STUDY OF REGULATIONS AND MARKET OPPORTUNITIES OF TRADITIONAL, COMPLEMENTARY AND INTEGRATIVE MEDICINES IN DIFFERENT COUNTRIES.

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Introduction:

- 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.”

- 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.”

- 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.

➢ Five domain classification of TCI:

SI. No.	Domain	Examples	
1	Mind-body interventions	Meditation	Yoga
2	Biologically based practices	Herbals	Prebiotic
3	Energy medicine	Reiki	Healing touch
4	Manipulative and body-based practices	Chiropractic	Osteopathy
5	Whole medical systems	Naturopathy	Ayurveda

[3]

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Literature Review:

- The WHO has performed two global surveys on TCI, the first in 2005 and the second in 2012
- WHO has divided the world into six regions: the African region, the South-East Asia region, the Eastern Mediterranean region, the Region of America, the European region, Western pacific region.
- WHO's TM Strategies:

2002-2005	2014-2023
Policy	Management
Safety, Efficacy & Quality	Safety, Efficacy & Quality
Access	Services [7]
Rational use [6]	-

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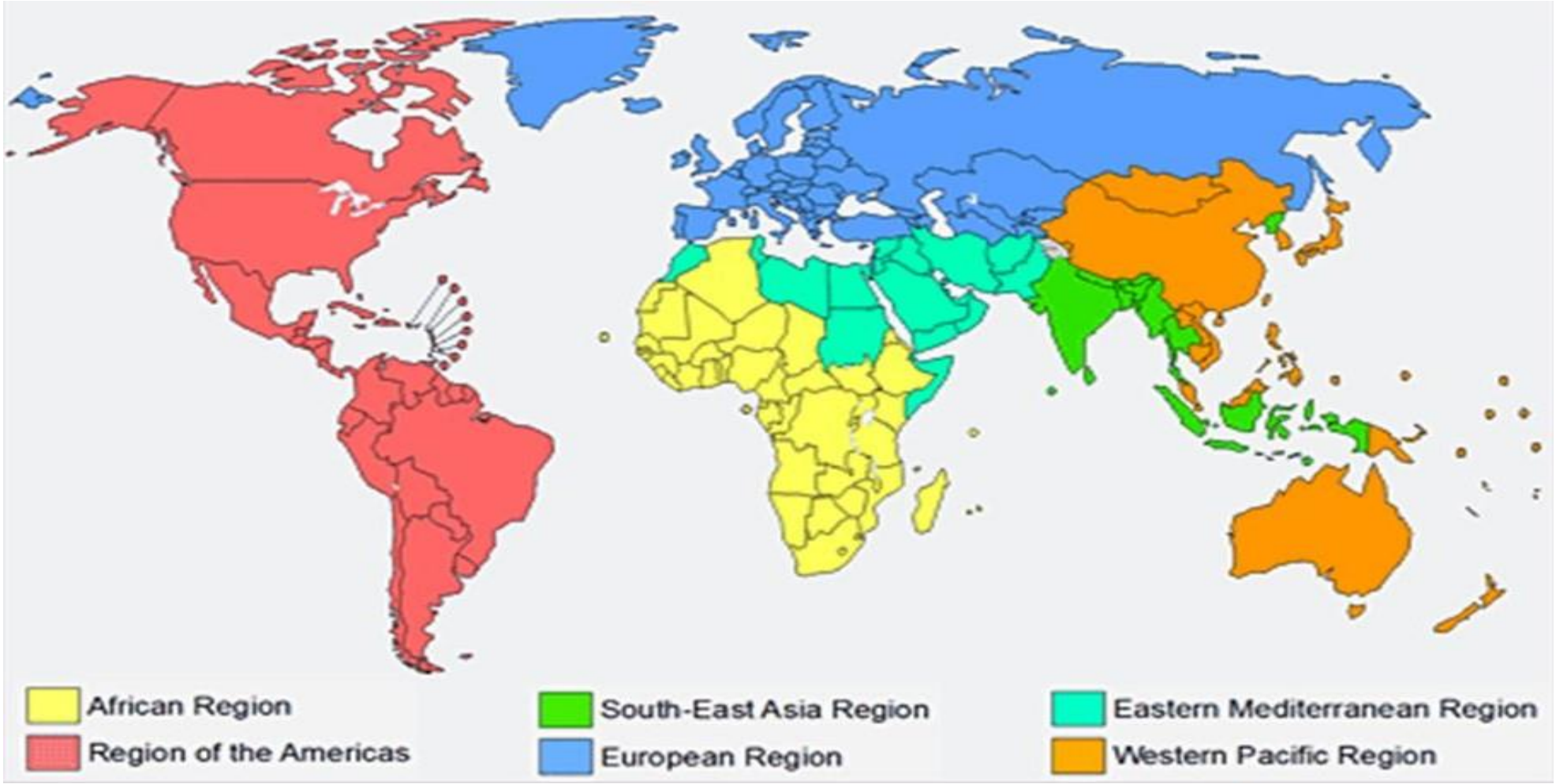
WHO regions



