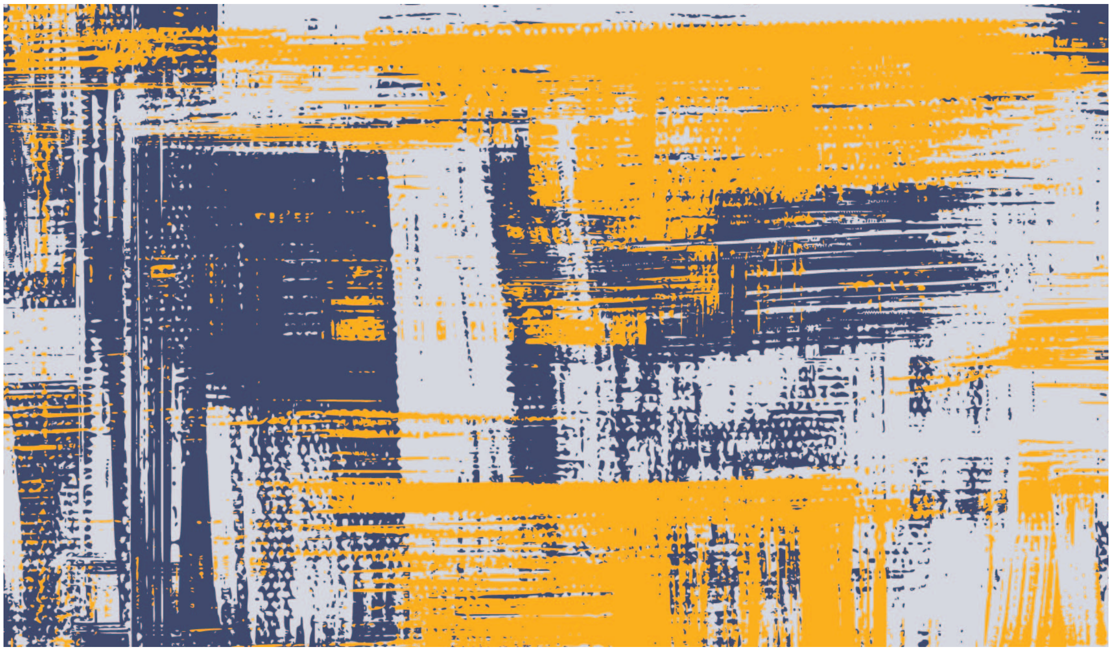
FROM EVIDENCE TO ACTION:
REGULATORY SCIENCE POLICY INSIGHTS



Categorizing how Divergent Definitions of Herbal and Traditional Medicines Influence Their Regulation: Application of the novel DART-HTM (Divergent Archetypes of Regulatory Terminology for Herbal and Traditional Medicines) framework

Isaac Nyarko, MS, MPH
Apurva Uniyal, MA, MS
Lawrence Liberti, PhD, BPharm, RAC

AUTHOR AFFILIATIONS

Isaac Nyarko, MS, MPH, is in the Doctorate cohort in Regulatory Science at the Department of Regulatory and Quality Sciences, USC

Apurva Uniyal, MA, MS, is a Regulatory Innovation Research Scientist at the DK Kim International Center for Regulatory Science, USC

Lawrence Liberti, PhD, BPharm, RAC, is a Director at the DK Kim International Center for Regulatory Science and an associate professor at the Department of Regulatory and Quality Sciences, USC

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Executive Summary

This report explores how divergent **definitions** of herbal and traditional medicines (HTMs) shape their regulation across jurisdictions. Definitions are not neutral descriptors but determinants of regulatory scope, standards, and oversight. Analyzing global trends, three recurring definitional themes emerge: ingredient origin, traditional knowledge, and intended use. To categorize global variation in how HTMs are defined and regulated, we introduce the DART-HTM Framework. These underpin six regulatory archetypes worldwide, ranging from pharmaceutical-style models to culturally grounded approaches with minimal oversight. Rather than surveying entire regulatory systems, this paper focuses on the definitional foundations that precede and shape regulation. We further examine the rise of alternate HTM regulatory pathways and the challenges of regulating HTMs prepared at the point of care, where product and practice overlap. We conclude by calling for a global dialogue on minimum definitional criteria that respect cultural variation while enabling regulatory coherence. This could inform regulatory alignment efforts and offer regulators a clearer foundation for classification, labeling, and policy enforcement.

