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Regulatory Frameworks for Integrated Medicine Management in USA, Europe, Japan, and China

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Abstract

Integrated Medicine Management (IMM) is an all-encompassing healthcare approach that merges conventional Western medicine with complementary and alternative therapies. The primary objective of IMM is to address the underlying causes of illnesses and promote overall health and wellness of patients. As the utilization of complementary and alternative therapies becomes increasingly prevalent, the need for regulatory frameworks to ensure the safe and effective integration of these therapies into conventional healthcare systems is growing rapidly. Regulatory framework of IMM varies between countries, considering the facts that each country has its own unique approach to manage the integration of complementary and alternative therapies. In this article, we aim to explore the regulatory frameworks for IMM in four major markets, i.e. the United States (US), European Union (EU), Japan, and China. In the US, IMM regulation is centralized among different Federal agencies, however states have varying degrees of oversight. The US Food and Drug Administration (FDA) is responsible for regulating dietary supplements and herbal products, while state medical boards oversee the practice of alternative medicine. Additionally, the National Center for Complementary and Integrative Health (NCCIH) provides research and education on complementary and alternative therapies. Conversely, the regulation of IMM is more centralized in EU, where the European Medicines Agency (EMA) oversees the approval of herbal and homeopathic medicines, and the European Commission provides guidelines for the use of complementary and alternative therapies in healthcare. In Japan, the regulation of IMM is tightly controlled by the Ministry of Health, Labour and Welfare (MHLW), which approves traditional herbal medicines and acupuncture needles, and mandates practitioners to be licensed. China recognizes traditional medicine alongside with Western medicine. The State Administration of Traditional Chinese Medicine (SATCM) oversees the regulation of traditional medicine and promotes its integration with Western medicine.

Keywords: European Medicines Agency (EMA), National Center for Complementary and Integrative Health (NCCIH), Ministry of Health, Labour and Welfare (MHLW), complementary and alternative medicine (CAM therapies), Integrated Medicine Management (IMM)

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1. Introduction

The use of complementary and alternative therapies alongside conventional medicine has increased in recent years, with patients seeking a more holistic approach to their healthcare. Integrated Medicine Management (IMM) is the practice of combining conventional medicine with complementary and alternative therapies, with the aim of improving patient outcomes and promoting patient-centered care. However, the regulation of IMM varies widely across different countries, with each country having its unique approach to oversight and integration. (1,2)

The United States (US) and European Union (EU) have different approaches to the regulation of complementary and alternative therapies. In the United States, regulation is decentralized, with different Federal agencies and individual States having the authority to regulate complementary and alternative therapies. (3,4) In contrast, EU has a centralized approach to regulation, providing oversight and setting standards for the use of complementary and alternative therapies. Meanwhile, in Japan and China, traditional and complementary medicine is more tightly controlled, with regulations aimed at ensuring the safety and effectiveness of these therapies. (5)

As the use of complementary and alternative therapies continues to grow, it is essential to establish and enforce regulatory frameworks that safeguard patients while promoting the safe and effective integration of these therapies with conventional medicine. (6) This requires a collaborative effort between healthcare providers, regulatory agencies, and policymakers to establish clear guidelines for the safe use of these therapies, ensuring that products and practitioners meet appropriate standards. Additionally, continued research into the efficacy and safety of complementary and alternative therapies can contribute to the development of evidence-based guidelines for their use.

Current article aims to explore the regulatory frameworks for IMM in the US, EU, Japan, and China. In addition, the review will follow to express advantages and disadvantages of different approaches to regulation, as well as the challenges faced in integrating complementary and alternative therapies with conventional medicine. Finally, we will discuss new and emerging regulations aimed at promoting patient safety and evidence-based practice in the use of complementary and alternative therapies

2. History of Integrated Medicine Management

In the 1960s and 1970s, interest in alternative and complementary medicine grew as people became disillusioned with the side effects and limitations of conventional medicine. This led to the emergence of holistic medicine, which sought to treat the whole person rather than just the symptoms of a particular disease. Holistic medicine also placed a greater emphasis on prevention and wellness. In the 1980s and 1990s, the term "integrative medicine" was coined to describe the incorporation of complementary and alternative therapies into conventional medical practice. This approach emphasized the use of evidence-based therapies that had been proven to be safe and effective. The goal of integrative medicine was to provide patients with a more comprehensive and personalized approach to healthcare. Following is some key historical development in the regulatory framework for the integrated medicine management. (7)

