their constituents. *Working Parties* are appointed for a defined period to deal with a specific aspect of the work or with a specific topic. The European herbal drugs (including plants, plant parts and extracts) quality monographs have been established by a group of scientists/experts through the Working Party 13A which consists of the scientists/experts from different member states.

Based on the survey of strategies adopted for Traditional Chinese Medicine (TCM)'s registration in EU (Leong et al, 2020, Wang et al, 2022), it was found that the establishment of a *TCM Working Party* at the European Directorate for the Quality of Medicines and Health Care (EDQM) has been an important strategy. Among several other *Working Parties*, the TCM Working Party for the quality monographs for Chinese herbal drugs in the Ph. Eur. has also been set up. This perhaps explains inclusion of

seven TCM products in EU and may be used as a reference for India's strategy for market entry in EU (Elaborated further in Section 5).

4.5 Legal Requirements for Food Supplements: Pathway Adopted by Indian Exporters

Till date no Ayush pharmaceutical has been registered as a medicine in EU. Based on interviews with industry representatives, herbs, extracts and finished goods are exported as food/dietary supplements, natural ingredients, food additives, spices and herbs.

Notification as sufficient regulatory requirement for marketing supplements

Food supplements can be placed in the market by notifying the competent authority, as per the EU food supplements legislation³⁰, Directive 2002/46/EC. The claims made for ingredients such as vitamins and minerals are organised under the European Food Safety Authority³¹. However, only the rules applicable to the use of vitamins and minerals in the manufacture of food supplements are laid down in the Directive. 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. The use of substances other than vitamins or minerals in the manufacture of food supplements for example Indian Gooseberry, i.e. *Emblica officinalis* or Amla extracts therefore continues to be subject to national rules. Implementing measures are adopted by Member States to establish the specific values for maximum and minimum levels for vitamins and minerals present in food supplements.

The General Food Law 2002³² is the legislative framework regulation for food safety in Europe. Food safety includes requirements on maximum residue levels (MRLs)³³, contaminants in food³⁴, microbiological contamination of food³⁵ and food hygiene³⁶. 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.³⁷ All food business operators need to implement the Hazard Analysis of Critical Control Points (HACCP)³⁸ system in their daily operations. Conformity assessments are comparatively more strict 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 and accepted or 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 list³⁹. 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 Law⁴⁰. 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.

For Ayush MAPs what could be of advantage is that this law includes exceptions for traditional food products from third countries. For these foods, there is a simplified notification process.

This applies to products from plants, animals and microorganisms from primary production that are not processed or are made with simple processing. A documented continued use of at least 25 years in the normal diet of a significant number of people in at least one country outside the EU however, is required⁴¹.

4.6 Legal Status and Regulation of CAM in EU

While market authorization of herbal and homeopathic products is regulated similarly in each country in accordance with EU Directives, there is no common approach to the regulation of CAM practice in Europe. There is a lack of coherence in training, education and provision of CAM in EU at the moment. The EU has, however, repeatedly confirmed that it is up to each member state to organize and regulate their health care system which also applies to CAM. Despite this, the Cross-border Healthcare Directive 2011/24/EU⁴² together with other Directives indirectly encourage some degree of harmonization. CAM practitioners can be registered in the European Commission database of regulated professions, and patients will probably have certain rights according to the Cross-border Healthcare Directive.

Ayurvedic medicine is directly mentioned in regulations in 4 out of 27 countries⁴³. For example in Hungary as per governmental decree 40/1997, Ayurvedic medicine is "an individual complex medical system" provided only by medical doctors⁴⁴. CAMbrella (2012) outlines that in Latvia Ayurvedic medicine has a legal status and was recommended as safe to wide application in the institutions of public health services", in Romania ayurvedic medicine is "legally recognized as a CAM therapy in the group "alternative therapies" in the law on CAM" and Slovenia has listed ayurvedic medicine in the CAM act as "a CAM system that may be used when carrying out CAM practices". In some countries Ayurvedic medicine is recognized as a therapeutic system

Table 4.2: Regulated CAM Practice in EU

	Ayurveda	Herbal medicine/ Phytotherapy	Naturopathy
Regulated treatment (Not regulated profession)	Hungary	Bulgaria	Cyprus
	Latvia	Germany	France
	Romania	Hungary	Germany
	Slovenia	Portugal	Portugal
		Romania	Romania
		Spain	

Source: CAMbrella, 2012

that may be provided by regulated health personnel (often doctors), but not directly mentioned in the regulations (CAMbrella, 2012). More information is required on these regulations.

