"Study of Regulations and Market Opportunities of Traditional, Complementary and Integrative Medicines in different countries"

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DECLARATION BY THE STUDENT

I hereby declare that this dissertation titled **"Study of Regulations and Market Opportunities of Traditional, Complementary and Integrative Medicines in different countries"** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in this text.

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List of abbreviations

SI No	Abbreviation	Description
1	TCI	Traditional Complementary Integrative
2	CAM	Complementary & Alternative Medicine
3	WHO	World Health Organization
4	WHA	World Health Assembly
5	NIH	National Institute of Health
6	T & CM	Traditional & Complementary Medicine
7	TM	Traditional Medicine
8	NCOP	National Council of Provinces
9	AR	Accelerated Registration
10	MCC	Medicine Control Council
11	SDG	Sustainable Development Goals
12	ADR	Adverse Drug Reaction
13	GLP	Good Laboratory Practice
14	GMP	Good Manufacturing Practice
15	TCAM	Traditional Complementary Alternative Medicine
16	GACP	Good Agricultural and Collection Practice
17	TM	Traditional Medicine
18	MCC	Medicine Control Council
19	TMPC	Traditional Medicine Practice Council
20	TMP	Traditional Medicine Practitioner
21	TAM	Traditional Alternative Medicine
22	IPR	Intellectual Property Rights
23	TAMD	Traditional and Alternative Medicine Directorate
24	OM	Orthodox Medicine
25	ISM & H	Indian System of Medicine and Homeopathy
26	ISM	Indian System of Medicine
27	AYUSH	Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy
28	CCIM	Central Council of Indian Medicine
29	CCH	Central Council of Homeopathy

30	DCO	Drug Control Organization
31	MFDA	Maldives Food and Drug Authority
32	TTM	Thai Traditional Medicine
33	TCM	Traditional Chinese Medicine
34	OPD	Outpatient Department
35	CTMO	Chief Thai Traditional Medicine Office
36	DTAM	Department of Thai Traditional and Alternative Medicine
37	FDA	Food and Drug Administration
38	THPP	Thai Herbal Preparation Pharmacopoeia
39	DHSS	Department of Health Service Support
40	UAE	United Arab Emirates
41	DHA	Dubai Health Authority
42	SOP	Scope of Practice
43	NCT	National Council for Tibb
44	NCH	National Council for homeopathy
45	SIPO	State Intellectual Property Office
46	SATCM	State Administration of Traditional Chinese Medicine
47	SFDA	State Food Drug Administration
48	OMP	Orthodox Medicine Practitioners
49	ISO	International Organization of Standardization
50	JP	Japanese Pharmacopoeia
51	PAFSC	Pharmaceutical Affair and Food Sanitation Council
52	TGA	Therapeutic Good Administration
53	OCM	Office of Complementary Medicines
54	ACCM	Advisory Committee on Complementary Medicine
55	OMM	Osteopathic Manipulative Medicine
56	GSP	Good Supply Practice
57	MHLW	Ministry of Health, Labor and Welfare
58	NCCIH	National Centre for Complementary and Integrative Health
59	CARG	Compound Annual Growth Rate
60	FDI	Foreign Direct Investment

INTRODUCTION

1. Introduction

Traditional, complementary, and integrative medicine (TCI) is a global entity that coordinates to leverage TCI medicines potential contribution to integrated health services, Health-related Sustainable Development Goals (SDG) and Coverage of Universal Health. [1]

According to World Health Organization (WHO), 65% to 80% TCI drugs are used in global healthcare practices.[2] In developing countries, more than 70% of the population still depend on TCI practitioners and their conventional medical knowledge to address healthcare requirements because of cultural and economic reasons. TCI is a heterogeneous field. Rather , it is a broad word encompassing more than 100 healing philosophies, methods, and treatment modes that allopathic medicine rarely studies, accepts, uses, or makes available.

Traditional medicine (TM) research gained pace after the World Health Assembly (WHA) raised awareness of its potential applicability by encouraging member states to employ TM practices in basic health care. Traditional medical practitioners (TMP), disease classification, a diagnostic system, and local concepts of sickness and illness were all investigated as part of the TM research. According to the WHO, Medicinal plants play a major role in the health-care systems of the poor nations. Alma Ata Conference in 1978 confirmed this, urging nations to prioritize using TM in their drug laws and regulations.[3]

1.1 Definitions according to WHO:

Traditional Medicine: **“**As defined by WHO, TM is the sum total of the knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness.” [1]

Complementary Medicine: **“**The terms ‘complementary medicine’ or ‘alternative medicine’ refer to a broad set of health care practices that are not part of that country’s own tradition or conventional medicine and are not fully integrated into the dominant health-care system. They are used interchangeably with traditional medicine in some countries.” [1]

WHO's Traditional and Complementary Medicine (T & CM) unit has been renamed "Integrated Medicine" in mid-2017 to encompass both T & CM and mainstream medicine's integrative approaches to policy, knowledge, and practise. Integrative is the name given to the unit presently. [4]

Herbal Medicine: "Herbal medicines include herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations." [1]

1.2 Five domain classification of TCI:

Numerous techniques lack widespread medical approval and lack scientific validation. The National Institutes of Health (NIH) in the United States has divided these techniques into five overlapping categories in order to organise a research agenda for these approaches.

1) Interventions with the mind-body
2) Methods that are grounded in biology
3) Energy medication
4) Body-based techniques and manipulative techniques
5) Integrated healthcare systems

1) Mind-body interventions:

The intrinsic linkages between ideas and physiological functioning are honoured in mind-body medicine. The mind and emotion are used to influence one's health and well-being in this therapy practise.

Example: Meditation, Hypnosis, Yoga, Biofeedback, Guided imagery, etc

2) Biologically based practices:

A purely biological approach involves using the body's own defenses—herbs, food, and vitamins—to strengthen, heal, and maintain equilibrium.

Example: Herbal products, Prebiotic, Amino acids, Fatty acids, etc

3) Energy medicine:

Energy therapies manipulate energy fields in order to enhance health and healing. NIH defines two separate classes.

• Biofield therapies Biofeedback refers to interventions that exert direct or indirect pressure on the energy fields that encircle and pierce the human body.

• Example: Reiki, Healing touch, Qi gong, etc

• Bioelectromagnetic-based therapies: There are methods that make usage electromagnetic fields in an unusual manner to aid healing.

Example: Pulsed, Direct current, Magnetic current, etc

4) Manipulative and Body-based practices:

It's a type of therapy that involves manipulating body parts while concentrating on the structures and processes of the body.

The body's systems include its bones and joints, soft tissues, circulatory, and respiratory systems.

Example: Chiropractic, Osteopathy, Reflexology, Massage, etc

5) Whole medical systems:

Whole systems of TCI are characterised as whole systems of thought and practise that have emerged independently of or in tandem to mainstream medicine.

Example: Homeopathy, Ayurveda, Naturopathy, etc.

T & CM is a vital and underutilised health resource with a wide range of applications, including the management and treatment of chronic illnesses linked to lifestyle choices as well as meeting the needs of ageing populations in terms of health. At a time when views are expanding, costs are rising, and the majority of economies are stagnant or contracting, many countries are working to extend access to basic healthcare benefits. T & CM are currently seeing a revival as a result of the unique health challenges..

The vast contrasts between the two systems, as well as the places where they overlap, should be taken into consideration by nations that desire to handle the unique health concerns of the twenty-first century. In a perfect society, TM would appear to be a treatment option provided by an effective, personalised healthcare system that incorporates curative and preventative care. [4]

LITERATURE REVIEW

2.Literature review

The WHO has performed two global surveys on TCI, the first in 2005 and the second in 2012. According to current data, 88% of Member States which corresponds to 170 countries, have acknowledged their usage of TCI.[4] The countries that have formally implemented TCI policies, laws, rules, programmes, and offices, as well as the total number of countries that employ TCI.

2.1 WHO regions

WHO has divided world into six regions.

1) African region
2) South-East Asia region
3) Eastern Mediterranean region
4) Region of the Americas
5) European region
6) Western pacific region

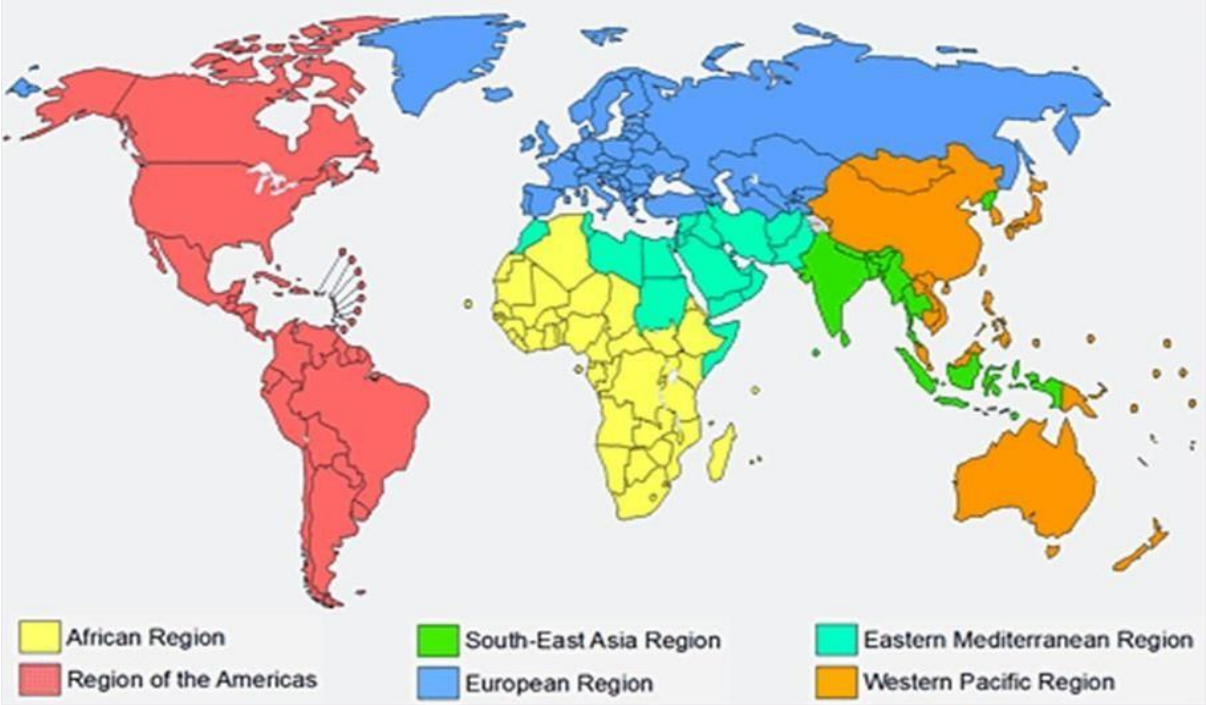

Figure 1: Six WHO regions

Source: WHO-Regions-WHO-Member-States-are-grouped-into-six-regions-Each-region-has-a-regional_fig1_333761265

WHO African region:

The WHO African region establishes national policy, controls T & CM and herbal medicines, and employs T & CM, as well as comparing regional percentages to global percentages for each indicator. Regional member states taken initiatives between year 2005 and 2018 to start developing national policy and regulations frameworks of T & CM practitioners and to undertake a number of key interventions. [4]

While the countries surpassed the general situation in practically every metric since around 2018, the region's percentage of Member States was lower than the world norm in two areas: regulation and herbal medicine registration. Latest update on TCI:

- Acupuncture has been shown to be effective in managing a variety of pain disorders, as well as hypertension, sadness, and sickness in the morning. It can alsohelp with post-operative pain and chemotherapy side effects.
- Chinese herb Artemisia annua, which has been proven to be successful over resistant malaria, and might be a major step forward in the fight against the disease's over 1 million yearly deaths.
- The plant Sutherlandia microphylla is being researched in South Africa for usage in HIV patients. In HIV-positive persons, the plant may boost their vitality, appetite, and body mass.[1]

Countries:

South Africa:

In 1996, as part of the national drug strategy, South Africa developed a national policy on T & CM. The Chiropractors, Homeopaths and Allied Health Service Professions 2nd Amendment Act of 1982 governs alternative medicine on a nationwide level. For TM, there is no national legislation or regulation.

The Directorate of TM, which has been formed in 2006, is the national headquarters for T & CM. The South African Medical Research Council, who includes a TM section, is supported by the government. Having 63 pharmacopoeias including monographs published in 2010, the South African Pharmacopoeia Monograph Program was implemented in 2010. Herbal medicines are not governed on a national basis; nevertheless, under planned laws herbal

medications should, at least to some extent, be monitored in the same manner as conventional pharmaceuticals. [4]

Ghana:

The Policy of TM Development in Ghana, which itself is connected to the Programme on Genetic Resources Protection, is Ghana's government policy on T & CM. T & CM's national office is the Ministry of Health's Traditional and Alternative Medicine Directorate. The Department for Scientific Research into TM plants is Ghana's T & CM research center. National laws and regulations regulating T & CM have included Food and Drugs Law of 1992,with Pharmacy Act of 1995 as well as the TMP Act. [4]

Nigeria:

Despite various actions, policies, and statements aimed at promoting Traditional Complementary and Alternative Medicine (TCAM) in Nigeria over the last few decades, implementation has been slow, primarily because some of these policies have failed to address challenges related to TM, such as recognition, uniform quality standards, drug availability, education standards, and evidence-based research. Country have limited regulations andCouncil for TCI. [4]

WHO South-East Asia region:

From 2005 to 2018, the region's Member States showed a significant commitment to T & CM policy, law, regulation, and national infrastructure.10 of the 11 member states in the region said they had a national T & CM policy, programme, office and expert committee. The area isalso well-known for its residents' use of T & CM. The number of countries regulating herbal medicine has increased the greatest, from seven in 2005 to ten in 2018. The number of Member States holding state research institutions for herbal remedies as well as T & CM, on the other hand, remained stable and showing that there is still opportunity for progress in the region. [4]

The South-East Region Publications Office works closely with WHO Press to become an important element of the WHO's knowledge management and communications culture. Each publication, which is closely linked to WHO's work, articulates a component of a global strategy, delivering information that can help move the world ahead via the protection and promotion of health, as well as a commitment to quality and focus on customer service. In October 2015, a regional action plan on TM was prepared following the 2013 Delhi Declaration on TM and support of WHO TM Strategy 2014–2023.

There are five areas of activity in this:

1) Surveillance of the TM system.

2) Advancing study into the organization and management of TM systems.

3) TMP/workforce capacity-building.

4) Systems for reporting adverse events.

5) Clear and concise communication. [1]

Countries:

India:

In 2002, the National Policy on Homoeopathy and Indian Systems of Medicine was published. Examples of national law on T & CM (amended in 2009) include the Drugs and Cosmetics Act of 1940, the Homoeopathy Central Council Act of 1973, and the Indian Medicines Central Council Act of 1970.

The Indian government established the Department of Indian Systems of Medicine and Homoeopathy in 1995 to serve as the national headquarters for T & CM, which is overseen by the Ministry of Health. The department's name was then changed to Department of Ayurveda, Yoga, Unani, Siddha and Homoeopathy (AYUSH). In 2014, a distinct Ministry of AYUSH was established. A nationwide effort to include T & CM into the National Health Service was started in 2014. The public sector and the government provide funding to T & CM for research.