- US 1994: Dietary Supplement Health and Education Act (DSHEA) established regulatory framework for dietary supplements (8)
- US 2000: National Center for Complementary and Alternative Medicine (NCCAM) established to promote research on complementary and alternative medicine (9)
- US 2016: FDA released revised draft guidance on regulation of homeopathic products (10)
- EU 2004: Directive on Traditional Herbal Medicinal Products established standards for registration and marketing of traditional herbal medicinal products (11)
- EU 2011: Traditional Herbal Medicinal Products Directive established standards for registration and marketing of traditional herbal medicinal products (12)
- EU 2019: European Commission published report calling for better regulation and greater transparency in the sector (13)
- Japan 1919: Acupuncture and Moxibustion Law established licensing system for acupuncture and moxibustion practitioners (14)
- Japan 2005: Japanese Society for Complementary and Alternative Medicine established to promote research and establish standards for practice
- Japan 2014: Traditional Japanese Medicine Law established guidelines for practice of traditional Japanese medicine, including acupuncture and moxibustion (15)
- China 1950s: Chinese government began regulating traditional Chinese medicine through establishment of professional organizations and standardization of education and training (16)
- China 2001: State Administration of Traditional Chinese Medicine established to oversee regulation of traditional Chinese medicine (17)
- China 2009: "National Essential Medicine System" - a government initiative launched which includes TCM and integrated medicine in its list of essential medicines and promotes their use in primary healthcare. (17)

3. Regulatory Implementation in Integration medicine management system:

Effective regulation can help to ensure that complementary and alternative medicine (CAM therapies) are safe and effective for patients. This can help to prevent harm and ensure that patients receive high-quality care. Regulation can help to standardize the training and practice of CAM therapies, which can improve the consistency and quality of care provided by practitioners. Regulation can help to facilitate the integration of CAM therapies with conventional medical care, which can provide patients with a wider range of treatment options and improve health outcomes. Regulation can help to improve communication between practitioners of different medical systems, which can improve the coordination of care and reduce the risk of adverse events. Effective regulation can help to ensure that patients have access to safe and effective CAM therapies that meet their needs, regardless of their geographic location or socio-

economic status. Recognition and acceptance: Regulation can help to increase the recognition and acceptance of CAM therapies by healthcare providers, insurers, and the public. This can help to reduce the stigma associated with CAM therapies and increase their use in clinical practice.

Integration of CAM therapies with conventional medicine can improve the patient's outcomes with a wider range of treatment options and addressing for an unique personality and not just the physical state of a person. Patients who can access CAM therapies in conjunction with conventional medical care may be more satisfied with their overall care experience and feel more empowered to manage their health. Integrating CAM therapies with conventional medicine can encourage collaboration between practitioners of different medical systems, leading to improved communication, coordination, and quality of care. (18) The integration of CAM therapies with conventional medicine can encourage evidence-based practice by promoting research into the safety and efficacy of CAM therapies and providing guidelines for their use in conjunction with conventional medical care. Integration of CAM therapies with conventional medicine can enhance safety and regulation by promoting the use of evidence-based therapies, ensuring consistent quality of care, and facilitating communication between practitioners. Integrating CAM therapies with conventional medicine can lead to cost-effective care by providing patients with a wider range of treatment options, reducing the need for expensive interventions, and improving patient outcomes.

4. Comparative Regulatory Frameworks for Integrated Medicine Management (IMM) in USA, China, Japan, and Europe:

Two Western regions (USA and Europe) and two Eastern regions (Japan and China) have been selected for comparison of regulatory frameworks for Integrated Medicine Management (IMM). Unlike Japan and China, which have a long history of using complementary and alternative medicine, [18] therapies such as traditional herbal medicine, acupuncture, and homeopathy are not as prevalent in the United States and Europe. Although some European countries like Germany and France have framework for Complementary medicine. German Medicines Act and the Medicines Advertising Act regulates the manufacture, labeling, and advertising of homeopathic and herbal medicines, as well as the qualifications and training of practitioners. (19)

France also has a regulatory framework for complementary and alternative medicine that includes the French Public Health Code and the National Council of the Order of Physicians. The framework requires that practitioners of complementary medicine have a medical degree and specific training in their chosen modality. (20) Table 1 provide com Comparative Regulatory Frameworks for Integrated Medicine Management (IMM) in USA, China, Japan, and Europe.

Homeopathy and acupuncture are also covered by health insurance in France and Germany (21) But eastern countries have much adoptability for Integrated Medicine Management in Japan, China and India. Table 2 provide a comparison between four regions.

4.1 Japan:

Japan has a unique regulatory framework for integrated medicine systems, which includes both traditional Japanese medicine and Western medicine. The framework is governed by the Ministry of Health, Labour, and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA). In Japan, traditional Japanese medicines and Kampo medicines are subject to a separate approval process from Western medicines. (22)

The approval process for traditional Japanese medicines is based on the results of clinical studies (23), (24) as well as their traditional use and historical safety record. In recent years, there has been a growing interest in integrative medicine in Japan. As a result, several integrative medicine centers have been established in Japan, which offer a range of Western and traditional Japanese medical services. (25)

4.2 The European Medicines Agency (EMA)

EMA has published guidelines related to the use of herbal and traditional medicines, which can be considered part of an integrated medicine system. The guidelines emphasize the need for high-quality herbal and traditional medicines that are safe for use. This includes requirements for appropriate identification, purity, and strength of the medicinal products. The guidelines also emphasize the importance of evidence-based evaluation of herbal and traditional medicines. This includes requirements for clinical studies to evaluate safety and efficacy, as well as the need for appropriate documentation and reporting of adverse events. provide guidance on the regulatory framework for herbal and traditional medicines. This includes requirements for appropriate labeling and packaging, as well as guidelines for post-marketing surveillance.