EU countries also regulate several other forms of CAM such as Herbal medicine and Naturopathy (Figure 4.2). Ayurveda could be practiced albeit under certain terms and conditions. For example, Germany regulates Herbal medicine or Naturopathy practice and has no specific regulation on Ayurveda. However, Ayurveda as a system is practiced under the broader category called “Heilpraktiker” wherein the “Heilpraktiker” must pass a public exam in conventional medicine subjects and register in order to get the licence to practise. Over 20,000 Heilpraktiker are members of the six leading Heilpraktiker associations⁴⁵.

4.7 Key Barriers

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.

Rules concerning nutrients as ingredients of food supplements are defined at the national level

The EU food supplements legislation⁴⁶, 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 authorized/ 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 2018⁴⁷. Natural ingredients are to be registered for use if they are not listed in the EU Novel Food Catalogue⁴⁸. 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 fast emerging 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) guidelines⁴⁹ 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 safety⁵⁰ 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.

Section: 5

UAE

5.1 Market Profile

The Middle East region comprising of countries like UAE, Saudi Arabia, Kuwait and Egypt is fast emerging as an export destination for traditional medicines. The market size was valued at USD 4.52 Bn in 2019 and is expected to grow at a CAGR of 22.75 per cent from 2020 to 2027 as per Grandview Research report (2021). UAE is expected to be the fastest growing country in the region owing to several factors. This includes high per capita spending, epidemiological profile of a developed region with high incidence of NCDs. Cardiovascular diseases (40 per cent) chronic respiratory diseases (5 per cent) Diabetes (5 per cent) cancers (15 per cent) are some of major NCDs. Overall NCDs account for an estimated 77 per cent of all deaths (WHO, 2018). Most importantly the high adoption of T&CM aided by formal recognition of such systems through

professional licences for practice of T&CM has enabled expansion of clinics/healthcare service providers and consumption of traditional medicine including Ayurveda⁵¹.

5.2 Exports to UAE: Emerging Trends and Patterns

Despite the size and population, UAE has come to claim a high proportion of India's Ayush exports (5.52 per cent) in 2021. Total exports of Ayush products to UAE have grown at 14.23 per cent during 2017-21. Ayush pharmaceuticals constitute 30 per cent 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 (Table 5.1) in UAE, although extracts exports have grown at an impressive 28.9 per cent over the period 2017-21.

Table 5.1: India's Ayush export to UAE (Value in USD Mn)

Category	Value exported in 2021(USD Mn)	CAGR (%) (2017-21)	Share as a % of total Ayush export (2021)
MAPs	34.02	17.13	48.82
Extracts	14.50	28.87	20.81
Medicants and Medicaments	21.16	5.33	30.37

Source: Authors' compilation based on Directorate General of Commercial Intelligence and Statistics (DGCI&S). Accessed on December 28, 2022

5.3 Registration as Drugs: Simplified Regulatory Systems for Ayush

UAE has adopted traditional medicine as an important part of disease management with a regulatory system in place for registration and import as drugs. For Ayush this has been one of the main reasons for high volume of export despite the smaller geography and population as compared to US and EU. Traditional, complementary and alternative medicine (TCAM) is regulated jointly by two departments at the Ministry of Health. The Drug Department regulates the registration of herbal, homeopathic, Ayurvedic and Chinese medicine, as well as natural products drugstores and pharmacies, while the Complementary and Alternative Medicine Unit coordinates the licensing and regulation of TCAM practitioners⁵².

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”⁵³. Traditional, herbal, complementary, and alternative medicine all fall under the purview of the aforementioned definition. Market authorisation for herbal medicines such as Ayurveda are taken through registration of ‘Pharmaceutical Product Derived from Natural Sources’⁵⁴. 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 Health⁵⁵. Registration requirements for evidence of quality, safety and efficacy include Certificate of pharmaceutical product (CoPP) or certificate of free sale of the product issued by the competent authorities in the country of origin⁵⁶. 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. 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 product⁵⁷.