Schedule E of the Drugs and Cosmetics Rules also covers herbal treatments. Ayurveda and Unani medicines have their own essential drug list; herbal treatments are classified according to their traditional usage and long record, as well as medical categorization. [4]

Maldives:

There is a policy framework in the Maldives that is exclusively focused on T & CM. The Act includes TM practice, pharmaceutical import and dispensing, A key statute governing complementary and alternative medicine, criteria for awarding TM practitioners licencing to practise, and the provision of traditional and alternative treatments services. The Medicines Act governs T & CM, and an alternative medicine law has been created. The national T & CM policy and legislation have been amended as of the end of 2016.There is also funding for T & CM research by Maldives government. [4]

Thailand:

T & CM Practice Guidelines in Thailand have been developed by the publication "T & CM Practise Guidelines in ASEAN"—an output of the ASEAN partnership in health work plan (2016–2020)—was published by the Department of Thai Traditional and Alternative Medicine (DTAM), Ministry of Public Health. The Protection and Promotion of TTM Information Act B.E. 2542 (1999), a law, protects Thai Traditional Medicine (TTM) one-of-a-kind statute enacted to safeguard and promote TTM knowledge, as well as to foster the long-term usage of TTM knowledge and medicinal plants. [4]

WHO Eastern Mediterranean region:

The region's Member States shown a noteworthy commitment to herbal medicine development and regulation between 2005 and 2018. T & CM is widely used among the population, as indicated by the fact that it is accepted by over 90% of the region's Member States. However, compared to other regions, this region has fewer government policies and programs on T & CM. [4]

A vision of healthy lifestyles and well-being for all people of all ages is included in the 2030 Agenda for Sustainable Development. It uses WHO data and projections from other United Nations organizations to show regional trends for 50 health-related development growth indicators from 2015 to 2019. [4]

Countries:

United Arab Emirates (UAE):

The UAE's national headquarters for T & CM was introduced in 1993 there under Ministry of Health. The Zayed Center of Herbal Research and TM at Abu Dhabi was founded in year 1998. The national law that handles herbal medicines includes Federal Law No. 20 of 1995 for "Medicines and Products Produced from Natural Sources." In order to assure compliance, firms must submit the most recent Good Manufacturing Practice (GMP) by their state communities, as well as specimens of their drugs to a facility certified by government agencies for testing. the same safety regulations apply as they do for traditional drugs. [4]

Pakistan:

In Pakistan, T & CM policy is integrated into the 2001 national health policy. The Unani, Ayurvedic, and Homeopathic Act of 1965 controls T & CM (revised in 1982 and 2003). The

Health ministry is in authority of T & CM. The National Institution of Health's TM Division's Drug Control Organization (DCO) operates as the national T & CM research institute. To gather Adverse Drug Reaction (ADR) data for T & CM goods, an online ADR reporting formhas been available since January 2018. Herbal medications make medical, health, and nutritivevalues claims and they are uncontrolled. [4]

Iraq:

Herbal Medicines Policy were published in 2010, is the national policy for T & CM. Since 1989, a national office under Ministry of Health has already been in handling T & CM concerns. The National Center for Drug Control and Research has a research division. [4]

WHO Western Pacific region:

From 2005 to 2018, the region's Member States demonstrated a strong commitment to T & CM, with 93% indicating that their populace use it. However, the rise of herbal medicine laws, regulations, and licencing did not fully match global percentages. [4]

China:

Traditional Chinese medicine (TCM) has a rather extensive regulatory framework according to the Regulations of the People's Republic of China on TCM, which were established in 2003, and the Perspectives on Developing and Encourage the Growth of TCM, which were released in 2009. The Outline of a Healthy China 2030 Plan, a 15-year plan to improve Chinese citizens' wellbeing, was released in 2016 by the State Council and the Governing Board of the Communist Party of China. The State Council published the Outline of the Strategic Plan for the Development of TCM (2016-2030), making TCM development a national policy. China, the People's Republic Law on Licensed Doctors, established in 1998, regulates all physicians, including those practicing TCM. The TCM Law went into force on July 1, 2017. [4]

Japan:

The Japanese government's attitude against Complementary and Alternative Medicine (CAM) was slow to shift. This was largely due to the fact that traditional medical techniques such as acupuncture and Kampo treatment have long been acknowledged by the government as valid medical practises. [4]

There is no comprehensive national rule or regulation which covers all elements of T& CM, regulations that relate to some sectors do exist. There is no institutional T & CM office

or expert committee; instead, existing agencies and committees deal with specific T & CM issues. The government supports some T & CM research programmes. Herbal medicine (including traditional Japanese Kampo remedies) is regulated by the Pharmaceutical Affairs Law, which was passed in 1960. [4]

Australia:

The National Medicines Policy of 2000 includes T & CM as a national policy in Australia. Prescription and non-prescription drugs, as well as alternative health care products, are all included in the word "medicine." Therapeutic products The Therapeutic Commodities Act of 1989 regulates the production of goods for human use. The Act that establishes the Australian laws governing production, shipping, and sale of therapeutic items is administered by the Therapeutic Products Administration (TGA) of the Australian government as well as the Therapeutic Goods Regulation 1990. Herbal medicine regulation started in 1989. [4]

WHO Region	Member States	National Policies	National or state-level laws & regulation	National Office	National research institute	Registration system	National program
African region	47	40	39	39	29	23	34
South-East Asianregion	11	10	9	10	7	10	10
Eastern Mediterranean region	21	9	12	13	10	17	4
Western Pacificregion	27	17	13	13	9	11	11
European region	53	11	21	15	11	45	7
Region of Americas	35	11	15	17	9	19	13
Total	**194**	**98**	**109**	**107**	**75**	**125**	**79**

Table 1: Number of member states in WHO regions having National policies, National or state level laws and regulations, National Office, National research institute, Registration system, and National program.

Source: Global Report 2019 [online] Available at:<https://www.who.int/traditional-complementary integrative medicine/WHO Global Report on Traditional and Complementary Medicine 2019. pdf. [Accessed 14 December 2021].

1.2 Various TCI Medication/ Practices:

Ayurvedic Medicine:

Ayurveda is an Indian natural treatment method that literally means "knowledge of life." It is a holistic medical method that emphasizes the body, mind, and spirit while attempting to restore the individual's natural equilibrium. Ayurvedic therapies for many ailments have been established in India (such as diabetes, heart disease, and neurological problems). An evaluation of the requirements for randomization, sample size, and appropriate controls in the Indian medical literature revealed that the standard of reported clinical studies in India frequently falls short of modern methodological standards. [6]

Dosha balance is stressed in Ayurveda teachings, and restraining natural desires is deemed harmful and said to cause illness. The three elemental doshas of vata, pitta, and kapha are described in Ayurveda treatises, with balance (Skt. smyatva) resulting in health and imbalance (viamatva) resulting in disease. [7]

Acupuncture:

It's a type of tiny needles are inserted into the body as part of a supplementary treatment. It belongs to TCM. Pseudoscience is acupuncture. Reflexology is normally safe when done by trained experts who utilise disposable needles and clean needle technique. When used properly, it has a low rate of mostly minor side effects. Errors and illnesses do occur, and they are frequently the fault of the practitioner, particularly when sterile techniques are employed. A 2013 study found that during the past ten years, reports of sickness transmission have drastically increased. Pneumothorax and infections were the most often reported adverse effects. [8]

Chiropractic:

It is a discipline of medicine that explores the connection between the human body's structure and function, particularly the spine. Adjustments to the spine or other regions of the body are performed with the objective of correcting alignment abnormalities, reducing discomfort, enhancing function, and promoting the body's natural ability to repair itself. The majority of chiropractic research has centered on spinal manipulation. Some people with low back discomfort, abnormalities of the joints in the upper and lower extremities as well as headaches,

neck discomfort, and benefit from spinal manipulation.

Herbal medicines:

Plant components utilized for their scent, taste, or medicinal qualities are known as herbs. One form of nutritional supplement is herbal medicine. To choose from, there are capsules, tablets, powders, tinctures, oils, etc. Many individuals believe that "natural" products are always safe and good for them. It isn't always the case, though. Herbal medicines aren't exposed to the same level of scrutiny that pharmaceuticals are. Some herbs, such as comfrey and ephedra, are toxic. Some plants may interact with prescription and over-the-counter medications. [10]

There are several methods to consume herbs, but the most popular option is as a liquid in the form of a herbal tea or plant extract. Tisanes, often known as herbal teas, are the liquid that is produced when herbs are extracted into water. There are numerous ways to make tisanes. Plant extracts, such chamomile or mint, are steeped in hot water to create infusions. Decoctions are slow-boiling extracts, usually made from tougher substances like roots or bark. Maceration is the cold infusion of mucilaginous plants like thyme and sage. Since tinctures are alcoholic preparations of herbs, they are stronger than herbal teas. [11]

Homeopathy:

It's a 200-year-old complementary medicine that claims to boost the body's natural healing response and ability to heal itself. According to those who practice it, it is a comprehensive type of medicine based on the concept of treating "like with like." It purports to boost the body's own healing response to illness by using specially made, highly diluted therapies. Homeopaths claim to treat the full person, including personality, lifestyle, and hereditary variables, as well as the disease's history. [12]

The phrase "remedy" refers to a material manufactured according to a specific technique and intended for patient use in homoeopathy; it should not be confused with the popularly recognized definition of the term, which is "a medicine or therapy that heals disease or relieves pain." When prescribing medicines, homoeopathic practitioners employ two sorts of references: materia medica and repertories. A homoeopathic Materia medica, which is a compendium of "drug pictures" ordered alphabetically by "remedy," describes symptom patterns associated with certain treatments. A homoeopathic repertory is a collection of therapies for each symptom in a database of disease symptoms. In homoeopathic therapy, a variety of animal, plant, and synthetic components are used. [13]

Naturopathy:

Naturopathic medicine, often known as "naturopathy," is a style of primary health care that emphasizes the use of natural therapies, medicines, and methods to promote people's inherent healing capacities. Naturopathic medicine, which is based on the premise that nature is the most effective healer, involves both ancient and modern treatments and blends centuries of natural, non-toxic knowledge with cutting-edge medical technology. Naturopathy is a complementary medicine that focuses on holistic health and healing. From prenatal to geriatric care, it incorporates all aspects of family health care. Naturopathic medicine focuses on identifying and curing the underlying causes of a patient's illness rather than just treating the symptoms. Naturopathic therapy is supported by modern scientific research from a range of areas. Despite the fact that both naturopathic and conventional medicine are founded on the same bio-medical sciences and employ the same diagnostic methods, their views and practicesmay diverge. Some of the most popular naturopathic treatments are electrotherapy, magnet therapy, reflexology, wet sheet packs, chest and abdominal packs, and reflexology. [14]

Osteopathy:

To find, treat, and prevent health issues, it involves moving, stretching, and massaging a person's muscles and joints. The principle that a person's health is based on how well their skeletons, ligaments, muscles, and tendons operate together forms the basis of osteopathy. Osteopaths utilise physical manipulation, stretching, and massage to promote joint mobility, ease muscular tension, and more improving blood circulation to tissues, and assisting the body in healing. They employ a variety of methods, but do not rely onmedicines or surgery. [15]

Traditional Chinese medicine:

It is based on the concept that qi, a form of energy, runs along meridians throughout the body. According to this idea, sickness can occur if the flow of qi through certain meridians is disrupted or uneven. TCM has been practiced by doctors in China for thousands of years, and it is gaining favor in many Western countries. [16]

It is a type of medicine was used for many years to treat, prevent, and diagnose disease. Its foundation is the idea that qi, or life force, circulates through the body's pathways and regulates a person's physiological health. TCM aims to restore and harmonise the body's naturally opposing yin and yang energies, which can obstruct qi and lead to sickness. Acupuncture, nutrition, herbal therapy, relaxation techniques, exercise, and massage cupping therapy, moxibution, gua sha, and red sage are all examples of TCM. [17]

Unani:

Unani Medicine is also known as Greco-Arab Medicine. Hippocrates' concept of our humours, which comprise blood, phlegm, yellow bile, and black bile, as well as The basis for this strategy is the four characteristics of hot, cold, moist, and dry states of a living human body. The seven principles (Umoor-e-Tabbiya) that the Arabian physicians translated from the Greek doctrines were the element (Arkan), temperament (Mizaj), humours (Akhlat), organs (Aaza), spirit (Arwah), capacities (Qowa), and functions (Afaal). This idea states that these principles are in charge of the body's constitution, health, and pathological disorders. The first stage in treatment in the Unani method is to create a regimen that normalizes and balancesthe extrinsic variables (such as air, water, and food) that cause ailments and diseases. [18]

1.3 WHO Traditional Medicine Strategies:

TCI medicines safety, effectiveness, quality, availability, preservation, and regulation are all challenges that policymakers, health professionals, and the general public are grappling with in various parts of the world. In most countries, TCI is still widely used, and its popularity is growing rapidly throughout the world. Simultaneously, attention in TCI is shifting away from products and toward practitioners and processes.

The WHO TM Strategy 2002-2005 assesses the state of TM/CAM globally and covers WHO's participation and actions in the field. But perhaps more importantly, it lays out a plan for WHO and its partners to make it possible for TM/CAM to contribute more significantly to lowering excess mortality and morbidity, especially among the poor.

Objectives of TM strategy 2002-2005 were related to:

1) Policy - Development and imply national TM/CAM policies and programmes, as needed to incorporate TM/CAM into the country's healthcare systems
2) Safety, Efficacy, and Quality - Boost the safety, effectiveness, and quality of TM/CAM by broadening the TM/CAM knowledge base and offering regulatory guidance
3) Access - the readiness and elevated price of TM/CAM, if necessary, with an emphasis on those who are less fortunate
4) Encourage professionals and clients to use appropriate TM/CAM in a therapeutically sound manner.[19]

As a result, WHO performed a global assessment of TCI's current situation and designs the WHO TM Strategy 2014–2023, which was aimed to address several major concerns.

Objectives of traditional medicines strategy 2014-2023 include:

1) Gaining understanding of TCI management through efficient national strategies

2) Strengthening TCI's quality assurance, security, appropriate application, and effectiveness through the control of goods, processes, and practitioners

3) To advance universal health coverage, TCI services should be adequately incorporated into the provision of healthcare services and self-care. [20]

1.4 Difficulties faced by member states according to second global survey

Lack of research data:

99 member states reported that they cite a lack of research data as their biggest problem. 86% of member states from the WHO's African region, 83% from the WHO's Americas region, 76% from the WHO's Eastern Mediterranean region, 47% from the WHO's European region, 90% from the WHO's South-East Asia region, and 87% from the WHO's Western Pacific region all brought up this issue. [4]

Lack of financial support for research on TCI:

86 member states reported were this difficulty. This issue was mentioned by 86% of member states from member nations from the WHO African area, 61% from the WHO Americas region, 71% from the WHO Eastern Mediterranean region, 47% from the WHO European region, 70% from the WHO South-East Asia region, and 74% from the WHO Western Pacific region.