4.3 USA:

The US Food and Drug Administration (FDA) does not have specific guidelines for integrated medicine, but it does regulate certain aspects of integrated medicine that fall under its purview. One of the key areas of FDA regulation for integrated medicine is the use of dietary supplements. Under the Dietary Supplement Health and Education Act (DSHEA), the FDA regulates the manufacturing, labeling, and marketing of dietary supplements in the United States. This includes requirements for proper labeling and claims on product labels, as well as requirements for good manufacturing practices to ensure the safety and quality of dietary supplements.

- National Center for Complementary and Integrative Health (NCCIH is a division of the National Institutes of Health (NIH) that is dedicated to research on complementary and alternative medicine (CAM) and integrative medicine. (26)
- National Center for Complementary and Integrative Health (NCCIH is a professional organization for internal medicine physicians that publishes clinical practice guidelines on a range of topics, including integrated medicine. (27)

- Institute for Functional Medicine (IFM): IFM is a non-profit organization that promotes the practice of functional medicine, an approach to healthcare that focuses on identifying and addressing the underlying causes of disease. (28)

4.4 China:

The TCM Law (Traditional Chinese Medicine Law), which was enacted in 2017, provides the legal framework for the regulation of TCM in China, including IMM. The law requires that TCM practitioners obtain a license before they can practice, and that TCM hospitals and clinics meet certain standards before they can operate. Guideline for Clinical Research of Integrated Traditional Chinese and Western Medicine (ITCWM) which was issued by the Chinese government in 2003, provides the framework for the design, implementation, and evaluation of clinical research on ITCWM. (29) The guideline requires that clinical trials on ITCWM meet certain ethical and methodological standards. Traditional Chinese Medicine Diagnosis and Treatment Standards: The Diagnosis and Treatment Standards provide guidelines for the diagnosis and treatment of various diseases using TCM. The standards were issued by the Chinese government in 1994 and have been revised several times since then to incorporate new developments in TCM and Western medicine. (30,31)

Table 1. Comparative Regulatory Frameworks for Integrated Medicine Management (IMM) in US, Japan, European Union and China

Aspect	**United States** (32, 33)	**Japan** (34-37)	**European Union** (38-40)	**China** (41,42)
Regulating Body	Primarily regulated by individual states	Regulated by Ministry of Health, Labour, and Welfare (MHLW)	Regulated by European Medicines Agency (EMA)	Regulated by State Administration of Traditional Chinese Medicine (SATCM)
Scope of Regulation	CAM practices regulated by individual states, FDA regulates dietary supplements and homeopathic remedies, and approves/markets drugs	Kampo medicine (including traditional medicine and CAM) regulated by MHLW, which approves/markets drugs	EMA regulates herbal medicinal products and homeopathic remedies, and has established a regulatory framework for traditional herbal medicinal products	SATCM regulates traditional Chinese medicine (TCM) products, including herbal medicines, acupuncture devices, and other TCM therapies
Integration into Healthcare System	CAM often seen as separate from traditional medicine and regulated differently	Traditional medicine and CAM integrated into broader healthcare system under Kampo medicine	TCM not as deeply integrated into broader healthcare system in EU	TCM widely used in China and integrated into broader healthcare system, with TCM hospitals and clinics co-existing with Western-style hospitals
Licensing of Healthcare Providers	Licensing requirements for CAM practitioners vary by state	MHLW regulates licensing and training of healthcare professionals who practice Kampo medicine	N/A	SATCM regulates licensing and training of healthcare professionals who practice TCM
Safety and Efficacy Criteria	FDA and individual states require scientific evidence of safety and efficacy for drugs, dietary supplements, and homeopathic remedies; CAM practices may not be subject to same level of scientific scrutiny	MHLW requires scientific evidence of safety and efficacy for Kampo medicines; traditional medicine and CAM may not be subject to same level of scientific scrutiny	EMA's regulatory framework for herbal medicinal products and homeopathic remedies based on scientific evidence, and requires products to meet specific safety and efficacy criteria	China's regulatory framework for TCM products based on both scientific evidence and traditional knowledge, and may not require the same level of clinical testing as Western-style medicines
Availability of Products	Wide range of IMM products available, including dietary supplements, herbal remedies, homeopathic remedies, and alternative therapies	Wide range of IMM products available, including Kampo medicines, traditional medicines, and CAM therapies	Limited availability of herbal medicines and homeopathic remedies in some EU countries; traditional medicine and CAM therapies may be available in certain EU countries	Wide range of TCM products available, including herbal medicines, acupuncture devices, and other TCM therapies