Source: WHO Member States are grouped into six regions. Each region has a regional office. The map shows the WHO regions and the location of the region. Available at: https://www.who.int/about/regions/en/

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Global market:

Market size value in 2020	USD 82.27 billion
Market size value in 2021	USD 100.04 billion
Revenue forecast in 2028	USD 404.66 billion
Growth Rate	CAGR of 22.03% from 2021 to 2028

[8]

- **Global market of TCI according to distribution channels**:

  Direct sales – 73% revenue share

  Distance correspondence – 22.90% [9]

  Hospitals and retail pharmacies [10]

- **Global market of TCI according to WHO region:**

Europe-33.35% [11]

Middle East and Africa-24.78%

Japan and Canada- 7.4 & 7.1% [12]

China- USD 32.9 billion

Asia-Pacific- USD 2.7 billion

- **Global market of TCI according to its therapy/medication:**

Botanicals-38.48%

Hypnotherapy- CARG 22.44%

Vitamin D3-7.95%[14]

Ayurveda-16.14%[16]

Yoga-36.75%

Herbal medicines-8.1% [13]

Acupuncture- 8.2%[15]

WHO Region	Member States	National Policies	National or state level laws & regulation	National office	National research institute	Registration system	National programme
African region	47	40	39	39	29	23	34
South-East Asian region	11	10	9	10	7	10	10
Eastern Mediterranean region	21	9	12	13	10	17	4
Western Pacific region	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

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].

Opportunities:

- Research and development [17]
- Foreign Direct Investment (FDI) [18]
- Trade in services [19]
- Knowledge base for active management [20]
- Covid-19 management [21]
- Resource utilization [22]

Challenges:

- Hard evidence is scarce [23]
- Complex reasons for popularity
- Ethics: Clinical research [24]
- Intellectual Property Rights (IPR)
- Financial and Insurance coverage
- Knowledge management and utilization [25]

Objectives of the Study:

- 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.

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Research Methodology:

- **Study plan:** Secondary data

- **Data Collection:** WHO reports

  Regulatory guidelines and financial reports

  Market forecasting data

  Official websites

  Scholarly articles- PubMed

  NCBI

Data analysis and Interpretation	✓ Data collection ✓ Qualitative data extraction ✓ Conclusion- regulatory process
Regulations	✓ 4 WHO regions ✓ 3 countries from each WHO region
Selection of countries	✓ Market ✓ Popular TCI practice ✓ National policy or rules and regulations

Countries selected for study

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

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South Africa:

- 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.
- 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."
- The AR Program is one of the recommended strategies for controlling supplementary medications.
- Regulatory guidelines:
  - Traditional use
  - Multi-ingradient TM product
  - Pharmaceutical quality
  - Labelling & packaging
  - Stability testing
  - Post-approval market monitoring
  - Safety
  - Therapeutic efficacy

Ghana:

- The government established the Traditional Medicine Practice Council (TMPC) Act in 2000 to establish the Traditional Medicine Council, which is in charge of registering all TMP's in the country.
- Policy of TM Development focuses on:
  - Regulatory legislation
  - IPR Protection
  - Research & Development
  - Public I.E & C on Rational use of TM
  - Standardization, quality assurance and large-scale production
  - Public Information, Education & use
  - Global Networking and Collaboration

Nigeria:

- In order to increase TM's contribution to the nation's formal healthcare 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:

- Facilitating the practice and growth of TM.
- Establishing guidelines for TM practice regulation to protect the public from quackery, fraud, and incompetence.
- Coordinating with state boards of TM to guarantee conformity to the Federal TM Board Act's policies and recommendations.
- Creating model TM clinics, herbal farms, botanical gardens, and TM production units throughout the country's geopolitical zones.
- Collaborating with organizations in Nigeria and abroad that have similar goals.