5.4 Regulation of Traditional Medicine Health Professional License

Similar to market authorisation simplified regulation of TM service and practice makes UAE an ideal destination for services export. The UAE issues professional licence in the fields TCAM, viz, Ayurveda, Chiropractic Medicine, Homeopathy, Naturopathic Medicine, Osteopathic Medicine, Therapeutic Massage, Traditional Chinese Medicine, Unani Medicine. While licence requirements vary across the Emirates, broadly Ayurveda practice licence can be obtained with a degree from accredited University, five years of clinical experience and English proficiency among others⁵⁸.

5.5 Key Barriers

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 per cent UAE ownership, are permitted to obtain licenses for import of Ayush goods⁵⁹. However, the licensing requirement does not apply to goods imported into free zones⁶⁰. There is one free zone for healthcare in UAE, i.e., the Dubai Healthcare City.

High SPS and TBTs for imports of MAPs and Extracts

Based on data available, despite encouraging growth of MAPs and Extracts exports to UAE, the state imposes high number of SPS and TBT measures as compared to US and EU.

High Tariffs for imports of Ayush

As compared to US and EU, UAE imposes comparatively higher tariffs for Ayush commodities (Table 6.1) .

Section: 6

Findings and Recommendations

Steady regulatory development in traditional, herbal, complementary and alternative medicines and allied services globally has been aiding Ayush goods export from India. USA, EU and UAE constitute major export destinations. Between 2017-2021 exports to few countries have recorded impressive growth. This includes Russia and Poland. Apart from Tariffs, TBTs, SPS, Pre-shipment formalities, non-technical barriers like non-automatic import licences as the main NTBs applicable to Ayush commodities under study. The ease of navigation of regulatory requirements for Ayush in major international markets has not been uniform. However, Indian exporters have adapted well with the available pathways and have managed to penetrate these markets.

It may be pointed out that barring UAE, Ayush pharmaceuticals are being marketed and distributed as herbal dietary supplements in other countries/regions under study (USA,

EU). Despite market authorisation registration provisions through the Herbal Directive in EU and Botanical Drug registration provisions in US Ayush pharmaceuticals have not yet been registered as drugs in these markets. It can be inferred that Ayush drugs' compliance with norms on traditional/herbal/botanical drugs, as the case may be, has been a challenge. 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.

In USA drug registration under the Botanical Drug category can be a market authorisation pathway for Ayush, although no Ayush drug is registered as yet. Ayush pharmaceuticals are being exported and distributed as dietary supplements owing to the limited regulatory

Table 6.1: Commodities as Percentage of Ayush Exports in US, EU and UAE (2021)

Countries	MAPs (%)	Extracts (%)	Pharmaceuticals (%)
USA	37.92	57.25	4.83
European Union	54.34	30.26	15.41
UAE	48.82	20.81	30.37

requirements although health claims are not permitted for labelling of dietary supplements. While Ayush systems are not yet recognised as medical systems, the emerging scenario whereby eleven states have enacted laws for C&AM practice is expected to open more opportunities for Ayurveda drugs exports in future. 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.

In EU, the Herbal Directive provides for drug registration of traditional herbal medicines. No Ayush pharmaceutical is registered as a herbal medicinal product in EU yet. Ayush drugs, MAPs and extracts are mostly marketed as food/dietary supplements. Food supplements can be placed in the market by notifying the competent authority, as per the EU Directive 2002/46/E. While EU provides a framework within which the food supplements and ingredients sector operates, regulatory differences at the national level exist. Conformity Assessment including traceability in EU are a major challenge as EU increasingly looks at more strict mandatory compliance of several standards. It is tough to draw a direct linkage with CAM service law and regulations to exports of Ayush drugs. While France has no specific law on Ayurveda practice, it still constitutes the biggest per centage of Ayurveda drugs to EU. At the same time while Germany has a long history of Ayurveda related practice, exports of Ayurveda goods constitutes a small per centage as compared to MAPs and extracts.

UAE allows for Ayush pharmaceuticals to be marketed as drugs. Similarly, the regulatory framework for Ayush services is made easy by regulatory provisions for medical care under TC&AM with professional licence for Ayurveda, Homeopathy and Unani medicine practitioners. Even with the comparatively

smaller size and population UAE has emerged as a major destination for Ayush exports owing to the inclusive regulatory ecosystem for TC&AM drugs and services although NTBs are high for the country.