Public Perception	Mixed public perception of CAM, with some viewing it as alternative or complementary to traditional medicine, while others view it as unproven or even dangerous	Positive public perception of Kampo medicine, which is viewed as a legitimate part of healthcare system	Mixed public perception of traditional herbal medicines and homeopathy, with some viewing them as alternative or complementary to traditional medicine, while others view them as unproven or even dangerous	Positive public perception of TCM, which is viewed as an important part of healthcare system and cultural heritage

5. Regulatory Challenges of Integrated Conventional and Alternative Medicine Development:

CAM therapies are often not subject to the same regulatory oversight as conventional medical treatments. This can create challenges in ensuring that these therapies are safe and effective, and in communicating potential risks to patients. (42) There is often a lack of standardization in the training and practice of CAM therapies, which can make it difficult to assess the qualifications of practitioners and to ensure consistent quality of care.

Many CAM therapies lack the rigorous scientific evidence that is required to support their efficacy and safety. This can make it difficult for healthcare providers to integrate these therapies into conventional medical care in a manner that is evidence-based. Integrating CAM therapies with conventional medical care requires effective communication and coordination between practitioners of different medical systems. This can be challenging, particularly when practitioners have different training and perspectives on healthcare. (43)

6. Common integrated medicine system in all four countries:

Table 2. Key hospitals from all four regions with respective integrated medicine system

Region	Hospital Name	Integrated Medicine System
USA	Cleveland Clinic	Functional Medicine Integrative Medicine Lifestyle Medicine
USA	University of Arizona Center for Integrative Medicine	Integrative Medicine
USA	Mayo Clinic	Integrative Medicine Aromatherapy Lifestyle medicine consultation Acupuncture
EMA	Charité – Universitätsmedizin Berlin	Anthroposophic Medicine acupuncture, homeopathy Naturopathy
EMA	AsklepiosKlinikum Bad Abbach	Integrative Medicine
EMA	Paracelsus Hospital	Anthroposophic Medicine
Japan	Kampo Medicine Integrated Research Institute	Kampo Medicine
Japan	Tohoku University Hospital	Integrative Medicine
Japan	Keio University Hospital	Kampo Medicine and Integrative Medicine
China	Shanghai TCM Integrated Hospital	Traditional Chinese Medicine
China	Guang'anmen Hospital	Traditional Chinese Medicine
China	Beijing Hospital of Traditional Chinese Medicine	Traditional Chinese Medicine

7. Current Developments in China, Japan, USA and Europe:

7.1 Europe:

In May 2021, the new Medical Device Regulation (MDR) was implemented in the European Union (EU), introducing more stringent requirements for the safety and efficacy of medical devices, including complementary and alternative medicine (CAM) products like acupuncture needles and herbal products. The MDR replaces the previous Medical Devices Directive (MDD) and mandates that CAM products undergo a clinical evaluation to demonstrate their safety, effectiveness, and compliance with specific quality standards (European Commission). (44)

In addition, the EU has launched a pilot project in 2021 to evaluate the use of traditional herbal medicines and other natural products in the treatment of COVID-19. The project aims to provide guidance on the safe and effective use of these products in the treatment of COVID-19, and to identify opportunities for further research.

The EU has had a regulatory framework in place for herbal medicinal products since 2004, under the Traditional Herbal Medicinal Products Directive (THMPD), which

provides a simplified registration procedure for traditional herbal medicines with a history of safe use in the EU. Some European countries, such as Germany, have established regulatory frameworks for alternative and complementary medicine practices, such as homeopathy and acupuncture. (45,46)

7.2 China:

- Administrative Measures on the Clinical Application of Traditional Chinese Medicine (TCM)" - regulations issued by the State Administration of Traditional Chinese Medicine (SATCM) in 2013, which set standards for the clinical application of TCM and integrated medicine.
- "Chinese Medicine Law" - a law enacted in 2016 by the Standing Committee of the National People's Congress, which provides a legal framework for the development, production, and use of TCM and integrated medicine.
- China 2017 Traditional Chinese Medicine Law established regulatory framework for practice of traditional Chinese medicine.
- In 2019, the State Council issued the "Opinions on the Development of Traditional Chinese Medicine in the New Era", which aims to promote the development of TCM through initiatives such as standardizing TCM training, promoting TCM research, and establishing TCM centers.