Inadequate systems for ensuring the security of T & CM products, especially herbal medicines:

75 member states were reported this difficulty. Lack of financial support on T & CM was mentioned by 68% of member states from the WHO African region, 61% member states from the WHO region of Americas, 59% of member from the WHO Eastern Mediterranean region, 39% member states from the WHO European region and 70% member states from theWestern Pacific region.[4]

Lack of expertise within national health authorities and control agencies:

This difficulty was reported by 70 member states. 67% member states from WHO of Americas, 44% member states from WHO European region and 50% member states from WHO south

east Asian region.

Lack of education and training for T&CM providers:

This difficulty was reported by total 73 member states and was mentioned by 61% member states from the WHO region of Americas and 71% of member states from the WHO Eastern Mediterranean region.[4]

1.5 Global market

The global CAM market was estimated to be worth USD 82.27 billion in 2020, and between 2021 and 2028, it is expected to grow at a CAGR of 22.03 percent. [21]

CAM market valued USD 192.0 billion in 2018. [22]

The trend started as a consequence of study into the capacity of several herbal plants to give effective treatment to COVID-19 patients, and it is predicted to increase the CAM market's development. Alternative medicine practitioners have run across a stumbling barrier in the form of a dearth of clinical data to back up their claims. However, major financing for clinical research along these lines is projected to overcome this barrier in the near future. [23]

The greatest market for alternative pharmaceuticals and therapies is in Europe, followed by Asia and North America. This is owing to a rise in the usage of natural therapies and alternative pharmaceuticals as well as technological breakthroughs in drug development. Additionally, Japan is expected to experience a solid growth rate in the alternative health care sector over the next five years due to a population that is ageing and high expenditure on alternative medicines and therapies in the country.

Due to growing populations and economies in developing nations like China and India, the need for alternative medicines and treatments in Asia is expected to increase. Furthermore, the worldwide alternative medicines and therapies market is predicted to benefit from the rapid increase in the ageing population, rising need for herbal medications, and rising demand for alternative drugs and natural therapies. [24]

2.5.1 National centre for Complementary and Integrative Health (NCCIH):

NCCIH is US government agency for scientific research on TCAM. The mission of NCCIH is to do scientific investigation and determine use and safety of TCAM for improving health care. NCCIH funds for:

- Scientific studies on integrative and alternative medicine.
- Instruction for researchers. Learn about available training options.

In Financial Year 2018, NCCIH had an achievement of 20.3% for scientific project financing. TCAM got USD 154.16 million in funding from NCCIH in the year 2021. The success rate is calculated by dividing the total number of funded competing applications by the total number of assessed competing applications. [23]

Global market of TCI according to distribution channels:

Direct sales:

Many local acupuncture and Ayurveda professionals and organizations also going towards direct distribution of CAM treatments to help boost their businesses.

In 2020, direct sales accounted for nearly 73.0 % revenue share. [21]

Distance correspondence:

Increased demand for virtual education and training programs including meditation andyoga and the increased usage of distant mental health treatments by the most of practitioners, are two significant causes contributing to this segment's strong revenue.

The distant correspondence segment is estimated to increase at the rate of 22.90 % from2021 to 2028.[21]

Education:

Based on the manner of service, the CAM market is divided into three categories as e-learning, therapeutic classes and direct consultation. The treatment class category, with a market share of 60.3% in 2018, produced the most income in the market during the last five years (2014-2018). [23]

Hospitals and retail pharmacies:

Over the course of the projection period, the hospital and retail pharmacies market is expected to maintain its leadership in the distribution channel sector of the global market for herbal medicines.

Innovating healthcare facilities and qualified professionals are turning to herbal medications as an option due to the increased incidence of infectious diseases and cancer worldwide. resulting in a considerable increase in the worldwide herbal medicines market.[25]

Global market of TCI according to WHO region:

Europe: In 2020, Europe had the highest proportion, 33.35%. Acupuncture, for example, is an example of CAM, which cover methods that are less depend on current pharmaceuticals. In Europe, Germany is predicted to grow at a CAGR of roughly 6.5%. [26]

Middle East and Africa: From 2021 to 2028, these regions are with a predicted growth rate of 24.78%. The number of practitioners of alternative medicine in the area has greatly increased. [21]

Asia-Pacific: In Asia-Pacific, the market for herbal beauty products is Leading the way are countries like Australia, India, and South Korea, with the Latin American region growing at a 5.8% CAGR over the course of the analysis period, to reach US$2.7 billion by 2026. [27]

China: It is expected that China, the economy with the second largest GDP in the world, will have a market worth US$32.9 billion in 2026, reflecting a CAGR of 10.8% throughout the time period under consideration.

Canada and Japan are two other significant geographic markets, with growth rates for the studied period predicted to be 7.4% and 7.1%, respectively.

[27]

Global market of TCI according to its therapy/medication:

Botanicals: Traditional alternative medicine, often known as botanicals, dominated the market in 2020, with a 38.48 percent share. Botanicals are mostly used complementary and alternative therapies in both developing and developed countries. [22]

Yoga: Yoga had the highest market share of 36.27 % in the body healing intervention segment in 2020.

Hypnotherapy is predicted to grow at the quickest rate in the mind healing area, with a CAGR of 22.44 % from 2021 to 2028.

*Herbal medicines :*Despite the COVID-19 mystery, it is predicted that the global market for herbal medicines will increase from US$110.2 billion in 2020 to US$178.4 billion by 2026, growing at an average annual rate of 8.1%. In the United States, the market for herbal medicines is projected to grow to $22.8 billion by 2021. Currently, the nation holds an 18.4% market share worldwide. [28]

The market for herbal medicines is expected to touch USD 391.22 billion by 2028, growth of a CAGR of 18.8% from 2020 to 2021, when it was forecast to be worth USD 98.60 billion.

[29]

Vitamin D3: From 2021 to 2026, With a 7.95% CARG, it is expected that the market share for vitamin D3 will increase by USD 928.48 million.

[30]

Acupuncture: The market for acupuncture needles was worth $95.80 million globally in 2018, and it is expected to increase by 8.2% year between 2019 and 2026 to reach $177.79 million.

[33]

Ayurveda: The worldwide Ayurveda market was anticipated to be worth USD 4.5 billion in 2019, with a CARG of 16.14% expected to reach USD 14.9 billion by 2026. [34]

2.5.2 Rising Demand for TCM from Developing Economies:

According to industry experts, availability of cheap TCM has expanded in growing nations of Asia Pacific and East Asia over the past 3 years as a consequence of increasing demand coming from the local drug manufacturing firm. Infrastructure initiatives and international TCM centres areprojected to improve the industrial capacity of the 3,000 TCM processing enterprises that are presently active. [31]

In 2016, the overall value of TCM imports and exports was 4.6 billion USD, accounting for 4.45% of the entire value of Chinese pharmaceutical imports and exports. [32]

2.6 Opportunities and Challenges

2.6.1 Opportunities

***Research and development*:** As there are lack of evidence of TCI's therapeutic use. High-quality TCI research necessitates a commitment from the research community, as well as ongoing financial support from governments and business. This commitment is necessary if the general public and healthcare practitioners are to have enough information about TCI's

safety and efficacy to make educated judgments about its use. We expect compelling evidence aningful contacts between conventional and complementary practitioners,

leading to the formation of interdisciplinary collaborations that incorporate verified complementary approaches into patient care. [35]

Foreign Direct Investment (FDI): FDI aids in the improvement of capital flow and the creation of a competitive market. If sufficient controls are in place, FDI can improve health services. Despite the polarized views on foreign direct investment in healthcare, there are considerable knowledge gaps that support these viewpoints. The majority of the literature is based on theories, hypotheses, and anecdotal data, hindering a thorough examination of the netbenefits of FDI in the health sector and the formation of well-informed policy recommendations.

FDI Opportunities:

- Pre-existing supply limitations are alleviated.
- Provider competition raises standards and quality while cutting pricing.
- Services, equipment, and treatment options that have recently become available.[36]

Trade in services: Trade in services will increase contribution to export diversification. The first is the provision of health services across national borders. The latter involves the typical mail delivery of test samples, diagnosis, and clinical consultation. It also encompasses telehealth or electronic delivery of health care. The latter uses interactive audiovisual and data communications to deliver services including diagnosis, second views, lab tests, surveillance, consultations, transmission and access to specialist data, records, and information, as well as continuous education and skill upgrades.[37]

Consumption overseas is also one of the mode of health-care commerce. The movement of customers to country that provides facility for diagnosis and treatment is referred to as this. Natural resources, the availability of complementary therapies, long treatment waitlists in the country of origin, and the close proximity of sending and receiving nations in terms of culture, language, and geography are all factors. are all factors that encourage such commerce. The consumption of health services internationally includes the movement ofmedical students and professionals for medical and nursing learning and skills. [38]

Knowledge base for active management: Knowledge base is required for its active management in hospitals and society. This management will aid in understanding following points:

- how TCI work and determining whether they are safe to use or not.

- determining their interaction with conventional medicine and how they do so.
- Check to see if specific therapies work and accomplish what they claim.
- Compare them to existing treatments to evaluate if they function just as well or better.
- find out if they improve the quality of life for those who are sick.[39]

Covid-19 management: TCI provides a variety of simple, Respiratory infection prevention and treatment alternatives supported by data, as well as strategies for building physical and mental toughness, are anticipated to be helpful. TCM is being promoted bythe Chinese government in COVID-19, with over 85 percent of patients adopting it in additionto modern treatment.

Whole medical systems and Biology based practices are widely used to treat Covid-19.[40]

***Resource utilization*:** Natural resources, which are abundant, can be used by TCI market participants to generate significant money. Alternative medicines are created using raw resources such as plants, earth, water, and other elements of nature. The two nations that export medical herbs most frequently are India and China, which also supply the most medicinal plants to market players.. So, there is opportunity to fully utilize these resources which will help to build good economy as well as health care system.[41]

2.6.2 Challenges

Hard evidence is scarce: For many TCI therapies there is no evidence available whether they are really helpful to treat disease or not. There will be no research if funding is not available. We won't be able to tell if TCI provides better than harm unless there is study. Nonetheless, this is the essential question that will determine its future role in health care. It's impossible to give simple answers or make broad generalizations. Each of the many techniques must be assessed independently and on its own merits. Some TCI's are safe, while others are not; some are effective, while others may simply be placebos. Only well-designed clinical research, it seems self-evident, can demonstrate the truth.[42]

***Complex reasons for popularity*:** People relay on their personal and past experiences and more believe in natural treatments than allopathy. The reasons for TCI's popularity are complicated; they alter with time and place, they might vary from therapy to treatment, and they differ from one person to the next. In essence, TCI's current popularity is not determined by a single factor, but rather by a complicated web of competing positive and negative incentives. Some of these are scathing indictments of our modern healthcare system. Whether or not this criticism is

valid, persons who turn to TCI often feel strongly about it, and mainstream medicine would be well to take it into consideration. Many individuals in low and middle-income nations choose TCI as their major source of healthcare because it is more culturally acceptable and the only kind of treatment that is affordable.

Ethics: Clinical research: There is need of assessment of safety, efficacy and study of potential mechanism of TCI approaches. Given how little is known about TCI, in terms of safety and cost-effectiveness, ethical questions are bound to arise.According to survey only 40% ayurveda manufacturers have WHO-GMP certificates inIndia.[43]

Intellectual Property Rights (IPR): As TCI grows in popularity, it's more important than ever to safeguard local communities' intellectual property. International law forbids the use of TM knowledge in the production of medications without the consent of people who possess the knowledge. State parties must respect, preserve, and safeguard customary practises, innovations, and expertise of local and indigenous communities,as well as encourage equitable benefit sharing from their use. Traditional and indigenous technologies, as well as traditional and indigenous technologies, will be encouraged and developed by contracting parties.

Financial and Insurance coverage**:** There is no more financial and insurance support given by government for TCI. The shortage of research funds, on the other hand, appears to be the largest hurdle for TCI research. TCI research is underfunded by the government, charities, and the corporate sector, resulting in investment that is far out of proportion to the prevalence of TCI usage. [44]

Knowledge management and utilization: There is no official source of data available regarding utilization of TCI. Information must be distributed across a broad spectrum of professional and business sectors to create sound standards of practise based on acknowledged levels of training and the secure and effective application of TCI therapies. The advancement of research and policy initiatives will require comprehensive information resources, but they will be difficult to provide. The information now available on the internet is restricted in breadth, and much of it is tied to commercial products being sold. [42]

Objectives of the study

3.Objectives of the study

The objectives of this study include:

- To understand the regulations for Traditional, complementary and Integrative medicines in selected countries.
- To analyze the market opportunities for TCI globally.
- To understand opportunities and challenges in uptake of TCI.

Research Methodology

➢ Methodology

1.3 Study plan: This study was carried out using secondary data resources.

To study regulations of TCI, four WHO regions and three countries from each WHO region were selected. Countries were selected based on their Market, popular TCI practices and the selected country either have National policy or rules and regulations to regulate TCI.

WHO region	**Countries**		
African region	South Africa	Ghana	Nigeria
South-East Asia region	India	Maldives	Thailand
Eastern Mediterranean region	UAE	Pakistan	Iraq
Western Pacific region	China	Japan	Australia

Table 2: Countries selected for study

1.4 Data collection:

Secondary data was collected from WHO reports, regulatory guidelines and financial reports of selected countries. News reports were accessed for market forecasting data. Official websites and scholarly articles were accessed through PubMed and NCBI for regulatory data collection.

1.5 Duration of study:

The research was place over a seven-month period, from October 2021 to April 2022.

1.6 Data analysis and Interpretation:

The data obtained from various sources was collected and analyzed qualitatively and then conclusion were drawn to make attempt at strengthening the regulatory process in selected countries and market scenario of TCI globally.

5 Results and Discussion

5.1 WHO African region

5.1.1 South Africa

5.1.1.1 : Overview of regulations:

Traditional healing would become a fundamental and recognized element of health therapy in South Africa, according to the African National Congress Health Plan of 1994, which raised the topic to the national health agenda. Consumers were permitted to choose who they get medical advice from, and and laws will be adjusted to allow the restricted use of traditional healers. A major policy statement in the strategy is, "People have the right to access traditional practitioners as part of their cultural history and belief system." Following the lengthy Traditional Health Care bill's submission as a paper in 2003, the Traditional Health Practitioners Act was adopted. A law known as Act 35 of 2004 was passed that year. The Interim Traditional Health Practitioners Council of South Africa was established by this Act, and it offered a legal framework to ensure the efficacy, security, and calibre of alternative healthcare systems. On the other side, the Constitutional Court mandated that this Act be sent back to Parliament since the National Council of Provinces (NCOP) had handled it improperly. [45]

5.1.1.2 Accelerated Registration (AR) Programme:

The AR Program is one of the recommended strategies for controlling supplementary medications. Technical experts representing each of the alternative medicine modalities have prepared a list of items. Product is tested to guarantee that it is created according to good manufacturing practices and that the contents are accurate as long as it contains medications from recognized pharmacopoeia in approved dosages. To date, the Medicines Control Council (MCC) has received approximately twenty-five thousand complementary medications, including TM, in order to enhance the implementation of the AR Programme.[45]

5.1.1.3 Regulatory guidelines:

South Africa has proposed National Policies and procedure for TCAM regulations in year 1992. The laws establish standards in order to improve and hasten the registration and regulation of TM. The rules cover THPs, organisations doing TM research, national drug regulatory bodies, and businesses developing related products.