Based on the study of regulatory profile of the three countries/region the following major observations have been made. These may also be considered as findings on the basis of which further actions/initiatives are recommended.

6.1 Key Recommendations

Botanical Drug Registration for Single Herb Ayush Products in USA

In the past a small number of herbal products have been approved for sale as 'botanical drugs' (see Section 3). Single herb botanical drug substances (e.g., Psyllium and Senna) are included in the OTC drug review, and witch hazel is currently marketed under an OTC drug monograph. The FDA classifies selected defined psyllium substances (Plantago Seed USP, Psyllium Hemicellulose USP, Psyllium Husk USP, and Psyllium Hydrophilic Mucilloid for Oral Suspension USP) as Generally Recognized as Safe and Effective (GRASE) bulk-forming active ingredients of laxative drug products. For India, the relevance of products like Psyllium is demonstrated by the fact that Psyllium (husk and seeds) constitutes the highest per centage (86.26 per cent in 2021) of India's total MAPs export to USA. Registration strategies of Ayush products, beginning with single herb botanical drugs, may earn substantial exports similar to psyllium.

A Working Party for Ayurveda in the EDQM, EU

So far, several herbal Traditional Chinese Medicine (TCM) medicinal products have been successfully registered by simplified registration procedure in the EU. This includes five single herbal medicinal products and two

multi-herbal combination products. Based on the survey of strategies adopted for TCM, the establishment of a TCM Working Party at the European Directorate for the Quality of Medicines and Health Care (EDQM) has been an important strategy. In EU, the European Pharmacopeia (Eur Ph) and the EDQM are important as a first point of reference for traditional medicines registration process (For details see Section 4). The Working Parties in the EDQM are appointed for a defined period to deal with a specific aspect of the work or with a specific topic. Among several Working Parties, the TCM Working Party for the quality monographs for Chinese herbal drugs (plants, parts and extracts) in the European Pharmacopeia has also been set up since 2008 and has guided in building the TCM Monographs in Eur Ph. This has formed the reference for registration of TCM products in EU. It is recommended that the Ministry of Ayush initiate setting up a similar Working Party for Ayurveda at the EDQM for enabling understanding and inclusion of Ayurveda monographs.

Bilateral Engagement for Tariffs and NTBs; High NTBs for MAPs and Extract in UAE and EU

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 6.1 and Figure 6.1 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.

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 trade barriers specially for medicinal plants and extracts.

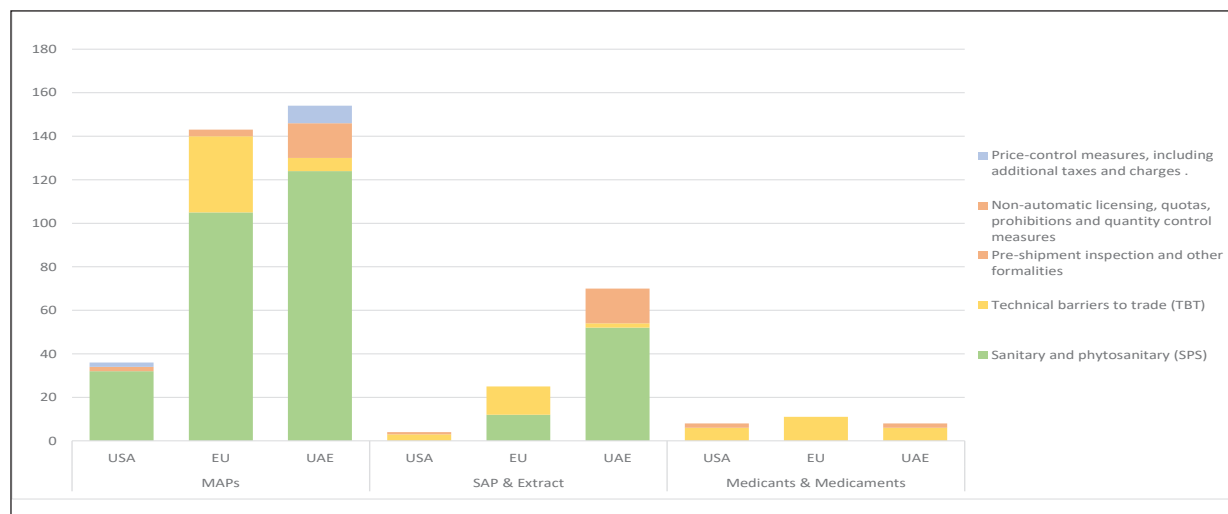
The NTMs outlined in Figure 5.2 are described in Annexure. SPS are most challenging NTBs specially for MAPs and Extracts. The most common SPS measures for MAPs for example in EU include prohibitions/restrictions of imports for SPS reasons, such as plants and plant products and their protection in Regulation (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