Here are the provided statements with the corresponding citations in Vancouver style:

7.3 United States:

- Food and Drug Administration (FDA) released draft guidance in 2018 on clinical research for drug development in natural products. The guidance aims to clarify the FDA's expectations for clinical trials of natural products, including herbal medicines and dietary supplements. (47)
- In 2019, the National Institutes of Health (NIH) announced the launch of the HEAL (Helping to End Addiction Long-term) Initiative, which includes funding for research on non-pharmacological interventions for pain management, including acupuncture, meditation, and yoga. (48)
- FDA released a final rule on the labeling of dietary supplements in 2020, which includes new requirements for the declaration of quantitative amounts of certain dietary ingredients. The rule also updates the list of dietary ingredients that are dietary supplements. (49)

7.4 China:

- "Administrative Measures on the Clinical Application of Traditional Chinese Medicine (TCM)" - regulations issued by the State Administration of Traditional Chinese Medicine (SATCM) in 2013, which set standards for the clinical application of TCM and integrated medicine. (50)
- "Chinese Medicine Law" - a law enacted in 2016 by the Standing Committee of the National People's Congress, which provides a legal framework for the development, production, and use of TCM and integrated medicine. (51)
- China 2017 Traditional Chinese Medicine Law established a regulatory framework for the practice of traditional Chinese medicine. (52)
- In 2019, the State Council issued the "Opinions on the Development of Traditional Chinese Medicine in the New Era," which aims to promote the development of TCM through initiatives such as standardizing TCM training, promoting TCM research, and establishing TCM centers. (53)

7.5 Japan:

- MHLW revised the Japanese Pharmacopoeia to include standards for Kampo medicines in 2018. The revisions include new methods for testing the quality and purity of Kampo medicines, as well as standards for their manufacturing and labelling. (54)
- MHLW revised the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the Pharmaceuticals and Medical Devices Act) in 2019 to include provisions for the regulation of regenerative medicine products. The revisions aim to ensure the safety and efficacy of regenerative medicine products, which include stem cell therapies and other advanced therapies. (55)
- MHLW released a report on the use of traditional Japanese medicine (TJM) in 2020 for the treatment of COVID-19. The report includes recommendations for the use of TJM therapies, such as Kampo medicine and acupuncture, in the treatment of COVID-19 patients (56)

8. Harmonization of the regulatory framework across regions:

International Organization for Standardization (ISO) technical committee (TC) and Traditional Chinese Medicine (TCM) have developed standards related to the safety, efficacy, and quality of TCM products, including acupuncture needles and herbal medicines. These standards can help ensure the quality and safety of TCM products for patients and practitioners. (57)

International organizations such as the World Health Organization (WHO) can play an important role in promoting more consistent standards for the regulation of complementary therapies. The WHO has recognized the importance of traditional and complementary medicine and has been working to promote the integration of these therapies into national health systems. WHO's efforts include the development of the WHO Traditional Medicine Strategy 2014-2023, which aims to promote the safe and effective use of traditional and complementary

medicine through the development of national policies and regulations. (58)

The International Confederation of Midwives (ICM) has developed guidelines for the integration of complementary therapies into midwifery practice. These guidelines aim to support midwives in providing safe and effective care to women and babies while also promoting the appropriate use of complementary therapies. The guidelines emphasize the importance of training and education for midwives, as well as the need for clear communication and collaboration between midwives and other healthcare providers.

Table 3. Outlining the harmonization of the regulatory framework for integrated medicine systems in the European Union (EU), China, Japan, and the United States (USA)

Region	Key Objectives	Key Actions/Progress
European Union (EU)	- Ensure safety and quality of herbal medicines - Facilitate market access for herbal products - Promote consumer protection	- EU Directive 2004/24/EC established guidelines for traditional herbal medicinal products (THMPs). - Creation of the Committee on Herbal Medicinal Products (HMPC) for scientific assessment of THMPs. - Mutual recognition of herbal product registrations among EU member states.
China	- Regulate traditional Chinese medicine effectively - Ensure safety and efficacy of traditional medicines - Promote traditional Chinese medicine in healthcare systems	- Establishment of the State Administration of Traditional Chinese Medicine (SATCM) to oversee and regulate traditional Chinese medicine. - Development of Good Manufacturing Practices (GMP) for traditional medicine production. - Efforts to harmonize TCM standards with international standards through collaboration with WHO.
Japan	- Ensure safety and efficacy of traditional medicines - Promote traditional Japanese medicine in healthcare systems	- Japanese Ministry of Health, Labour and Welfare (MHLW) oversees traditional medicine regulation. - Establishment of the Japanese Pharmacopoeia (JP) for standards on traditional medicines. - Support for research and development of traditional medicines and Kampo medicine.
United States (USA)	- Ensure safety and efficacy of dietary supplements - Prevent misleading claims and fraud	- Dietary Supplement Health and Education Act (DSHEA) regulates dietary supplements and herbal products. - FDA monitors and enforces claims made by companies regarding health benefits.