It is estimated that 70% of the South African population seeks primary healthcare from one of the more than 200000 THPs. It is for this reason that TM techniques have gained acceptance in South Africa. As a result, it is quite disappointing that the TM system is currently unregulated by legislation. The National Department of Health has made some headway in developing a regulatory framework for THP registration, regulation, and control (THP Act No. 22, 2007). The Council will supervise the certification as well as regulation of healing practices by adopting practice norms. The African TM Expert Committee, which advises the MCC, is also supposed to speed the legislation system. [46]

5.1.1.4 Recommended structure of the south Africa guidelines for registration of TM:

Traditional use: TM systems have existed for millennia and have a different conceptual framework than modern medicine. As a result, herbal remedies intended to be used without the assistance of a medical professional for evaluations, prescriptions, or therapy monitoring is described using traditional terminology. For a long period, the usage of such drugs must have been well-established and well accepted among a large number of THP's. Long-term use and experience are required to demonstrate efficacy. The plant's botanical identity must be established using scientific data. This data found in medical manuals, pharmaceutical handbooks, and pharmacopoeias.

Pharmaceutical quality: The MCC and the producers share responsibility for ensuring the quality of TM products. Quality control standards were addressed in the WHO guidelines for TM registration in South Africa in 2005. Additional requirements, such as verifying that the active ingredients in raw materials and final goods are the same, should be implemented. Compliance with pharmacovigilance during the collection of raw materials and production of finished goods, good agricultural and collecting practise (GACP), good laboratory practise (GLP), and good manufacturing practise (GMP) must be enforced. Raw and final quality requirements should besupplied, detailing the product's physical, chemical

quality control test protocols. If the substance is a multi-component formulation, every herb element in the formulation should be mentioned.

Stability testing: The applicant's stability data must demonstrate that the product planned for sale will be have safety, quality, and efficacy for specified shelf life. The stability of the parts that make up the finished product is significant because most TM products are considered active components in their whole. Chromatographic fingerprinting, as well as other sensory and physical testing, should be used to determine this. Within the stipulated shelf life, the product's known active components should not change considerably. Suitable chromatographic profiling should be used to justify the reported shelf life of items containing unknownmedicinal actives that have not been measured.

Safety: TM use should not be utilized in place of safety, but it should be considered while assessing safety. When traditional use is utilized to demonstrate safety, the duration, method, and dose should all be consistent with the intended use. The product's overall formulation, dose, mode duration of usage, patient population (including youngsters, the elderly, pregnant women, and nursing mothers), method of administration, and any interactions with critical pharmaceuticals all play a role in its safety.

Therapeutic efficacy: It is important to consider long-term TM use while assessing effectiveness. To support traditional use, bibliographical evidence from herbal literature, pharmacopoeias, peer-reviewed scientific research, and other sources must be included with the application.

Studies conducted in vitro and in vivo could make up this proof.

The sort of evidence offered will be characterized by the indications for usage and past observations reported in testimonies by doctors, THP's and patients. For new TM formulations, fresh evidence may be necessary. This new evidence should cover pharmacodynamics, pharmacokinetics, bioavailability, and clinical trials, among other topics. THPs should have their TM products assessed for pharmacodynamics, pharmacokinetics, and bioavailability effects using in vitro and in vivo animal models, according to registration recommendation. Pharmacodynamics describes the likely mode of action, as well as the dose and dosing intervals, as well as potential medication interactions. Pharmacokinetics is the study of what happens inside the body after a patient takes a medicine, including ADME.

The proportion of a drug that reaches systemic circulation is referred to as bioavailability.

Multi-ingredient TM products: In actuality, most African TM products are made up of several

plants that have been combined together to create a single product. Some multi-herbal drugs are the product of decades of study, and the ingredients are considered to contribute an unknown spectrum and proportion of active compounds to their entire therapeutic usefulness. In a novel multi-herbal product, each plant product should be examined independently for quality, safety, effectiveness, and stability.

Labelling and packaging: The WHO standards for South Africa include some stringent criteria for TM labelling. A quantitative list of the active ingredients, plant names, dose information, therapeutic indications, manufacturing and expiration dates, lot information, and manufacturer's name are all included in the WHO's 2005 data. The goal is to show that patients are able to comprehend and follow labelling instructions. Packaging is part of the GMP regulations for TM product manufacturers. The primary container's kind, nature, size, and grade, as well as the closing technique and, for liquid products, the fill capacity, should all be indicated.

Post-approval market monitoring: All levels of the health sector should build national surveillance systems to track and evaluate any known negative effects of conventional medication. The surveillance system's goal is to give customers confidence in the security and calibre of TM. Additionally, it would guarantee industry compliance with TM regulatory standards and guidelines. [46]

5.1.2 Ghana

5.1.2.1 Regulations overview:

Various government administrations in Ghana have recognized the value of TM . The Ghana Psychic and Traditional Healers Association, established in 1961, and the Centre for Scientific Research into Plant Medicine, established in 1975, serve as examples of this. The government established a TM coordination unit in 1991, and in 1992 it was followed by the Food and Drugs Board, which was in charge of, among other things, approving the sale of TM products to the general public. The government established the Traditional Medicine

The government established the Traditional Medicine Practice Council (TMPC) Act in 2000 to establish the Traditional Medicine Council, which isin charge of registering all TMP's in the country.

There is no one document that coordinates the government's overall policy orientation in this area, despite the fact that all of these legislation offer a legal policy underpinning for the development of traditional medicine. The objective is to create a comprehensive policy framework or direction that may serve as the foundation for both the government's short- and long-term TM objectives. It transcends industry divisions and offers a broader national perspective that all industries must embrace. In order to incorporate the products and benefits into the nation's health-care delivery system, the government's policy is to continue research and development on TM. Successor governments have recognised the TM promise. [47]

5.1.2.2 Policy

The policy has main focus on :

Practice of traditional medicine and regulatory legislation:

a) All TMP's must join an association and join the TM Council in order to improve the practice and eliminate quacks from the system.

b) The umbrella association of TM should be encouraged to establish training and instructional programmes on acceptable manufacturing processes in order to support real practitioners.

c) TMP's must keep detailed records of all their procedures.

d) TM practitioners should be encouraged to employ sophisticated diagnostic and monitoring equipment while diagnosing and managing patients.

e) TM must be available in all public health facilities. The goal is to provide patients/clients with a variety of health service options from which to choose.

f) Appropriate standards of practice were established as facilities improve, making legislation enforcement easier.

Organization and management of traditional medicine associations:

The Traditional Alternative Medicine Directorate (TAMD) has been bolstered in order to better mobilize and coordinate practitioners at all levels. This is to guarantee that all of the groups are

well-organized, in order to improve the flow of information available to all TM practitioners. The management of practitioners will be devolved to all levels of government. The Traditional Medicine Practice Council has been in charge of enforcing laws in the private sector, in particular.

IPR Protection:

Practitioners don't share information about their expertise (practice and preparation) because of the lack of trust, fear of losing their livelihood, an oath of secrecy and the need to maintain their standing and reputation.

TMPs cite the aforementioned observations as justifications for not disclosing critical information and expertise about their processes and goods. Plants cannot be copyrighted, but plant knowledge and plant product formulation can be.

Policies:

a) TMP's were taught on all elements of patent, copyright, and trademark laws.

b) The IPR system were protect and exploit indigenous knowledge held by TMP's and other scientists.

Professionalization of TM/CAM through formal training:

a) Training for TM to increase their knowledge and practice skills has been provided. The government is covering the expense of such training.

b) A training programme for TMP training at all levels must be designed.

c) Allopathic health practitioners, and vice versa, should be encouraged to learn and practice TM.

Research and Product Development:

a) To conduct research and document the results of TCI practices, TMP must be trained in research procedures.

b) To ensure relevance, guidelines for efficacy and safety research in respect to TM products must be supplied.

c) Clinical trials of TM items have been guided by guidelines.

d) All adverse effects of plant medicine products must be documented and reported by TMP's and all reported cases must be investigated.

e) Through research, interaction between TMP's and allopathic practitioners has been encouraged. Seminars, seminars, and symposia are all available.

f) To enhance the development of TM, all national research institutions must be equipped to conduct research on TM practices.

g) The TAMD will seek entrepreneurial partnerships for product development in order to commercialize TM products that have been proved to be beneficial in areas of public concern.

Public Information, Education and Communication on Rational use of TraditionalMedicine:

a) Public education on the values, benefits, and risks involved with these practices should be increased.

b) The Directorate work with the Ministry of Education/Ghana Education Service to integrate TM courses into university curricula.

c) The media must be educated and supported in order to promote TM.

Standardization, quality assurance and large-scale production:

a) TMP's have been assisted in standardising their medical product so that batches provided for sale are uniform.

b) Manufacturing facilities must be examined on a regular basis to ensure that excellent manufacturing practices are followed as per GMP.

c) Before traditional medical medicines can be registered, TMP's must give critical information about their products.

d) Ministry of health will encourage allopathic practitioners to use TM goods.

Documentation, information exchange and baseline data collection:

a) TMP's should be encouraged and supported to keep track of any biological/medicinal items they utilise in their practices.

b) In order to determine mediators and objectives, suitable baseline data must be collected.

Biodiversity conservation and sustainable harvesting:

a) Commercial collectors are educated and trained in sustainable harvesting procedures.

b) Large-scale collectors must be registered, and their operations must be supervised.

b) All large-scale projects are obliged to report their replanting programme in order to improve monitoring and sustainability.

d) Commercial collectors of medicinal plant parts have to restore the plants they destroy with some of their resources.

e) The country's current biodiversity has been analysed, and its use is documented.

f) TMP's have been encouraged to nurture their sources of materials and are financially supported in doing so.

Global Networking and Collaboration:

Policy: A list of international collaborators should be compiled and updated on a regular basis.

Key employees should be able to participate in appropriate local and worldwide courses, workshops, and conferences.

Practice of TM and regulatory legislation:

a) Commercialization of TAM products on a large scale should be promoted and financially supported.

b) Through teaching and the provision of TAM medical products at public health facilities, widespread local usage of TAM medicinal products will be encouraged.

Integration of TM/CAM into national health systems and commercialization:

a) The TMPC encourage TMPs to enhance their knowledge and abilities through training and education in order to strengthen collaboration between TMPs and OMPs (Orthodox Medicine Practitioners).

b) In the short term, the TMPC will offer training programmes similar to those organized for TBAs in order to strengthen TMP procedures.

c) The government will help higher education institutions that want to start TM training programmes.

d) The Ministry will promote collaboration between TMP's and OMP's by educating all parties involved in order to achieve cooperation.

e) At the product level, integration will take place by putting them at the disposal of both practitioners.[47]

5.1.3 Nigeria

5.1.3.1 Regulation:

The National TM Development Program was established in 1997. Since then, the Federal Ministry of Health has taken steps to publicly recognize and improve the practice of TM. These are some of the measures:

a) The National Technical Working Group on TM was established and given its formal opening.

b) The Federal TM Board Decree, the National Policy on TM, the National Code of Ethics for the Practise of TM, and the Minimum Standards for TM Practise in Nigeria.

c) Support for TM at the federal level.[48]

5.1.3.2 TM Act of Nigeria:

In order to increase TM's contribution to the nation's formal health-care delivery system, all state health ministries were compelled to create boards of TM in 1994. The TM Council of Nigeria Act, which was proposed in the year 2000, comprised the following functions:

a) Facilitating the practice and growth of TM.

b) Establishing guidelines for TM practice regulation to protect the public from quackery, fraud, and incompetence.

c) Coordinating with state boards of TM to guarantee conformity to the Federal TM Board Act's policies and recommendations.

d) Creating model TM clinics, herbal farms, botanical gardens, and TM production units throughout the country's geopolitical zones.

e) Collaborating with organizations in Nigeria and abroad that have similar goals.[48]

.2 WHO South-East Asia region

.2.1 India

.2.1.1 National Policy on Indian systems of medicine and homoeopathy (ISM and H policy):

To uplift the development of Ayurveda, Siddha, Unani, Yoga, Naturopathy, and Homoeopathy in India, the ISM & H Policy was established in 2002. This study aims to assess public health professionals' perspectives on the current ISM and H Policy implementation.

The basic objectives of this Policy were:

(a) (a) To use ISM & H for preventative, promotional, reducing, and curing treatment in order to promote good health and expand access to healthcare, particularly for those without insurance.
(b) To develop model institutions, Centres of Excellence, and to provide funding for the construction of physical infrastructure in order to raise the standards of educators, physicians, and researchers.
(c) To guarantee accessible, cost-effective ISM & H services and medications.
(d) To make it easier to obtain authentic raw pharmaceuticals that are required by pharmacopoeia standards and contain necessary ingredients in order to boost drug quality for both domestic use and export.
(e) By incorporating ISM & H into the health care delivery system and National Programmes, you may make the most of the large infrastructure of hospitals, dispensaries, and doctors.
(f) Inform other stakeholders and healthcare professionals about the benefits of these systems in India and elsewhere.
(g) To give these systems every chance to grow and develop, as well as to fully utilise their potential, strength, and rebirth,

Due to their Availability, cost-effectiveness, inclusion and mobility, Indian Systems of Medicine have the potential to become providers of the healthcare that the bulk of our population demands.

extensive public acceptability, comparatively low cost, little technical input, and expanding economic value.

Policy support:

1) According to the government, Ayurveda, Homoeopathy, Siddha, Unani, Yoga, and Naturopathy provide broad variety of cost-effective and efficacious preventative, promotive, and curative treatments, and that these systems should be included in our health-care strategy. The government has acknowledged the curiosity to study Indian medical systems as well as the opportunities that has created.

2) In 1999, the Central Council for Health and Family Welfare suggested that every primary health care centre have at least one ISM & H physician on staff, and that ISM & H physicians fill vacancies caused by a dearth of allopathic professionals. It was also determined that Central Government employees should be paid for treatment received in ISM hospitals.

Financing ISM and H:

Stakeholders have expressed concern that the ISM & H receives just 2% of nation's overall health allocation, whereas 98 % is spent on western contemporary treatment. To fully utilise ISM's potential and contribute more significantly to health care, a corrective and promotional programme must be implemented. Infrastructure consolidation and creation, ISM & H drugs and supplies, therapists, promoting awareness about the potency of the systems, and arranging laboratories all these priorities for the ISM & H sector. The allocation at the state level is still pitiful. Even money that have been set aside are either not released or are not used.

Medical education:

Concerns regarding medical education at ISM & H have been expressed. A five-and-a-half-year undergraduate degree and a three-year post-graduate programme were created by the Homoeopathy Central Council Act of 1973 and the Indian Medicines Central Council Act of 1970, respectively., including adequate clinical exposure and internship. There are 404 ISM & H colleges in the country according to 2019 data. Various educational laws have been enacted by the Central Councils in order to enforce basic educational levels.