India:

- 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.
- Policy support – Finance
  Medical Education
  Drug Standards, Regulation & Enforcement
  Revitalization of Local Health Traditions
  Research in ISM
  Access to information
- The Ministry of Health and Family Welfare established a separate Department for ISM & H in 1995. In November 2003, it changed its name to the Department of AYUSH.
- Schedule T: GMP for Ayurvedic, Siddha, and Unani medicines. Under this, the government has mandated that all manufacturing facilities adhere to GMPs.

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.

Maldives:

- Alternative and Traditional Medicines can be registered by an importer, a Party designated by the product manufacturer (e.g., the holder of a marketing license), and the product manufacturer.
- The products for registration are divided into 2 categories.
  - Alternative Medicine
  - Traditional (Dhivehi beys)
- The list of medications permitted to be imported, disseminated, produced, and marketed in the Maldives is known as the Approved Alternative/ Herbal Medicine List
- Product information: This provides the specific product information for which the dossier is being submitted for registration.
- Post-market surveillance: Adverse Drug Reactions will also be monitored for one year for traditional treatments.

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Thailand:

- 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.
- Regulatory bodies:

a) Department of Thai Traditional and Alternative Medicine (DTAM), Ministry of Public Health

b) Food and Drug Administration (FDA), Ministry of Public Health

c) Department of Medical Sciences, Ministry of Public Health

d) Department of Health Service Support (DHSS), Ministry of Public Health

e) Thai Traditional Medicine (TTM) Council

f) Office of the Higher Education Commission, Ministry of Higher Education, Science, Research and Innovation.

UAE:

- 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 their decision-making skills.
- TCAM procedure involves the following procedures, which are outlined in the following rules (SOP):

SOP for Ayurveda

SOP for Chiropractic

SOP for Homeopathy

SOP for Naturopathic medicines

SOP for Osteopathic medicine

SOP for therapeutic massage

SOP for Unani medicine

Pakistan:

- In Pakistan, the policy on TCI is integrated into the national health policy of 2001.
- 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.
- National Council for Homoeopathy (NCH): 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.

Iraq:

- 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 healthcare 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.
- Challenges faced:
  - The lack of meaningful human resource management frameworks and ability within the Health Ministry and governorates to strategically plan, deploy resources, and 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.

China:

- *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.

- The State Council issued two documents –

  1) The Regulations of the People's Republic of China on TCM (2003).

  2) The Opinions on Supporting and Promoting the Development of TCM (2009).

- 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.

Japan:

- There is no National law or regulation that covers the entire area of TCI
- The law includes 12 chapters with 89 articles
- 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.

Australia:

- Therapeutic Goods Act (TGA),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.
- National Medicines Policy of 2000: The TGA regulates drug manufacturing, distribution, promotion, and labelling in Australia. Italso teaches how to enter drugs into Australia's Therapeutic Goods Register.
- Guidelines for registration of Complementary Medicines:
  - ✓ Route of evaluation and registration
  - ✓ Quality, Safety & Efficacy
  - ✓ Product & Consumer Medicine Information
  - ✓ Post market review [42]

Limitations of the study:

- Difficult to focus on each therapy or medication of TCI.
- Availability of data - Safety, efficacy and quality.
- 4 WHO regions – 12 countries.
- Data by WHO is available only till 2012.
- Limited info about Global market.

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Conclusion :

- Regulations for harmonization
- Helps to build economy
- Easily available and affordable
- Whole medical systems
- Support and funding for R & D
- Safety, efficacy and quality
- Challenge as well as opportunity for world health care systems.

Thank You