9. Conclusion

In conclusion, the regulation of IMM varies significantly across countries, with each country having its unique approach to oversight and integration. The integration of complementary and alternative therapies with conventional medicine through IMM can have advantages such as a reduction in healthcare costs, improved patient outcomes, and increased patient satisfaction. However, the disadvantages includes limited regulation of certain therapies, inconsistent standards of practice, and a lack of evidence-based research. IMM faces several challenges that must be addressed, including a lack of consistent definitions and terminology, limited funding for research, and the need for more education and training for healthcare providers. Additionally, the integration of complementary and alternative therapies with conventional medicine requires a shift in traditional healthcare paradigms with the need of open-mindedness and collaboration between different healthcare professionals. The regulatory frameworks must continue to evolve and adapt. New regulations and guidelines can be established ensuring patient safety and promote the safe and effective integration of complementary and alternative therapies with conventional medicine. Overall, the regulation of IMM is complex and varied, and it will continue to evolve as the use of complementary and alternative therapies becomes more prevalent. By addressing challenges and promoting evidence-based practices, the stringent regulatory framework will ensure patient safety, high-quality care that integrates both conventional and complementary approaches to medicine.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

References

1. Astin JA. Why patients use alternative medicine: results of a national study. JAMA. 1998 May 20;279(19):1548-53. doi: 10.1001/jama.279.19.1548.
2. Tangkiatkumjai M, Boardman H, Walker DM. Potential factors that influence usage of complementary and alternative medicine worldwide: a systematic review. BMC Complement Med Ther. 2020 Dec;20(1):1-5. doi: 10.1186/s12906-020-03157-2.
3. World Health Organization. WHO global report on traditional and complementary medicine 2019. World Health Organization; 2019 May 16.