Drug Standards, Regulation & Enforcement:

The DCA Act govern drug manufacturing and related matters. Drugs' safety, efficacy, quality, and rational use still not verified. Despite the fact that the Act includes an enforcement mechanism, which is also in effect in most states, the implementation of the enforcement measures leaves a lot to be desired.A considerable proportion of enterprises are hesitant to use GMP. Formulary and pharmacopoeia standards preparation has been accelerated, but there is still much to be done.

Medicinal plants:

For the manufacture of their medications, ISM & H mostly utilise plant components. Due to overexploitation, unsustainable practices, biodegradation, and population pressure, this traditional foundation is dwindling. Extraction and acquisition from the wild are both restricted. Several species have gone extinct or endangered as a result of the lack of a systematic system for collecting and supporting the regeneration of such plants. The industry is always confronted with the issue of raw material supply and quality. In the absence of a reliable supply of high-quality raw pharmaceuticals and an enforcement framework, drug adulteration and substitution are believed to be common.

IPR of ISM:

Foreign interest in historical manuscripts and treatises about plant formulations and therapeutic uses has piqued and these medicinal uses have been copyrighted as innovations by them, despite the fact that they are already in the public domain and thus cannot be patented.

Revitalization of Local Health Traditions:

Indigenous TM knowledge held by people, communities, and tribal has not been fully tapped, documented, or authenticated, in addition to the documented information. Over time, such knowledge erodes, resulting in irrevocable harm. Over 10,000 examples of folk medicine have been documented by our Research Councils, but there are still tens of thousands more. The providers of such information have not received enough acknowledgment, monetary remuneration, or assistance in obtaining patents for their work.

ISM Practitioners Medical Tourism and Export:

The demand for plant-based treatment options in other nations is rapidly expanding. Furthermore, tourists and travellers are flocking to India for treatments such as Panchakarma

and Yoga. Medical tourism benefits ISM & H system while also being a significant source of foreign revenue. A quality chain of Panchakarma Centres, yoga therapy, meditation, and teaching facilities has yet to be established.

Research in ISM:

Indian medical systems have been around for millennia, and some of them, including therapy, therapies, and medications, have a long track record of acceptance and use. While modern scientific validation of all of these is not desired, the importance of fundamental, clinical, and pharmacological research cannot be emphasised. Users are looking for proof of safety and efficacy. Despite the fact that the Study Councils have been studying for more than 30 years, there is still much to be done. Research hasn't kept up with the times, and it hasn't been refocused or prioritized either.

Access to information:

In Western countries, the medical profession and the general public have taken a cautious approach to ISM, limiting the scope of ISM doctors' treatments and therapies, as well as their ability to encroach on areas outside of mainstream medicine's jurisdiction. Most people are unwilling to look beyond the biological paradigm and its treatment alternatives, giving Indian Systems of Medicine and health-care solutions little attention and space, despite the fact that they have been shown to be both cost effective and long-lasting. In a health-care system that emphasizes patient autonomy, these conflicts of interest and ethical concerns have gone unresolved. [49]

.2.1.2 AYUSH

The Ministry of Health and Family Welfare established a separate Department for ISM & H in 1995. In November 2003, it changed its name to Department of AYUSH. The department is in charge of developing and disseminating a number of officially recognised frameworks, including Ayurveda, Yoga, Naturopathy, Siddha, Unani, and homoeopathy. For each of these systems, pharmacopoeia committees were established to develop drug standards. They receive assistance from the Homoeopathy Pharmacopoeia Laboratory and the Indian Medicine Pharmacopoeia Laboratory. To establish and uphold standardised educational standards, the Central Council of Homoeopathy (CCH) and the Central Council of Indian Medicine (CCIM) were established. as well as regulating professional practises in Indian Systems of Medicine and Homoeopathy, respectively.

The following are the schedules and rules of the act that pertain to Ayurveda, Siddha, and Unani systems:

- The initial schedule was replaced by Act 13 of 1964, which became effective in 1969. The schedule specifies the traditional Indian pharmacopoeias that must be observed while prescribing Ayurvedic, Siddha, and Unani drugs.
- On September 15, 1964, the Second Schedule became effective. It outlines the requirements that must be fulfilled when generating medications. (Amended by Gazette of India, Part II, Section 3(1), Page 1643,
- Schedule E: Ayurvedic (including Siddha) and Unani systems of medicine's Schedule E (1): List of dangerous substances classed as plant, animal, or mineral (added by Notifn. No. 1-23/67-D dated 2 2-1970).
- Schedule T: GMP for Ayurvedic, Siddha, and Unani medicines. Under this , the government has mandated that all manufacturing facilities adhere to GMPs.

  Rules:

  - Rules: Part XVI (Parts XVI, XVII and XVII added by S.O. 642, date, the 2-2-1970 (with effect from 21.2.1970)

Ayurvedic (including Siddha) and Unani medications are manufactured for sale. It provides information on how to obtain a licence, a loan to start a business, and the identity and purity of raw materials.

- Part XVIA: Acceptance of organisations for conducting research on Ayurvedic, Siddha, and Unani medicines as well as the natural resources used in their production on behalf of licence holders for the manufacturing process for selling Ayurvedic, Siddha, and Unani medicines (Ins by G.S.R. 701(E), dt. 27-7-2001 and subs. by G.S.R.73(E), dt. 31-01-2003).
- Part XVII: Ayurvedic alcohol packaging, and restrictions
- PART XIX The regulations governing the use of Ayurvedic, Siddha, and Unani remedies (Ins. by G.S.R. 519(E), Dt., and 26.6.1995)

A categorization for herbal medications was established depending on their market accessibility, and the characteristics of the herbs.

- Category 1: products that have been in use for >five years;
- Category 2: products that have been in use for <five years; and
- Category 3: novel medications.

Herbal medications are classified according to whether they contain processed or unprocessed plant parts, as well as if they contain potentially dangerous herbs. Safety and efficacy requirements differ depending on the product's classification and market availability. The Ayurvedic Pharmacopoeia of India and the Unani Pharmacopoeia of India are two major multivolume national pharmacopoeias in India that are legally binding. [51]

Several sources are used to create national monographs, including a national database on medicinal plants used in Ayurvedic medicine and monographs found in national pharmacopoeias. Herbal medications were subject to the same GMP rules as conventional pharmaceuticals, which required adherence to information published in pharmacopoeias. Drug licensure, inspection, and testing are used to guarantee that these standards are met. Standard safety requirements include those for typical pharmaceutical items, as well as special requirements for traditional use with no known harmful effects and references to scientific research on related products. Herbal medications have been used safely for millennia in Ayurveda, according to the Indian Ayurvedic Pharmacopoeia, and there is a formal regulatory mechanism for safety requirements. Toxicology research are now divided into three categories: medications containing harmful chemicals, hydro-alcoholic extracts, and other solvent extracts. There are 4,426 herbal medications in the market according to 2018 data. Essential medication lists exist for each of India's three traditional medicine systems; the Ayurveda list has 315 herbal medicines, the Unani list contains 244 herbal medicines, and the Siddha list contains 98. These lists were published in the years 2001, 2000, and 2001.[51]

.2.2 Maldives

.2.2.1 Regulations:

If a medicine has been used in the Maldives for at least 30 years, it is called TM. During this time, the active components, indications for use, strength and dose, dosage form, and method of administration must have remained unchanged. If the level of a component in a product has been lowered over time, the product's safety after the change must be demonstrated with proof

from books, practitioner statements, or experts in the field. Strong evidence from reference books or statements from TMP's will suffice to verify a medicine is actually a TM. If the medications are new goods created in the Maldives with changes to the components or composition of TM, or if you cannot give evidence of traditional use, the medicine's safety must be guaranteed. In such circumstances, along with the application form and dossier, the rationale for components, effects of active compounds against their indication for use, and identification of active ingredients and excipients must be included. Traditional medications that may cause bad responses or side effects must be proven safe, according to applicants. The advantages of the drugs must outweigh the disadvantages. [52]

Alternative and Traditional Medicines can be registered by an importer, Party designated by the product manufacturer (e.g., the holder of a marketing licence) and the product manufacturer.

The products for registration are divided into 2 categories.

1. Alternative Medicine
2. Traditional (Dhivehi beys)

To register a product, an "Application Form for Registration of Alternative Medicine/Dhivehi Beys" (MTG/RE-HP/Fo 0045) must be filled out and sent to the Maldives Food and Drug Authority (MFDA) with all relevant documentation. A dossier is a collection of documents that outline the technical characteristics of the product being registered as well as paperwork pertaining to the manufacturing facility.

The list of medications permitted to be imported, disseminated, produced, and marketed in the Maldives is known as the Approved Alternative/ Herbal Medicine List (MTG/RE-AH/Li 0018). The Approved Alternative/Herbal Medicine List (MTG/RE-AH/Li 0018) is updated monthly, posted to the Ministry of Health and MFDA websites, and a notice of the upload is published in the Gazette. Products are added to the list after they have been registered and a comprehensive dossier has been submitted. The product's registration is valid for five years, during which time it can be imported, sold, and manufactured in the Maldives.

Product information: This provides the following specific product information for which the dossier is being submitted for registration.

a) Brand name: The brand name of the medicinal product submitted for registration, b) Quantitative particulars (active and non-active ingredients) of all the constituents of the

medicinal product, c) primary use and therapeutic indications, d) Dosage form, e) Route of administration, f) Contraindications and adverse reactions, g) Shelf life, h) Justifications for any safety precautions and precautions to be taken for the storage of the medicinal product, i) product availability (pharmacy, general sale, prescription based), j) Storage conditions, k) Proposed Dispensing category.

Post-market surveillance: Products that have been approved with a complete dossier will be subjected to monthly post-market surveillance, as outlined in the post-market surveillance plan. Adverse Drug Reactions will also be monitored for one year for traditional treatments. Following the registration of a new product, the applicant will be given a form to track the ADR for traditional medicine re-registration or renewal. [52]

.2.3 Thailand

.2.3.1 Overview

The CAM Practise of the Art of Healing Act B.E. 2542 (1999) recognises TCM and chiropractic.

The Health Facilities Act, B.E. 2541 (1998) lays out requirements for health facility certification, including that service givers should be qualified doctors and that a facility must hold a licence under the Act .

If the following requirements are satisfied, the WHO classifies Thailand's TAM system as an integrative system:

a) The national drug policy of the relevant nation includes TM/CAM.
b) Services and goods are licenced and governed.
c) Both public and private establishments offer TM/CAM therapy.
d) A number of health insurance programmes provide coverage for TM/CAM therapy.
e) Useful research is conducted.
f) TM/CAM education is offered. [53]

.2.3.2 Policy supporting the use of T & CM in the health care system

T & CM in the policy of health care services: Thai TM is supported by the Thai Constitution, (2017),that states in Article 55 "the State shall use Thai TM for the delivery of care to the Thai people."encourage and aid in the development of TTM knowledge to maximise its benefits. Additionally, the promotion of TTM in the health sector as well as the development of TM, herbal drugs, and other herbal remedies for the improvement of the Thai economy are included in the current government's 20-Year National Strategy (2017-2036).

Policy on the Development of TTM Service Provision: Since 2002, the Department of Thai Traditional and Alternative Medicine (DTAM) has developed a number of projects to provide Thai traditional medical services in the state.. These projects include:

- The Thai Traditional Health Promotion Centre, founded in 2001, was the first to provide TTM services in provinces by providing medical exam and treatment. Prescription of herbal thai medicine.
- By hiring The development of TTM in Thailand's health promotion hospitals began in 2010. TTM doctors will work in these facilities to provide community TTM services, especially for paralysed and paretic patients as well as seniors. This initiative placed a strong emphasis on proactive community activities. Additionally, as a result of this expansion, publications and a body of information on Thai indigenous medicine from many tribes were compiled.
- The Pilot TTM Hospital Project was started in 2004 with the aim of creating a practical model of TTM service delivery, with a focus on the application of TTM recipes and impromptu TTM cures for particular patients. This covers both outpatient and inpatient medical exams, assessment, and therapies.
- Providing complete TAM services in Thailand - In 2016, a project was started to create specialised TTM clinics for four illnesses/symptoms, including, and upper respiratory ailments, based on the context of each hospital. This was done in order to integrate TTM, acupuncture from TCM.
- To improve and expand TAM services at the safeguarding of TTM knowledge and the advancement of health, "TTM working" at the provinces and local levels

groups" were formed in Provincial Health Offices and public health service facilities in 2017 to continue implementing the health service development plan. In addition, each of the 12 health regions has CTMO who is responsible for a) driving, controlling, regulating, and monitoring Thai traditional and alternative medical services within his or her own health region, b) preparing strategic proposals outlining existing problems and challenges, as well as proposed solutions, and c) supporting local Thai traditional and alternative medicine activities.[53]

.2.1.2 Regulatory bodies: National administrative and regulatory bodies on T & CM service system

The following are important government offices and professional councils, as well as their roles in T&CM service regulation and technical assistance:

1) DTAM, Ministry of Public Health:

a) Serves as a core agency and policy maker.

b) b) Develops and puts into place procedures for registration to protect the nation's and individuals' rights to TTM knowledge, including TTM equations, TTM texts, treatises, and collections of TTM equations.

c) Creates the Thai Traditional Digital Knowledge Library (TTDKL) to catalogue TTM antecedents.

d) Develops standards and provides technical support for providers, herbal medications, and Nuad Thai practitioners.

e) Development of curriculam and programmes for staff members, as well as supports and improves TTM internship programme sites and practicum sites for undergraduate students in 12 health care zones around the nation.

f) Collaborates with the TTM Council and the Consortium of TTM Network Institutes to produce TTM workforce.

g) Registers ,certifies Thai practitioners of indigenous medicine.

h) Establishes standards for TM formulations (Thai Herbal Preparation Pharmacopoeia: THPP).

i) Reviews TTM and TCM drug registration documents in conjunction with the (FDA).

j) Makes use of the TTM Knowledge Fund to finance initiatives related to the promotion and preservation of TTM knowledge as well as to provide grants for TTM research initiatives

2)FDA, Ministry of Public Health:

a) Regulates the manufacture, importation, and promotion of Items.

b) TTM and TCM products are registered under the Herbal Product Act, B.E. 2562.

c) Incorporates Thai herbal and TM into the NLEM.

1) Department of Medical Sciences, Ministry of Public Health:

a) The Thai Herbal Pharmacopoeia establishes standard requirements for herbal ingredients.

b) Analysis and analyses the quality of marketed herbal medicines on a regular basis.

c) Provides local manufacturers with an analytical service for quality control of herbal medications.

2) Department of Health Service Support (DHSS), Ministry of Public Health:

a) Acts as the Profession Commission's secretariat office in the Branch of TCM & Chiropractic, enforcing the Practice of the Art of Healing Act B.E. 2542. (1999).

b) The Practice of the Art of Healing Act, B.E. 2542, licences and regulates TCM practitioners and chiropractors (1999).

c) Approves TCM schools, as well as their curricula, degrees, and certifications.

d) In the Facilities Act, B.E. 2541, licences and controls TTM and TCM clinics(1998).

3) Thai Traditional Medical Council:

a) Enforces the TTM Professions Act, which was enacted in B.E. 2556.(2013).

b) Under the TTM Profession Act B.E. and provides licences to practitioners, as well as organises licencing exams (2013). c) Establishes TTMstandard curricula, as well as validates TTM schools, curricula, degrees, and certifications.

d) Regulates and supervises TTM practitioners' code of conduct and ethics.