Table 6.2: Effective Applied Tariff Rates for Ayush products

Countries	Spices	MAPs	Extracts	Medicants	Medicaments
European Union	0.52	0	0	0	0
United Arab Emirates	5	5	5	0	0
United States of America	0.71	1.9	0.32	0	0

Source: WITS database.

Figure 6.1: 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						

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. One of the Non- technical barriers to trade in EU includes the Non-Automatic Licensing is applied to Endangered species to control imports of endangered species listed in Appendices I, II, and III of CITES. In UAE, an important export barrier to UAE under this law is the import licensing requirements where only UAE-registered companies, with least 51 per cent UAE ownership, are permitted to obtain licenses for import of Ayush goods¹.

Data on country wise permissible list of MAPs for Exports

Many of the significant Indian 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 and may be addressed by the Ayush Export Promotion Council (AEPC).

Services export through Mode 3, and Mode 4; Effective strategies for quality health professionals to drive sales of Ayush pharmaceuticals

Despite the geographical size UAE has emerged as an important market facilitated by enabling laws permitting practice of Ayush and other

traditional medicine systems. The UAE issues professional licence in the fields of Traditional, Complementary and Alternative Medicine (TCAM) with structured regulations for practice and professionals. Mode 3, i.e., commercial presence of several Ayurveda hospitals and clinics and Mode 4, i.e., presence of registered practitioners have been contributing to fast growth in consumption of Ayush drugs in UAE. Similarly, while US and EU are yet to recognise Ayush as a medical profession, BAMS (Bachelor of Ayurveda, Medicine and Surgery) graduates can officially practice medicine after having acquired a license, for example as a “Heilpraktiker,” a practitioner of natural medicine in countries like Germany (Rosenberg, 2022). In USA, eleven states have enacted laws for practice of CAM thereby opening avenues for CAM services. Quality health professionals from India can create the relevant demand through consumers/ patients thus driving exports in US and EU in future.

B2C sales and distribution channels through capacity building for small manufacturers

Distribution channels of TCAM from India to all three countries/regions, include five major pathways. This includes 1) wholesale distribution companies servicing retail stores, 2) wholesale distribution companies servicing practitioners (Doctors of TCM, Ayurveda, Naturopathy, among others), 3) mail order companies servicing consumers, 4) online e-commerce platforms and 5) Own Company Outlets (health stores, clinics, daycare centres and spas).

Based on interviews with industry representatives, the marketing channel adopted by most exporters is through the B2B for all categories –herbs, nutraceuticals and Ayush pharmaceuticals. Often, importers are distributors marketing a domestic brand or entities selling brands of the exporter. For example, importers can import foods into the United States without prior sanction by FDA, provided the facilities that produce, store, or

otherwise handle the products are registered with FDA, and prior notice of incoming shipments is provided to FDA. This export pathway requires adherence to standards indicated by the importer.

The B2B supply chain of Ayush goods is often long and is riddled with several middlemen on both sides of the border. Small manufacturers often do not export directly but their authorized dealers are exporting their products to countries they desire to

eventually export and market products directly to selected markets. Barring countries like UAE with regulatory norms inhibiting direct sale of goods, it is possible to manage the supply chain integration by reducing the number of middlemen from the producer to the consumer. Stronger market linkage, market information and quality processing with standards subscriptions adhering to conformity assessment requirements can enable B2C exports of Ayush.