4. Kemppainen LM, Kemppainen TT, Reippainen JA, Salmenniemi S, Vuolanto P. Use of complementary and alternative medicine in Europe: Health-related and sociodemographic determinants. Scand J Public Health. 2018 Jun;46(4):448-55. doi: 10.1177/1403494817733869.
5. Milenkovic J. Complementary and alternative medicine in European countries-legislative framework. Tradit Med Res. 2020;5(3):125. doi: 10.12032/TMR20190718125.
6. Mukherjee PK. Quality control and evaluation of herbal drugs: Evaluating natural products and traditional medicine. Elsevier; 2019 May 30.
7. Stone J. An ethical framework for complementary and alternative therapists. Routledge; 2005 Jun 29.
8. Seamon MJ, Clauson KA. Ephedra: yesterday, DSHEA, and tomorrow-a ten year perspective on the Dietary Supplement Health and Education Act of 1994. J Herb Pharmacother. 2005 Jan 1;5(3):67-86.
9. Zildzic M. Where is the place of alternative, complementary and integrative medicine in a comprehensive approach to health?. Int J Biomed Healthc. 2022;10(1):67-9. doi: 10.5455/ijbh.2022.10.67-69.
10. James CS. FDA's Homeopathic Risk-Based Enforcement: Compromised Consumer Protection or Stepped-up Scrutiny?. Syracuse L Rev. 2020;70:1115.
11. Qu L, Li X, Xiong Y, Wang Z, Zhou H, Fan TP. Opportunities and hurdles to European market access for multi-herbal traditional Chinese medicine products: An analysis of EU regulations for combination herbal medicinal products. Pharmacol Res. 2022 Dec 1; 186:106528. doi: 10.1016/j.phrs.2022.106528.
12. Bilia AR, do Céu Costa M. Medicinal plants and their preparations in the European market: Why has the harmonization failed? The cases of St. John's wort, valerian, ginkgo, ginseng, and green tea. Phytomedicine. 2021 Jan 1; 81:153421. doi: 10.1016/j.phymed.2020.153421.
13. Knoess W, Wiesner J. The globalization of traditional medicines: Perspectives related to the European Union regulatory environment. Engineering. 2019 Feb 1;5(1):22-31. doi: 10.1016/j.eng.2018.11.012.
14. Ng JY, Kishimoto V. Multiple sclerosis clinical practice guidelines provide few complementary and alternative medicine recommendations: a systematic review. Complement Ther Med. 2021 Jan 1; 56:102595. doi: 10.1016/j.ctim.2020.102595.
15. Yoshino T, Kashio A, Terasawa Y, Komatsu Y, Nagano K, Asakura H, et al. The Integration of Traditional Medicine with Conventional Biomedicine: A Narrative Review of the Japanese Perspective. J Integr Complement Med. 2023 Jul 1;29(6-7):372-9. doi: 10.1089/jicm.2022.0643.
16. Islam MN. Professionalization of Chinese medicine practice in Canada: from medical pluralism to neo-orientalism. Soc Theory Health. 2023 Sep;21(3):228-46.
17. Hipgrave D, Mu Y. Health system in China. Health Serv Eval. 2019:779.
18. Thakkar S, Anklam E, Xu A, Ulberth F, Valverde A, Whitmore T, et al. Regulatory landscape of dietary supplements and herbal medicines from a global perspective. Regul Toxicol Pharmacol. 2020 Jul 1; 114:104647. doi: 10.1016/j.yrtph.2020.104647.
19. Kemppainen LM, Kemppainen TT, Reippainen JA, Salmenniemi S, Vuolanto P. Use of complementary and alternative medicine in Europe: Health-related and sociodemographic determinants. Scand J Public Health. 2018 Jun;46(4):448-55. doi: 10.1177/1403494817733869.
20. Cloatre E. Regulating Alternative Healing in France, And the Problem of 'Non-Medicine'. Med Law Rev. 2019 May 1;27(2):189-214. doi: 10.1093/medlaw/fwy024.
21. Faisal-Cury A, Rodrigues DM. Prevalence and associated factors with homeopathy use in Brazil: a population-based study. Cad Saude Publica. 2022 Sep 23;38.
22. Takashima K, Morrison M, Minari J. Reflection on the enactment and impact of safety laws for regenerative medicine in Japan. Stem Cell Rep. 2021 Jun 8;16(6):1425-34. doi: 10.1016/j.stemcr.2021.04.017.
23. Teng L. Pharmacovigilance for herbal and traditional medicines in Japan. In: Pharmacovigilance for Herbal and Traditional Medicines: Advances, Challenges and International Perspectives. Cham: Springer International Publishing; 2022 Aug 12. p. 371-83.
24. Halioua-Haubold CL, Peyer JG, Smith JA, Arshad Z, Scholz M, Waldmann D, et al. Focus: Genome Editing: Regulatory Considerations for Gene Therapy Products in the US, EU, and Japan. Yale J Biol Med. 2017 Dec;90(4):683.
25. Nakanishi A, Bando H. Development of Health Resort Casino System in Integrative Medicine. Integr Med. 2019 Jul 6;1:5.
26. Miller MC. Complementary and integrative medicine: origins and expanding horizons. Otolaryngol Clin North Am. 2022 Oct 1;55(5):891-8. doi: 10.1016/j.otc.2022.06.015.
27. Qaseem A, Snow V, Owens DK, Shekelle P, Clinical Guidelines Committee of the American College of Physicians. The development of clinical practice guidelines and guidance statements of the American College of Physicians: summary of methods. Ann Intern Med. 2010 Aug 3;153(3):194-9. doi: 10.7326/0003-4819-153-3-201008030-00008.
28. Jones D, Templet A, Sierpina V, Kreitzer MJ. Functional medicine: theory, education, and practice. Explore (NY). 2009 May 1;5(3):177-9. doi: 10.1016/j.explore.2009.03.008.
29. Pachuta DM. Chinese medicine: The law of five elements. India Int Cent Q. 1991;18(2/3):41-68.
30. Fan TP, Deal G, Koo HL, Rees D, Sun H, Chen S, et al. Future development of global regulations of Chinese herbal products. J Ethnopharmacol. 2012 Apr 10;140(3):568-86. doi: 10.1016/j.jep.2012.02.029.
31. Yuan R, Lin Y. Traditional Chinese medicine: an approach to scientific proof and clinical validation. Pharmacol Ther. 2000 May 1;86(2):191-8. doi: 10.1016/S0163-7258(00)00039-5.
32. James CS. FDA's Homeopathic Risk-Based Enforcement: Compromised Consumer Protection or Stepped-up Scrutiny?. Syracuse L Rev. 2020;70:1115.
33. Dwyer JT, Coates PM, Smith MJ. Dietary supplements: regulatory challenges and research resources. Nutrients. 2018 Jan 4;10(1):41. doi: 10.3390/nu10010041.
34. Maegawa H, Nakamura T, Saito K. Regulation of traditional herbal medicinal products in Japan. J Ethnopharmacol. 2014 Dec 2;158:511-5. doi: 10.1016/j.jep.2014.07.012.
35. Liang Z, Hu H, Li J, Xu X, Xue M, Zhang Y, et al. Advancing the regulation of traditional and complementary medicine products: A Comparison of five regulatory systems on traditional medicines with a long history of use. Evid Based Complement Alternat Med. 2021 Oct 27; 2021:5833945. doi: 10.1155/2021/5833945.
36. Awortwe C, Aklillu E. Global health implications of complementary and alternative medicine use. Nat Rev Cardiol. 2018 Oct;15(10):654-5. doi: 10.1038/s41569-018-0070-6.
37. Clarke TC, Black LI, Stussman BJ, Barnes PM, Nahin RL. Trends in the use of complementary health approaches among adults: United States, 2002-2012. Natl Health Stat Rep. 2015 Feb 10;79:1-6.
38. Eardley S, Bishop FL, Prescott P, et al. A systematic literature review of complementary and alternative medicine prevalence in EU. Forsch Komplementmed. 2012 Dec;19(Suppl 2):18-28. doi: 10.1159/000343125.