4) *The Ministry of Higher Education, Science, Research, and Innovation's Office of the Higher Education Commission:*

TTM's "Thai Qualifications Frameworks for Higher Education" are established, and TTM curriculum are utilised. TTM and applied TTM curricula of higher educational institutions areapproved in partnership with the TTM Council. [53]

.2.1.3 Thai Pharmacopoeia

Because of the complexities of the testing methods, agreements were created to ensure the quality of raw pharmaceuticals, but not compound therapies made from them. Various government agencies are in charge of quality monitoring and specifications for crude pharmaceuticals. The Thai Pharmacopoeia Committee, for example, has been tasked with ensuring the quality of pharmaceuticals marketed in Thailand, and the Department of Medical Sciences has been selected to lead it. Monographs on crude pharmaceuticals are written, with some referring to international pharmacopoeias like the British and US Pharmacopoeias.[54]

The following standards must be met, according to Drug Act B.E.2510 (A.C. 1967) and its revisions by government affairs division FDA Ministry of public health, Thailand :

Section 49. The categories of licenses for traditional drugs are as follows:

(1) A permit to manufacture TM.

(2) A permit to market of TM.

(3) A licence allowing TM to be imported or ordered into the kingdom.

In respect of the medication that he produces, imports, or orders into the Kingdom, a licensee under (1) or (3) is likewise presumed to be licenced under (2).

Section 50: A Section 49 licence must include coverage for the licensee's employees or agents. Unless the licensee can establish that he had no knowledge or control of the act, an act of a

licensee's employee or agent covered by paragraph one is deemed to constitute the licensee's act.

Section 51: Licenses obtained under Section 49 are valid until December 31st of the year in which they were issued. Before his licence expires, a licensee who intends to renew it must apply for renewal. Once the application is submitted, the business can continue to operate until the licensor issues an order refusing to renew the licence. Ministerial Regulations explain the rules, processes, and criteria that must be followed when applying for renewal or approval.

A licensee whose licence has been expired for less than one month may file an exemption application stating the reason for the extension; however, the exemption application does not provide a defence for offences committed prior to the application for licence extension, which is considered conducting business with an expired licence. You will not be able to apply for a renewal after one month has passed since your licence expired.

Section 52: If the licencing authority refuses to issue or renew a licence, the applicant has thirty days to file a written appeal with the Minister after receiving notice from the licencing authority that the licence will not be issued or renewed. The Minister's decision will be final.

Section 53: Even if it's a direct wholesale to a licensee to distribute TM, no licensee shall create or distribute TM outside of the place mentioned in the licence.

Section 54: Persons licenced to produce TM must have a TMP on duty during business hours who is required to act in accordance with Section 68. A TMP shall be on duty as the person performing the duty under Section68 during the operating hours for the person requesting for a licence in clause somebody who creates more than fifty formulas.

Section 55: Persons authorised to offer traditional pharmaceuticals shall have a TMP on duty at all times during business hours who is required to operate in accordance with Section 69.

Section 56: TMP licenced to import TM must have TMP on duty at the place of importation or warehousing of drugs between business hours, with the duty to act as stipulated in Section 70.

Section 57: Persons with a licence to manufacture TM must:

- erect a sign in a public area in front of the premises for producing drugs in accordance with the category of licence that can be seen from the street, as follows:

(a) A sign indicating that it is a pharmaceutical manufacturing facility; (b) A sign indicating the person in charge's first and last names, as well as his or her qualifications and office hours.

Ministerial Regulations govern the appearance, colour, and size of the sign, as well as the size of the literal and the text displayed on the sign.

1. Labels relating to the registered formula must be fastened to containers and packaging for medications produced and must always be completely labelled to show:
2. Use labels and related literature that conform to the registered formula and include simple language. If the associated content is written in language other than Thai, then must be translated.
3. Compile the information of medications manufactured or marketed in accordance with Ministerial Rules.
4. Follow the Ministerial Regulations to the letter.

If the medicine cannot display the text in (2) (a) to (j) on the container, it must at least display the text in (2) (a), (c), or (d) (d). [54]

5.3WHO Eastern Mediterranean region

5.3.1 United Arab Emirates:

5.3.1.1 Regulation

In the Emirate of Dubai, UAE, the Dubai Health Authority (DHA) is in charge of regulating (TCAM) practice.

TCAM personnel' Scope of Practice (SOP) covers the acts for which they have been taught, certified, and competent and also their decision-making skills. These operations, which are defined by the definition of properly licensed TCAM practise, which is supplemented by standards, education, and is influenced by the configuration, surroundings, and nation's health needs and also the changing state of health care practice, are influenced by the environment, and peoples medical needs as well as the changing state of primary care.

TCAM procedure involves the following procedures, which are outlined in the following rules (SOP):

Ayurveda: Rule 161A exempts Ayurvedic (including Siddha) and Unani medications from certain labelling and packing requirements if they are to be exported and may be altered to suit the specific needs of the legislation of the country importing them. [55]

SOP for Ayurveda:

1. Surgical treatments and the use of prescription drugs are not permitted in the practice

of Ayurveda. Ayurveda practise includes, but is not limited to, physical examinations and laboratory tests for diagnostic reasons, physiological functional testing and clinical laboratory tests.

2. A certified Ayurveda specialist can provide, order, prescribe, or organize Ayurveda treatments of Therapeutic yoga, Diet consultation, pranayama exercises, and meditation are all available. As long as it complies with TCAM facility rules, Ayurvedic herbal medications can be prescribed. Massage and musculoskeletal manipulation in accordance with Ayurvedic instruction.

SOP for Chiropractic:

1. Physical examinations and laboratory tests are ordered in accordance with chiropractic education and training. Snail and other articular adjustments and also In order to protect or treat neurological, skeletal, or soft tissue conditions, manipulations are performed. Chiropractic adjustments, hot/cold water therapy, and durable medical equipment are included. Health education and counselling are two different things. A licensed radiologist must do radiological testing. The practice of chiropractic medicine does not involve the Licensee's aid in emergency situations.
2. In his practice of chiropractic medicine, a licensed chiropractor must adhere to the principles and fulfil the obligations. The Licensee must possess a wide variety of patient-centered skills, including the ability to combine examination and diagnosis while remaining sensitive to the needs and culture of the patient. They must be able to refer when necessary. According to Chiropractic Principles, the individual patient's knowledge guides the decision to utilize Chiropractic and its effectiveness in a given situation.

SOP for Homeopathy:

1. The inspection, assessment, or treatment of a symptom or human ailment is considered part of the homoeopathic profession. Proposing to dispense or order such homoeopathic medication for the use of another individual, unless otherwise permitted by legislation. In the practice of homoeopathy, the licensed practitioner offering the services must assure patient safety and evidence-based care. Licensed homoeopaths are not allowed to expand their area of practice unless they have the necessary training or expertise to investigate alternative treatments. The Licensee must possess a wide variety of patient-centered skills, including the ability to combine examination and diagnosis while remaining sensitive to the needs and culture of the patient. They must understand the

basic scientific approach to common illnesses as well as serious or life-threatening common conditions, and they must be able to refer when necessary. The decision to utilize homeopathy and its success in a given case are determined by the individual patient's understanding, according to Homeopathic Principles.

SOP for Naturopathic medicines:

1. Diagnostic scientific examinations, in accordance with naturopathic learning and skills, such as clinical laboratory tests and physiological functional testing, are examples of activities that may be incorporated in the practice of Naturopathic Medicine. Diagnostic imaging scans are ordered in accordance with naturopathic knowledge. All medical examinations that are not in accordance with naturopathic medical learnings and skills must be directed to a qualified health care professional for execution and interpretation.
2. In his practice of Naturopathic Medicine, a Licensee who holds Naturopathic License should follow some principles and fulfil the following requirements. These are in addition to any other restrictions imposed by these Rules and the General Licensing Rules, as well as any conditions imposed by DHA health regulations on such Licensee's License:
    a) The Licensee must have a broad range of patient-centered abilities, including the ability to combine evaluation and assess how sensitive are the patient requirements and culture. They should be familiar with fundamental scientific approach to ordinary illnessesas well as significant or life-threatening common ailments, and they must be able to refer when necessary.
    b) If the Licensed Naturopath has any reservations regarding the patient's condition or clinical course, the patient must be referred to a general medical physician or specialists. A referral should not even be denied or hindered when a patient gets a better opinion. A Licensed Naturopath is in charge of keeping a thorough record regarding their patient's medical history, as well as speeding diagnostic tests and consultations and cooperating with other medical experts.

SOP for Osteopathic medicine:

1. 1. Physiological or research lab exams, include but can’t be restricted to clinical laboratory tests and metabolic functional testing, are part of the practice of Osteopathic medicine and are associated with Osteopathic training and education for clinical objectives.
2. For execution and interpretation, any diagnostic procedures outside the scope of

naturopathic medical education and training must be referred to a qualified healthcare professional. Treatment options include electrotherapy, cranial osteopathy, hot/cold hydro(water)therapy, osteopathic manipulative medicine (OMM), and therapeutic exercise. The following are recommended: vitamins and amino acid along with the minerals plus the enzymes, botanicals and their extracts, over-the-counter medications.

3. The Licensee must have a broad range of patient-centered abilities, including the ability to integrate examination results with the diagnosis with sensitivity to patient requirements and culture. The decision of usage of Osteopathy and its success in a given instance is determined by the understanding of patient, according to Osteopathic Principles. When a Licensed Osteopath is unsure about a patient's diagnosis or response to treatment, he or she must refer the patient to a general medical doctor or a specialist. When a patient requests a second opinion, a referral should not be denied or discouraged.

SOP for therapeutic massage:

1. Massage is a non-pharmaceutical treatment. Bodywork that entails the use of soft tissue manipulation methods on the body in order to decrease tension, exhaustion, and discomfort while also boosting circulation. Massage therapists manipulate the soft tissue, which includes the skin, muscles, tendons, ligaments, and connective tissue.

Examples: Ayurvedic Massage Therapy (e.g.: Panchkarma), Traditional Chinese Medicine Massage (Tui na), Lymphatic Massage (Lymph Drainage Therapy), Acupressure, Aromatherapy, Bowen technique, Deep tissue massage, Feldenkrais method, Reflexology, Rolfing, Shiatsu, Sports massage, Traditional Thai massage, etc.

2. The Licensee must have a broad range of patient-centered abilities, including the ability to integrate inspection and diagnosis with consideration for the needs and culture of the patient. They must be knowledgeable of the fundamental scientific theories that underlie both minor and serious common illnesses, and they must be able to consult them when necessary. According to massage principles, the patient's knowledge determines whether or not to utilise massage and how successful it will be in a certain situation. It is necessary to personalise the patient's medical history and physical examination. Evaluation of the patient's sensitivity to medical treatment, as well as the patient's likely reaction and response to the treatment chosen.

SOP for traditional Chinese medicine:

1. Physiological examination : diagnostic reasons, including and is not restricted to clinical laboratory tests, by TCM education and training, are examples of TCM practice.

Investigations that are not aligned with naturopathic medical education and practice should be performed and interpreted by a properly licensed healthcare specialist.

2. The Licensee must possess a broad variety of patient-centered talents, including the capacity to combine examination and diagnosis while remaining sensitive to the needs and culture of the patient. They must be able to refer when appropriate and comprehend the basic scientific approach to common illnesses as well as major or life-threatening common disorders. The Licensed TCM Professional is responsible for keeping a thorough record of their patient's medical history, including timely diagnostic testing and consultations, as well as working with other medical specialists. A Licensed TCM Professional must additionally fulfill the Training And Professional Development criteria for licensing,

SOP for Unani medicine:

1. Physiological investigations in accordance with Unani education and training for diagnostic reasons may be part of the practice of Unani medicine. Unani drugs and therapeutic procedures, including cupping, are used to prevent or correct constitutional dysfunction. Cupping can be done dry or wet, with the latter necessitating sterile techniques. All diagnostic tests not in line with naturopathic medical education and training must be directed to a suitably credentialed healhealthcarecialist for execution and interpretation. Hydrotherapy with therapeutic exercise within the scope of the Unani Practitioner's training are gadgets such as therapeutic devices and durable medical equipment. Health education provides advice on how to live a healthy lifestyle.
2. A Licensee who holds an Unani License must meet some standards when practicing Unani medicine. The Licensee must possess a wide variety of patient-centered skills, including the ability to combine examination and diagnosis while remaining sensitive to the needs and culture of the patient. They must know the all medical conditions and should be able to refer when necessary. The choice to use Unani and its success in a given situation are decided by knowledge of the individual patient, according to Unani Principles. [55]

The national legislation specific to herbal medicines is Federal Law No. 20 of 1995 for "Medicines and products produced from natural sources."[56]

5.3.2 Pakistan

5.3.2.1 CAM practiced in Pakistan are regulated under Unani, Ayurvedic and Homoeopathic (UAH) Act of 1965

The following are some of the steps made to revitalize and promote the system:

Design of concepts for a National Policy on TM

a) Completion of the Master Plan for the establishment of the National Policy
b) The Federal Cabinet and the NASCH have adopted the "Tibb-e-Unani, Ayurvedic, Homoeopathic, Herbal and Bio-chemic Medicines Drugs 2010" Act, which would control the manufactureand storage, import plus export of TM
c) Medicinal plant standards and specifications are currently being developed.

Chapter 3: Practitioners registration:

23. For the registration under UAH Act, Applicant's credentials were checked and name filed under this section with Acts provisions and should pay the fees as mentioned.

24. Registration of Unani, Ayurvedic and Homoeopathic Practitioners:

Individual who passed qualifying exam can apply for registration under the Medical Council Ordinance, 1962 (XXXII of 1962) is eligible to apply for registration as a homoeopath.

Chapter 2: Offences, Penalty and Procedure:

37. Persons not registered under Act not to practice:

A Tabib, Vaid, or Homoeopath who is not registered is not permitted to sign birth and death certificates and also not allowed to performed surgery as per rules. [57]

5.3.2.2 Traditional/complementary/alternative medicine research and development

In Pakistan, the majority of medicinal plant research is at the documentation stage. The research is mostly done in universities, and it is done as an ethno botanical resource listing. Various institutes have recently conducted research on various medicinal plants to determine their antibacterial, antiplatelet, and ACE inhibitory components, inflammatory, analgesic, gut modulatory, and antidiarrheal properties.[58]

5.3.2.3 The National Council for Tibb (NCT):

It is in charge of establishing the Tibb-e-Unani and Ayurvedic systems of medicine's curriculum, education, and examinations, as well as registering Tabibs who pass the examination. The remaining members of the council are nominated by the federal and

provincial governments. 14 of the 22 council members are elected by postal ballot. Members serve for a five-year term. The president is chosen by the council members themselves. With NCT, the count was roughly 45,799 Hakims/Tabibs and 537 Vaids, as well as about 28 Tibbia colleges. A five-year BEMS programme, as well as M. Phil and PhD programmes, are offered by two universities.