Introduction

Herbal and traditional medicines (HTMs) have long played a vital role in global health systems, particularly in Asia, Africa, and Latin America. This was acknowledged as far back as 2002 by the World Health Organization (WHO, 2002). However, as these products increasingly enter formal healthcare and commercial markets, questions regarding their regulation have come to the forefront. This paper does not attempt a comprehensive review of regulatory systems for HTMs; instead, we focus on the foundational role of definitions in shaping regulatory approaches.

Regulation starts with classification, which depends on how products are defined (Jackson, 2012). Here we examine the hypothesis that definitions are not merely descriptive but prescriptive. We suggest that definitional choices are at the root of much regulatory diversity across jurisdictions. Our observations indicate that definitional variation worldwide significantly contributes to regulatory fragmentation and diversity as applied to HTMs. Therefore, the legal and regulatory definitions of these products are critical determinants of regulatory policies, scope, stringency, and strategies affecting their control.

Definitions as the Gatekeeper of Regulation

Across jurisdictions, three main definitional themes consistently emerge regarding HTMs: (1) the origin of ingredients, (2) coherence with an established traditional medicine theory or system, and (3) the intended use, typically for health maintenance, prevention, or treatment **(Figure 1)**. Definitional choices by regulatory authorities often reflect how they interpret and prioritize these three themes.

Notably, the United States Food and Drug Administration (FDA) does not formally define HTMs as a distinct category. Instead, its regulatory approach, centered on dietary supplements and therapeutic claims, bypasses the need for definition, underscoring how the absence of definition can also serve as a gatekeeping mechanism. In the United States, HTMs are primarily classified as dietary supplements under the Dietary Supplement Health and Education Act (DSHEA) of 1994 (Office of Dietary Supplements (ODS), 2021). These products cannot make specific therapeutic claims and, therefore, do not require pre-market approval. However, HTMs marketed with therapeutic intent are categorized as medicines and must undergo the full Investigational New Drug (IND) and New Drug Approval (NDA) process, requiring substantial data on quality, safety, and clinical efficacy. This approach relies heavily on the intended use aspect of classification.

Definitions from the WHO and the European Medicines Agency (EMA) illustrate different approaches to ingredient scope, traditional knowledge, and intended use.

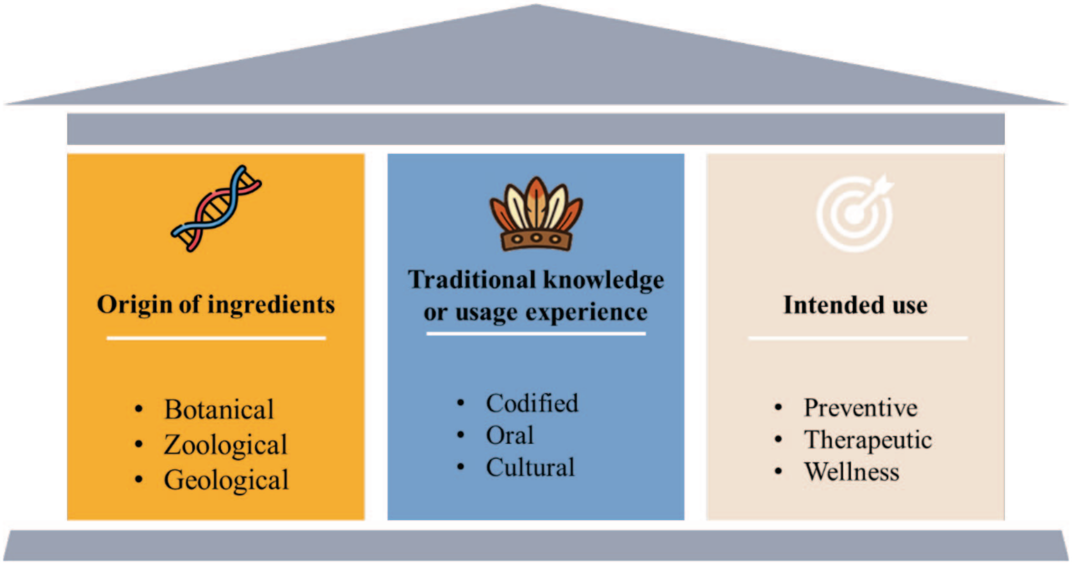
There is an increasing presence, and in some cases, co-existence of HTMs in national health systems and global markets (Lakshmi et al., 2014). Although individual countries define HTMs differently, the WHO and EMA are the only global/regional authorities that have issued explicit, and comprehensive definitions within formal regulatory frameworks. No other global or regional initiative has established a universally accepted definition of HTMs. Instead, most defer to WHO classifications or only provide technical guidelines related to quality, manufacturing, or labeling without addressing foundational definitional clarity.