Non- Tariff Measure Classification

A. Sanitary And Phytosanitary Measures

A1 Prohibitions/restrictions of imports for sanitary and phytosanitary reasons

A12 Geographical restrictions on eligibility

A13 Systems approach.

A14 Authorization requirement for sanitary and phytosanitary reasons for importing certain products

A15 Authorization requirement for importers for sanitary and phytosanitary reasons

A19 Prohibitions or restrictions of imports for sanitary and phytosanitary reasons, not elsewhere specified.

A2 Tolerance limits for residues and restricted use of substances

A21 Tolerance limits for residues of or contamination by certain (non-microbiological) substances

A22 Restricted use of certain substances in foods and feeds and their contact materials

A3 Labelling, marking and packaging requirements

A31 Labelling requirements

A33 Packaging requirements

A4 Hygienic requirements related to sanitary and phytosanitary conditions

A41 Microbiological criteria of the final product

A42 Hygienic practices during production related to sanitary and phytosanitary conditions

A49 Hygienic requirements not elsewhere specified

A5 Treatment for elimination of plant and animal pests and disease-causing organisms in the final product or prohibition of treatment

A59 Treatments to eliminate plants and animal pests or disease-causing organisms in the final product not elsewhere specified or prohibition of treatment

A61 Plant-growth processes

A63 Food and feed processing

A64 Storage and transport conditions

A8 Conformity assessment related to sanitary and phytosanitary conditions

A81 Product registration and approval requirement

A82 Testing requirements

A83 Certification requirements

A84 Inspection requirements

A85 Traceability requirements

B. Technical Barriers To Trade

B3 Labelling, marking and packaging requirements

B31 Labelling requirement

B32 Marking requirements

B33 Packaging requirements

B7 Product quality, safety or performance requirements

B8 Conformity assessment related to technical barriers to trade

B81 Product registration/approval requirements

B82 Testing requirements

B83 Certification requirements

B84 Inspection requirements

B85 Traceability requirements

C. Pre-Shipment Inspection And Other Formalities

C1 Pre-shipment inspection

C2 Direct consignment requirements

C3 Requirement to pass through specified port of customs

C4 Import monitoring, surveillance and automatic licensing measures

C9 Other formalities not elsewhere specified

E. Non-Automatic Import Licensing, Quotas, Prohibitions, Quantity-Control Measures And Other Restrictions Not Including Phytosanitary Measures Or Measures Relating To Technical Barriers To Trade

E1 Non-automatic import-licensing procedures other than authorizations covered under the chapters on sanitary and phytosanitary measures and technical barriers to trade

E12 Licensing for non-economic reasons

E125 Licensing for the protection of public health

E3 Prohibitions

E32 Prohibition for non-economic reasons

F. Price-Control Measures, Including Additional Taxes And Charges

F6 Additional taxes and charges levied in connection with services provided by the Government

F61 Custom inspection, processing and servicing fees

F62 Merchandise-handling or -storing fees

F65 Import licence fees

F69 Additional charges not elsewhere specified

Endnotes

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- ¹⁷ Id. see also U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, Overview of Dietary Supplements.
- ¹⁸ Section 6, Dietary Supplement Health and Education Act (DSHEA)
- ¹⁹ Id. see also U.S. Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements, claims that can be made for conventional foods and dietary supplements.
- ²⁰ Josef Brinckmann, 2008, Support to Sustainable Export Development of Indian Natural Medicinal Products: A Needs Assessment Study (India), International Trade Center, Geneva.
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FITM: The FITM has been established in the RIS with the participation of the Ministry of AYUSH as a common platform for all actors and stakeholders to contribute to pragmatic policy-making in the area of Traditional Medicine (TM) and Traditional Knowledge and to develop pro-active policies and strategies. The broad objectives of the FITM are to: undertake/ commission studies on various issues pertaining to Indian TMs, IPRs and regulatory frameworks for traditional medicinal knowledge; examine trade policy with reference to TMs; prepare cogent and coherent policy and strategy responses on emerging national and global developments; provide critical inputs such as policy briefs, briefings and reports to the Government of India in a continued and sustained way; and to facilitate interactions with experts and stakeholders and policy-makers from India and abroad. It would also provide Fellowships and Scholarships for studies in the area of TMs, arrange invited talks by national and international experts, and organize periodic consultations.

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