5.3.2.4 National Council for Homoeopathy (NCH):

Like NCT, NCH is in charge of designing curriculum, education, homoeopathic system of medical examinations, and homoeopathic doctor certification. Members of the council are chosen in the same way that members of the National Council for Tibb are. In Pakistan, there are approximately 118,000 registered homoeopaths and 135 approved homoeopathic colleges. There are three universities that provide a five-year BHMS programme as well as M. Phil and PhD programmes.

It is in charge of designing the curriculum, education, and examinations for the Tibb-e-Unani and Ayurvedic systems of medicine, as well as registering Tabibs who pass the examination. The federal and provincial governments nominate the remaining members of the council. 14 of the 22 council members are elected by postal ballot. The government has never governed the manufacturing industry. Manufacturers, on the other hand, self-regulate by establishing standards to ensure product safety and quality. [57]

5.3.3 Iraq

5.3.3.1 Health policies and systems:

Healthcare system, nationwide pharmaceuticals and technologies, extending the family practice program, enhancing quality and safety, and strengthening the health information system are among the national priorities set in 2018 and the health sector strategic plan. The Ministry of Health is constructing a curriculum framework, which will entail a 3 years strategic plan, as well as analyzing and implementing a full system for health-care provider licensure, regulation, accreditation, and quality assurance. In June 2010, with technical aid from Medical Corps, standard setting guidelines for primary health care facilities were created. The accrediting system, on the other hand, is still in its infancy. With recent large increases in out-of-pocket expenses, health finance has developed drastically in the past 50 years, shifting from a welfare state model to the introduction of user fees and the building of self-sustaining institutions. Per capita health expenditure has more than doubled in the previous 10 years.

External help for the health sector was always limited, even during the embargo, when state capital ability was strained. Contribution approaches in the form of social and private insurance coverage are being studied by numerous lawmakers and leaders of private sector professional groups.

The distribution of health-care facilities among governorates and between rural and urban populations is inequitable. Clinics that provide primary health care to a specific population are known as primary care clinics. International donors and nonprofit organizations that are actively engaged in the health-care sector are a crucial source of assistance. As a consequence of growing potential of health and medical sciences academic institutions, as well as recent governments' expanding health-care spending, the number of certified health people has been gradually increasing. The lack of meaningful human resource management frameworks and ability within the Health ministry and governorates to strategically plan, deploy resources, identify priorities as well as activation functions and cost-effective remedies for the health workforce is one of the challenges facing the health workforce. Other problems include the need to raise the quality of health professional education, particularly for nurses and allied health professionals, as well as an internal and external "brain drain" of professional competence. Family practice became an overarching service delivery strategy for the Ministry of Health in early 2012. A basic health-care plan has been authorized, and it is being administered and extended throughout the nation. The increasing outbreak of noncommunicable diseases, associated with existing technological advances, requires a new aspect of health services, professional examinations, and health care system strategies which result in a centralized and comprehensive model of health care that integrates prevention, early diagnosis, effective treatment and rehabilitative services. As a consequence, a new set of skills and competences are required, and governments must move fast to adapt the present medical education paradigm and enhance future health research. All duties of the national regulatory authority remain in existence despite the absence of clinical trials control. A list of necessary pharmaceuticals for basic health care has been developed, as has a multispectral medication simplification group focusing on antibiotic resistance. Lack of a government policy on healthcare technology, flaws in allocation of resources methods, limited local production capacity, limited capacity to evaluate the clinical safety, efficacy, and performance of new technologies, and the absence of an autonomous organization to control medical products, especially in the private sector, that everything hinder access to health technologies. [59]

5.4WHO Western Pacific region

5.4.1 China

5.4.1.1 Regulation and Law

China has enacted a slew of legislation to regulate TCM. Many of these laws and restrictions apply to modern medicine as well as TCM. Some of the most important laws and regulations are listed below:

The People's Republic of China's Drug Administration Law of 1984:

This is the primary law that governs the manufacture, distribution, and preparation of all pharmaceuticals. This law, which was revised in 2001, also applies to TCM.

1987 Regulation on Wild Medicinal Resources Protection: The main goal is to ensure the long-term collecting of wild medicinal resources while also fostering medicinal plant cultivation. It divides medicinal plants found in the wild into three categories:

- Class 1: Endangered, rare and precious wild medicinal species
- Class 2: Important wild medicinal species
- Class 3: Major wild medicinal species

Traditional Chinese Medicines Protection Regulations, 1993: This TCM National Regulation intends to enhance the quality of all varieties of TCM, encourage TCM development, and, greatest importantly, protect the constitutional legitimate interests of TCM producers

TCM Regulations of the People's Republic of China, 2003: This law governs the formation of medical institutions, TCM research and practises, as well as the responsibilities and fines that may result from failure to follow the requirements.

Traditional Chinese Medicine Law of the People's Republic of China, 2017: It establishes laws for the TCM industry as well as requirements for practitioners in order to boost the industry's legitimacy and competence. It also demands for TCM to be protected as "state secrets," among other things. Healthcare treatments, protection and management of Chinese medicine, professional skill education, academic research, cultural and historic transmission and safety as well as promoting measures and legislative requirements, are all covered by the law. The law addresses the creation and improvement of a regulatory framework for traditional Chinese medicine, as well as the protection of intellectual property and comprehensive supply chain quality monitoring of medical products.[60]

5.4.1.2 Policies and programmes

As can be observed from the following paragraphs, the preceding laws and regulations were enacted as a result of government policy directives.

The Federal Medium & Long-Term Training program for Scientific and Technological Development (2006-2020) defines four main tasks for policymaking ministries: TCM inheritance, innovation, modernization, and internationalization. With the goal of contemporary TCM research development and production technologies, this has formed therapy, evaluation technologies, and research standards for TCM. It is vital to mix TCM's traditional background with life-science developments in order to develop it. The goal is to transform TCM into clinical efficacy. This programme asks for a diverse and multichannel investment structure to support the advancement of TCM, which can be developed, among other things, through foreign collaboration assets.[61]

5.4.1.3 Regulatory and administrative framework

The National Health and Family Commission is responsible for TCM administration. In 1986, the State Council created TCM's independent management. The establishment of TCM administrations operating directly under the central government in all provinces, autonomous areas, and municipalities has created the institutional framework for the development of TCM.

State Intellectual Property Office: Patent law in China protects innovative TM items, processes, and applications. This comprises herbal preparations, herbal medicine extracts, herbal medicine-containing foods, herbal formulas preparation methods, and new medicinal indications for classic formulae. 4,1482 TCM-related patent applications, or 1.4% of all patent applications, were submitted to the Chinese State Intellectual Property Office (SIPO) between 1985 and 2007; 12,690 of those applications were eventually granted, or 3.3 percent of the total. The majority of candidates were American citizens. [61]

The State Administration of Traditional Chinese Medicine (SATCM) and the State Food and Drug Administration (SFDA):

TCM is regulated by these two government agencies. These are the main regulatory bodies in China for TM, and they both draught and oversee the implementation of TCM legislation and best practises. TCM must first be licenced by the SFDA before being promoted as a drug. TCM Regulations, or particular national legislation on TCM, have been in existence since 2003. On the other hand, these regulations lack any requirements for safety or efficacy and are only intended to promote TCM. As a result, legislation controlling the safety and efficacy of TCMs

are enacted by different state bodies and provincial governments.

The following are some notable international standards subscriptions:

• GMP: GMP for herbal commodities has been created in China based on WHO-GMP. China has made significant progress in the development of TCM in recent years.

• GLP (for nonclinical laboratory studies) and GCP (for clinical laboratory studies): GLP and GCP are governed under Law of 2001.

• Good Supply Practice (GSP): Article 16 of the People's Republic of China's Drug Administration Law of 2001 governs TCM's GSP.

International Organization Standardization (ISO)/TC249: Establishing international standards for TCM is a major component of China's national plan. The Secretariat of the) TCM Technical Commission (code: ISO/TC249) was founded in Shanghai in 2010. 36 It is TCM's only technical commission.[62]

5.4.2 Japan

5.4.2.1 Japanese Pharmacopoeia (JP)

Following consultation with the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) and in accordance with the provisions of Article 41, Paragraph 1 of the Pharmaceutical Affairs Law, the Ministry of Health, Labour, and Welfare (MHLW) developed and published the JP to regulate the traits and qualities of PAFSC. The Ministry specifies and publishes the JP, a manual of drug standards.The PAFSC's Subcommittee on the JP met in November 2001 to review recent medical and pharmaceutical breakthroughs. The basic compilation policies, which detailed the features and responsibilities of the JP, the actual processes followed to establish the basic policies for the 15th edition, the date of enforcement, and details on the composition of the Committee on the JP, were developed.

The PAFSC researched content limits, clarified their significance and their specifications in a report titled "Future Approaches to the JP," and released the JP's fundamental content rules.[63]

5.4.2.2 Japan Pharmaceutical affairs law

The law includes 12 chapters with 89 articles. The chapters are as following:

Chapter I General Provisions

Chapter II Pharmaceutical Affairs Council

Chapter III Pharmacies

Chapter IV Manufacturers and Importers of Drugs, etc.

Section 1. Manufacturers

Section 2. Importers

Chapter IV-2 Designated Review Organizations

Chapter V Selling Drugs and Selling and Leasing Medical Devices

Chapter VI Standards and Tests for Drugs, etc.

Chapter VII Handling of Drugs, etc.

Section 1. Handling of Poisonous and Powerful Drugs

Section 2. Handling of Drugs

Section 3. Handling of Quasi-Drugs

Section 4. Handling of Cosmetics

Section 5. Handling of Medical Devices

Chapter VIII Advertising of Drugs, etc.

Chapter IX Surveillance

Chapter IX-2 Designation, etc. of Orphan Drugs and Orphan Medical Devices

Chapter X Miscellaneous Provisions

Chapter XI Penal Provisions [64]

5.4.3 Australia

5.4.3.1 Therapeutic Goods Act,1989

The TGA's goal is to uphold and retain an Australian national system of regulations to guarantee the efficacy, availability, and quality of therapeutic commodities like pharmaceuticals.

The TGA regulates drug manufacturing, distribution, promotion, and labelling in Australia. It also teaches how to enter drugs into Australia's Therapeutic Goods Register. All parties who produce or manufacture medications for distribution in Australia, as well as those who import

or export pharmaceuticals, are subject to TGA regulation.

The Therapeutic Goods Regulations are designed to make it necessary or easy to carry out or give effect to the TGA by prescribing things relevant to the manufacturing, supply, advertising, registering, or listing of drugs in Australia.[65]

Types of complementary medicines

Traditional and Herbal medicines are named as complementary medicines in Australia.[66]

5.4.3.2 Guidelines for registration of Complementary Medicines:

Registration and scheduling: A registrable supplemental medicine is an unscheduled.

Eligibility for registration: Product get registered if it passed the evaluatory assessment as mentioned under Act. Excipients were also evaluated by complementary medicines office.

Route of evaluation and registration: Applications go through four or five phases after fees have been paid: pre-assessment, evaluation, peer review, potential consideration by the Advisory Committee on Complementary Medicines (ACCM), conclusion, and, if authorised, implementation. The pre-assessment procedure also verifies that all necessary fees have been paid and that all necessary information has been provided. The data is analysed, and a report iscreated outlining the findings. To guarantee consistency in evaluation, evaluation reports are evaluated inside the Office of Complementary Medicine (OCM). The ACCM may be advised,
and it could can provide a guideline to the Secretary of the Board of Health and Ageing's Delegate.

Quality: The product, as well as its active components and excipients, must be disclosed. The data is analysed to establish the product's quality, including the constituents' identification, contaminants, and stability. Where applicable, the examination also considers information about production procedures and levels of GMP.

Efficacy and safety: The pharmacokinetics and pharmacodynamics evaluations were performed and there is no need of in vitro tests as human experience for safety are considered.

Labelling and presentation: The labelling must adhere to the law as well as the current Therapeutic Goods Labelling Order. To ensure accuracy and uniformity, the TGA has list specified number of labelling requirements including batch number, expiry date, manufacturing details and information for consumer.

Product Information and Consumer Medicine Information: This is most important part as product information must be given to the consumer. Along with labelling the leaflet containing information about product description, its pharmacological actions, Clinical trials information, contraindications, precautions, Adverse drug reactions, dosage information and overdosesafety should be mentioned.

Product changes: Changes too many aspects of a Registered complementary medication, unlike changes to listed complementary medicines, require prior permission (Notification). Section 11 specifies which changes can be made without prior approval and which ones require it.

Post market review: To guarantee that medicines marketed in the nation meet quality standards and are both efficient and safe, the complementary medicines office collaborates with other TGA departments to establish a robust post-market surveillance plan..[67]

Limitations of the study

6. Limitations of the study

The study was more focused towards Policies and Regulations for whole TCI because it is difficult to focus on each and every therapy or medication of TCI. The safety, efficacy and quality data is available only for limited medications or therapies. For regulations, study is limited to 3 countries from 4 WHO regions. Data by WHO, is available only till 2012 from second global survey which was updated in 2018 and released in 2019. Limited information about global market of TCI is available.

Conclusion

7. Conclusion

There is need to bridge the gap existing in regulations for harmonization. TCI helps to build economy of global market. TCI therapies or medications are easily available and affordable as compare to pharmaceuticals because most of the TCI therapies or medications are locally available. But when it comes towards Whole medical systems domain which includes Homeopathy and Ayurveda, they have same demand or popularity as Allopathy in the market. If TCI gets support and funding for research and development then in future TCI will be able to prove its safety, efficacy and quality using ancient knowledge which is challenge as well as opportunity for Worlds health care systems.

REFERENCES

8. REFERENCES

1. Traditional, Complementary and Integrative Medicine [Internet]. WHO.int. 2022 [cited 7 January 2021]. Available from: https://www.who.int/health topics/traditional complementary and integrative medicine #tab=tab1.
2. Grandviewresearch.com. 2021.Complementary and Alternative Medicine Market Report, 2021-2028. [online] Available at: <https://www.grandviewresearch.com/industry analysis/complementary alternative medicine market> [Cited 14 October2021].
3. Primary health care [Internet]. Unicef.org. 1978 [cited 2 January 2022]. Available from: https://www.unicef.org/media/85611/file/Alma Ata conference 1978report.pdf.
4. Global Report 2019 [online] Available at:<https://www.who.int/traditional-complementary integrative medicine/WHO Global Report on Traditional and Complementary Medicine 2019.pdf. [Cited 14 December 2021].
5. Koithan M. Introducing Complementary and Alternative Therapies [Internet]. 2022 [cited 4 January 2022]. Available from: http://2019 Jan 1; 5(1):18-20. Doi: 10.1016/j.nurpra.2008.10.012. PMID: 20046927; PMCID: PMC2754854.
6. Understanding Alternative Medicine [Internet]. WebMD. 2022 [cited 3 April 2022]. Available from: https://www.webmd.com/balance/guide/understanding-alternative-medicine #091e9c5e800351f8-3-6
7. What Is Ayurveda? [Internet]. WebMD. 2022 [cited 3 April 2022]. Available from: https://www.webmd.com/balance/guide/ayurvedic-treatments.
8. Acupuncture - Wikipedia [Internet]. En.wikipedia.org. 2022 [cited 3 April 2022]. Available from: https://en.wikipedia.org/wiki/Acupuncture.
9. [Internet]. Lhp-ca.com. 2022 [cited 3 April 2022]. Available from: https://www.lhp-ca.com/resources/pdf/ChiropracticAnIntroduction.pdf.
10. Topics H. Herbal Medicine: MedlinePlus [Internet]. Medlineplus.gov. 2022 [cited 3 April 2022]. Available from: https://medlineplus.gov/herbalmedicine.html#:~:text=Herbal%20medicines%20are%20one%20type,safe%20and%20good%20for%20them.
11. Herbal medicine - Wikipedia [Internet]. En.wikipedia.org. 2022 [cited 3 April 2022].