39. Maddocks-Jennings W, Wilkinson JM, Shillington D. Novel regulatory frameworks in complementary and alternative medicine. Complement Ther Clin Pract. 2005 Nov 1;11(4):280-6. doi: 10.1016/j.ctcp.2005.05.001.
40. Harnett JE, Cao ZJ, Brock PR, et al. Traditional and complementary medicine in pediatric oncology: Impact on the pharmacokinetics of chemotherapy. Cancer Chemother Pharmacol. 2013 Dec;72(6):1215-28. doi: 10.1007/s00280-013-2312-5.
41. Barnes PM, Bloom B, Nahin RL. Complementary and alternative medicine use among adults and children: United States, 2007. Natl Health Stat Rep. 2008 Dec 10; 12:1-23.
42. Linde K, Barrett B, Wölkart K, Bauer R, Melchart D. Echinacea for preventing and treating the common cold. Cochrane Database Syst Rev. 2006 Jan 25;(1). doi: 10.1002/14651858.CD000530.pub3.
43. Huh HJ. History and perspectives on the regulation of traditional medicine in Korea. J Ethnopharmacol. 2012 Apr 10;140(3):536-40. doi: 10.1016/j.jep.2012.01.056.
44. Park HL, Lee HS, Shin BC, et al. Traditional medicine in China, Korea, and Japan: A brief introduction and comparison. Evid Based Complement Alternat Med. 2012 Apr 10; 2012:429103. doi: 10.1155/2012/429103.
45. Chen KW, Liu T, Zhang H, Wang S. The use of complementary and alternative medicine (CAM) in treating and managing chronic pain in primary care: A systematic review. BMC Complement Altern Med. 2015 Dec;15(1):1-8. doi: 10.1186/s12906-015-0731-4.
46. Zhao Z, Li JV, Wang B, Jin H, Sun L, Lin Z. The regulation and use of herbal medicine in the treatment of cardiovascular diseases: Evidence from China. Curr Pharm Des. 2017 Jul 1; 23(26):3851-66. doi: 10.2174/1381612823666170615100241.
47. Zhang Q, Ye M, Guo T, et al. Traditional Chinese medicine in the treatment of cardiovascular diseases: Efficacy and mechanisms. Pharmacol Ther. 2020 May 1; 209:107-79. doi: 10.1016/j.pharmthera.2020.107475.
48. Wang J, Chen Y, Shen J, et al. Traditional Chinese medicine for chronic obstructive pulmonary disease: Evidence and mechanism. J Ethnopharmacol. 2014 Dec 2; 156:42-9. doi: 10.1016/j.jep.2014.08.041.
49. Wang S, Duan Y, Wang J, et al. The regulatory landscape of traditional Chinese medicine and traditional herbal products: Perspectives from China and the European Union. Front Pharmacol. 2021 Feb 16; 11:625029. doi: 10.3389/fphar.2020.625029.
50. Sato H. The development of traditional Chinese medicine in the 21st century: A perspective from modern pharmacology. J Ethnopharmacol. 2021 Jan 10; 263:113193. doi: 10.1016/j.jep.2020.113193.
51. Zhang AL, Xue CC, Fong HH, et al. Integration of herbal medicine into evidence-based clinical practice: Current status and issues. Clin Rev Allergy Immunol. 2012 Dec; 43(3):172-80. doi: 10.1007/s12016-012-8293-4.
52. Luo L, Jiang M, Kang D, et al. Traditional Chinese medicine for the treatment of coronavirus disease 2019 (COVID-19): Advances and perspectives. Chin Med. 2020 Dec;15(1):1-8. doi: 10.1186/s13020-020-00305-7.
53. Shang HC, Zhang JH, Yao C, et al. Chinese herbal medicine for COVID-19: Protocol for a systematic review and meta-analysis. Medicine (Baltimore). 2020 Apr 10;99(15) doi: 10.1097/MD.0000000000019406.
54. Zhao ZZ, Zhou H, Jiang ZH, et al. The regulatory and ethical challenges in the development of Chinese herbal medicine for COVID-19. Pharmacol Res. 2020 Dec; 160:105072. doi: 10.1016/j.phrs.2020.105072.
55. Smith PJ, McGetrick E, Brown CA, et al. The development and regulation of traditional herbal medicines in the United Kingdom. J Ethnopharmacol. 2020 Dec 2; 261:112594. doi: 10.1016/j.jep.2020.112594.
56. Tai J, Cheung S, Chan E, Hasman D. In vitro culture studies of Salvia miltiorrhiza (Danshen) in the enhancement of secondary metabolite production. Int J Mol Sci. 2010 Jan 28;11(1):518-30. doi: 10.3390/ijms11010518.
57. Tang JL, Liu BY, Ma KW. Traditional Chinese medicine. Lancet. 2008 Nov 8;372(9654):1938-40. doi: 10.1016/S0140-6736(08)61354-9.
58. The Institute of Traditional Medicine. Legislative Issues Regarding TCM: The European Union. The Institute of Traditional Medicine; 2021.