Available from: https://en.wikipedia.org/wiki/Herbal medicine.

12. Homeopathy - Better Health Channel [Internet]. Betterhealth.vic.gov.au. 2022 [cited 3 April 2022]. Available from: https://www.betterhealth.vic.gov.au/health/conditionsandtreatments/homeopathy.
13. Vikaspedia Domains [Internet]. Vikaspedia.in. 2022 [cited 3 April 2022]. Available from: https://vikaspedia.in/health/ayush/homoeopathy.
14. Doctors E. An Introduction to Naturopathic Medicine [Internet]. East Valley Naturopathic Doctors. 2022 [cited 3 April 2022]. Available from: https://www.eastvalleynd.com/introduction naturopathic medicine.
15. Osteopathy Introduction [Internet]. Zana.com. 2022 [cited 3 April 2022]. Available from: https://zana.com/a/osteopathy-introduction.3567.
16. Traditional Chinese Medicine [Internet]. Wa.kaiserpermanente.org. 2022 [cited 3 April 2022]. Available from: https://wa.kaiserpermanente.org/kbase/topic.jhtml?docId=aa140227spec.
17. NCI Dictionary of Cancer Terms [Internet]. National Cancer Institute. 2022 [cited 3 April 2022]. Available from: https://www.cancer.gov/publications/dictionaries/cancer terms/def/traditional Chinese medicine.
18. [Internet]. Jag.journalagent.com. 2022 [cited 3 April 2022]. Available from: https://jag.journalagent.com/ias/pdfs/IAS 1812730.pdf.
19. Unani medicine [Internet]. Encyclopaedia Britannica. 2022 [cited 3 April 2022]. Available from: https://www.britannica.com/science/Unani medicine.
20. WHO traditional medicine strategy 2002-2005 [Internet]. Apps.who.int. 2022 [cited 6 January 2022]. Available from: https://apps.who.int/iris/handle/10665/67163?show=full.
21. WHO traditional medicine strategy: 2014-2023 [Internet]. Who.int. 2022 [cited 12 January 2022]. Available from: https://www.who.int/publications/i/item/9789241506096.
22. Grandviewresearch.com. 2022. Complementary and Alternative Medicine Market Report, 2021-2028. [cited 11 March 2022]. [online] Available at: <https://www.grandviewresearch.com/industry analysis/complementary alternative medicine market>
23. NCCIH.gov 2022. [Online] Available at: <https://www.nccih.nih.gov/> [Cited 11 March 2022].
24. WIRE, B., 2022. Global Complementary & Alternative Medicines Market Analysis & Forecast to 2024 Research and Markets.com. [online] Businesswire.com. Available at:

<https://www.businesswire.com/news/home/20200204005716/en/Global Complementary Alternative Medicines Market Analysis Forecasting 2024 Research and Markets.com> [Cited 15 March 2022].

25. Persistence Market Research 2022. Alternative Medicines and Therapies Market - Global Industry Analysis and Forecast to 2020. [cited 9 March 2022]. [online] Available at: <https://www.persistencemarketresearch.com/market-research/alternative medicines therapies market.asp>
26. Grand View Research, I., 2022. Complementary and Alternative Medicine Market Size Worth $404.66 Billion By 2028: Grand View Research, Inc.[online] Prnewswire.com. Available at: <https://www.prnewswire.com/newsreleases/complementary and alternative medicine market size worth 40466 billion by 2028 Grandview research inc301229658.html> [cited 5 April 2022].
27. Ltd, R., 2022. Herbal Medicines Global Market Trajectory & Analytics. [online] Researchandmarkets.com. Available at: <https://www.researchandmarkets.com/reports/5302363/herbal-medicines-global-market-trajectoryand#:~:text=Amid%20the%20COVID%2D19%20crisis, 8.1%25%20over%20the%20analysis%20period.> [Cited 7 March 2022].
28. Globe Newswire News Room. 2022. Herbal Medicine Market Global Sales Are Expected to Reach US$ 550 Billion by 2030, as stated by insight SLICE. [online] Available at: <https://www.globenewswire.com/news-release/2021/02/16/2176036/0/en/Herbal-Medicine-Market-Global-Sales-Are-Expected-To-Reach-US-550-Billion-by-2030-as-stated-by-insightSLICE.html> [cited 5 April 2022].
29. 2022. [Online] Available at: <https://www.verifiedmarketresearch.com/product/herbal-medicine-market/> [cited 28 March 2022].
30. Prnewswire.com. 2022. Ayurveda Market to grow by USD 6.81 bn from 2021 to 2026 | Evolving Opportunities with BACFO Pharmaceuticals India Ltd. & Charak Pharma Pvt.|17000+ Technavio Reports. [online] Available at: <https://www.prnewswire.com/news-releases/ayurveda-market-to-grow-by-usd-6-81-bn-from-2021-to-2026--evolving-opportunities-with-bacfo-pharmaceuticals-india-ltd--charak-pharma-pvt17000-technavio-reports-301457097.html> [cited 5 April 2022].
31. Allied Market Research. 2022. Acupuncture Needles Market Size & Growth | Analysis by 2019-2026. [online] Available at:

<https://www.alliedmarketresearch.com/acupuncture-needles-market> [cited 7 April 2022].

32. Grandviewresearch.com. 2021. Complementary And Alternative Medicine Market Report, 2021-2028. [online] Available at: <https://www.grandviewresearch.com/industry-analysis/complementary-alternative-medicine-market> [cited 4 September 2021].
33. Persistence Market Research. 2022. Global Market Study on Traditional Chinese Medicine | Persistence Market Research (PMR). [online] Available at: <https://www.persistencemarketresearch.com/market-research/traditional-chinese-medicine-market.asp> [cited 3 April 2022].
34. Biomedical 2022. [Online] Available at: <https://cmjournal.biomedcentral.com/articles/10.1186/s13020-018-0167-z> [cited 7 April 2022].
35. Nahin R. Stephen E Straus. Research into complementary and alternative medicine: problems and potential [Internet]. 2001 [cited 3 April 2022]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1119420/
36. Policy note for discussion at the second session of the 2020 Roundtable on Investment and Sustainable Development [Internet]. 2020 [cited 3 April 2022]. Available from: https://en.wikipedia.org/wiki/OECD.
37. Tahir N, Thomas P, Li S. Challenges and opportunities in integrating complementary and alternative medicine into mainstream of the Malaysian healthcare system. 2015. http://koreascience.or.kr/article/JAKO201509651112009.page[cited 7 April 2022].
38. Chanda R. Trade in health services [Internet]. Academia.edu. 2001 [cited 3 April 2022]. Available from: https://www.academia.edu/es/9058748/Trade_in_health_services1.
39. Bach E. Cancer Research UK | British Heritage [Internet]. British Heritage. 2002 [cited 3 April 2022]. Available from: http://britishheritage.org/en/cancer-research-uk.
40. Seifert G, Jeitler M, Stange R, Michalsen A, Cramer H, Brinkhaus B et al. The Relevance of Complementary and Integrative Medicine in the COVID-19 Pandemic: A Qualitative Review of the Literature. 2022[cited 3 April 2022].https://pubmed.ncbi.nlm.nih.gov/33363186/
41. WIRE B. Global Complementary & Alternative Medicines Market - Analysis & Forecast to 2024 - ResearchAndMarkets.com [Internet]. Businesswire.com. 2022 [cited 3 April 2022]. Available from:

https://www.businesswire.com/news/home/20200204005716/en/Global-Complementary-Alternative-Medicines-Market---Analysis.

42. Ernst E. The role of complementary and alternative medicine [Internet]. 2000 [cited 3 April 2022]. Available from: http://www.bmj.com.
43. 11. Traditional and Complementary Medicine: Analysing Ethical Challenges [Internet]. Core.ac.uk. 2016 [cited 3 April 2022]. Available from: https://core.ac.uk/download/pdf/96678290.pdf.
44. 12. Bodekar G, Kroonenberg F. A Public Health Agenda for Traditional, Complementary, and Alternative Medicine. [Cited 3 April 2022]. Available from: https://pubmed.ncbi.nlm.nih.gov/12356597/. 2002.
45. Traditional and Complementary Medicine. South African Health Review, 12, 175-188. - References - Scientific Research Publishing [Internet]. Scirp.org. 2022 [cited 12 March 2022]. Available from: https://www.scirp.org/reference/ReferencesPapers.aspx?ReferenceID=2254740.
46. Ngcobo M, Nkala B, Moodley I, Gqaleni N. Recommendations for the Development of Regulatory Guidelines for Registration of Traditional Medicines in South Africa [Internet]. Academia.edu. 2022 [cited 12 February 2022]. Available from: https://www.academia.edu/es/16571968/Recommendations_for_the_Development_of_Regulatory_Guidelines_for_Registration_of_Traditional_Medicines_in_South_Africa.
47. Policy guidelines on Traditional medicine development [Internet]. [Cited 12 February 2022]. Available from: https://dl.icdst.org/pdfs/files4/9499e0e4a02239063fe515ce1df2eb6a.pdf.
48. Pharma and Alternative Medicine Industries in Nigeria [Internet]. Hciabuja.gov.in. 2020 [cited 20 March 2022]. Available from: https://hciabuja.gov.in/pdf/Nigeria%20Pharma%20Report%20as%20amended%20-%20Sent%20to%20client-May%2020,%202020.pdf.
49. National Policy on Indian Systems of Medicine & Homoeopathy-2002 [Internet]. Webrate. 2022 [cited 7 February 2022]. Available from: https://webrate.org/index.php/site/indiascienceandtechnology.gov.in/.
50. Central Council of Indian Medicine: Ministry of Ayush, Govt. of India [Internet]. Ccimindia.org. 2012 [cited 7 February 2022].
51. Regulatory Scenario of Herbal Medicines: A Global Review - International Pharmaceutical Industry [Internet]. International Pharmaceutical Industry. 2022 [cited

12 January 2022]. Available from: https://international-pharma.com/regulatory-scenario-of-herbal-medicines-a-global-review.

52. Murshid m, haque m. Bangladesh National Drug Policy 1982-2016 and Recommendations in Policy Aspects [Internet]. 2019 [cited 12 February 2022]. Available from: https://www.researchgate.net/publication/333905673_Bangladesh_National_Drug_Policy_1982-2016_and_Recommendations_in_Policy_Aspects.
53. [Internet]. 2022 [cited 12 April 2022]. Available from: http://www.dtam.moph.go.thTraditional and Complementary Medicine Practice Guidelines in ASEAN: Thailand Section
54. Heritage sites to boost Thailand's revenue - Pattaya Mail [Internet]. Mail. 2013 [cited 3 February 2022]. Available from: https://www.pattayamail.com/business/heritage-sites-to-boost-thailands-revenue-28642.
55. The Dubai Health Authority is a government organization overseeing the health system of Dubai, United Arab Emirates [Internet]. Health regulation department Dubai health authority; 2011 [cited 12 February 2022]. Available from: https://www.google.com/search?q=Traditional%2C+Complementary+and+Alternative+Medicine+Scope+of+Practice&rlz=1C1CHWL_enIN871IN871&sxsrf=APq-WBsyqQKGee9Pg-GWQrbFFSKi9CP4pg%3A1649775349400gws-wiz.
56. Federal law NO 20 of 1995 Re: Medicines and Products Derived from Natural Sources [Internet]. 2022 [cited 8 February 2022]. Available from: https://www.khidi.or.kr/fileDownload?titleId=259327&fileId=1&fileDownType=C&paramMenuId=MENU01872,
57. Malik F, Hussein s, Khalid n. 4 Alternative and Traditional Medicines Systems in Pakistan: History and Regulation, Trends, Usefulness, Challenges, Prospects and Limitations [Internet]. Academia.edu. 2012 [cited 8 February 2022]. Available from: https://www.academia.edu/71088285/4_Alternative_and_Traditional_Medicines_Systems_in_Pakistan_History_Regulation_Trends_Usefulness_Challenges_Prospects_and_Limitations.
58. The unani, ayurvedic and homeopathic practitioners Act, 1965 (II of 1965) | National Council for Tibb [Internet]. Nct.gov.pk. 1982 [cited 8 February 2022]. Available from: http://www.nct.gov.pk/uah-act-1965/

59. WHO country cooperation strategy at a glance: Iraq [Internet]. Who.int. 2016 [cited 8 February 2022]. Available from: https://www.who.int/publications-detail-redirect/WHO-CCU-17.01-Iraq.
60. China's policy initiative for national and global promotion of tcm [Internet]. Ayushportal.nic.in. 2022 [cited 12 February 2022]. Available from: https://ayushportal.nic.in/pdf/China Policy Initiatives National and Global PromotionofTCM.pdf.
61. The National Medium- and Long-Term Program for Science and Technology Development (2006- 2020) - An Outline [Internet]. Readkong.com. 2020 [cited 1 April2022]. Available from: https://www.readkong.com/page/the-national-medium-and- long-term-program-for-science-and-9879332
62. State Administration of Traditional Chinese Medicine: The total number of TCM diagnosis and treatment in 2020 will reach 1.06 billion | tellerreport.com [Internet]. Tellerreport.com. 2022 [cited 1 April 2022]. Available from: https://www.tellerreport.com/news/2022-01-21-state-administration-of-traditional- chinese-medicine--the-total-number-of-tcm-diagnosis-and-treatment-in-2020-will- reach-1-06-billion.rJ-8cQjvTF.html
63. Japanese perspective [Internet]. 2004 [cited 12 February 2022]. Available from: https://www.researchgate.net/publication/8236584 Complementary and Alternative Medicine Japanese Perspective/fulltext/0f5a697e3829a193f26450.pdf.
64. Pharmaceutical Administration and Regulations in Japan [Internet]. Nihs.go.jp. 2022 [cited 8 April 2022]. Available from: https://www.nihs.go.jp/mhlw/yakuji/yakuji- e20110502-02.pdf
65. Regulation of Medicines in Australia [Internet]. Paperzz.com. 2001 [cited 12 March 2022]. Available from: https://paperzz.com/doc/8862338/regulation-of-medicines-in- australia
66. Therapeutic Goods Administration - Wikipedia [Internet]. En.wikipedia.org. 2018 [cited 12 January 2022]. Available from: https://en.wikipedia.org/wiki/Therapeutic Goods Administration.
67. Australian Regulatory Guidelines for Complementary Medicines (ARGCM) Part I: Registration of Complementary Medicines [Internet]. Globi-reg.com.

2011 [cited 12 February 2022]. Available from: https://globi-reg.com/wp-content/uploads/2018/09/GN-20-R1-Guidance-on-Clinical-Evaluation17Dec-pub.pdf