Definitions are not neutral — they determine what gets regulated, how, and why.

The WHO offers the most globally recognized and inclusive definition, describing traditional medicine as:

> *"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*

Figure 1.
The 3 Pillars of HTM Definitions



> *health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness."* (WHO, 2013).

This definition is philosophical, system-neutral, and culturally grounded, embracing both tangible and intangible knowledge systems.

In contrast, the EMA adopts a narrower and more technical framework. Herbal medicinal products are defined as:

> *"Any medicinal product exclusively containing as active ingredients one or more herbal substances, one or more herbal preparations, or a combination of the two."* (EMA, 2009)

Furthermore, EMA defines traditional herbal medicinal products as those with at least 30 years of documented use (15 within the EU), intended for self-medication, and required to meet defined quality and safety standards.

Other countries, such as Cambodia, South Korea, and certain African countries, adopt broader definitions encompassing animal parts, fungi, and minerals, reflecting traditional ethnomedical practices. In most Asian countries, HTMs are defined by traditional theories (culturally embedded systems of health and disease rooted in historical philosophies, cosmologies, or medical doctrines codified texts, and historical usage, validating classical formulations through cultural continuity). Regulatory frameworks in these countries often accept long-standing usage as justification for partial or full exemption from clinical trials, particularly those with well-established safety profiles. In regulating HTMs, these definitions explicitly recognize non-allopathic practices such as African Traditional Medicine, Traditional Chinese Medicine (TCM), Ayurveda (India), and Kampo (Japan).

In Ghana, HTM definitions encompass both plant-based and culturally embedded remedies, blending WHO-influenced standards with local traditions. This hybrid approach presents enforcement challenges, including registration difficulties and quality control issues (Asase, 2023).

The DART-HTM (Divergent Archetypes of Regulatory Terminology for Herbal and Traditional Medicines) Framework

To categorize global variation in how HTMs are defined and regulated, we introduce the DART-HTM Framework **(Table 1)**. The framework is based on archetypes developed through a comparative analysis of HTM definitions and regulatory frameworks across 44 countries, using data from national guidelines, WHO documentation, and regional regulatory sources. The archetypes reflect recurring patterns in how countries define HTMs and link those definitions to regulatory models, evidence thresholds, and permitted claims. They offer a practical way to compare systems that, while diverse, often follow similar logics. **Figure 2** provides a global snapshot of how countries align with the six DART-HTM regulatory archetypes proposed herein.

Critical Reflections on Global HTM Definition Oversight

As countries attempt to regulate HTMs,

they face tensions between safeguarding public health, preserving cultural knowledge, and enabling market innovation. Two underlying questions arise: *Are definitions reactive or proactive? Are HTM regulatory pathways solutions or compromises?*

Regulatory categories can legitimize or marginalize medical traditions.

Table 1.
The Six Regulatory Archetypes: The DART-HTM Framework

Archetype	Definition Basis	Regulatory Model	Evidence Requirement For Market Entry	Allowed Claim Type	Representative Countries
Pharmaceutical-Grade Regulator	HTMs are narrowly defined as plant-based substances with therapeutic intent, requiring demonstration of safety and efficacy, via clinical or bibliographic evidence. They are treated similarly to conventional pharmaceuticals.	Regulated as medicinal products; rigorous pre-market requirements	Clinical or bibliographic evidence	Therapeutic	Germany, France, Switzerland, Russia, Turkey, United Kingdom, Singapore
Traditional Systems Integrator	HTMs are defined in traditional medical systems (e.g., Ayurveda, TCM, Kampo), reflecting system-based logic, historical use, and formal categorization of classical vs proprietary formulations.	Dual track: classical vs. proprietary formulas	Traditional use documentation or pharmacopeial reference	Therapeutic within traditional paradigm	India, China, Thailand, Japan, Indonesia, Pakistan, South Korea, Thailand, Macau, Vietnam
Complementary Health Product Model	Definitions are broad, framed around wellness, functional support, or traditional use. HTMs are positioned as non-pharmaceuticals, with focus on access, limited claims, minimal evidence requirements, and regulated as natural health products or complementary medicines.	Supplements or natural health products; minimal pre-market review	Traditional use or bibliographic evidence; tiered by claim	Structure/function; some minor therapeutic claims	Australia, Brasil, Canada, México, Panamá, Dominican Republic, Israel
Cultural Traditionalist	HTMs are defined loosely or culturally, drawing on ancestral, religious, or indigenous knowledge. Formal definitions are often absent or symbolic, with circulation based on ethnomedical legitimacy rather than scientific validation.	Minimal oversight; traditional use-based frameworks	None or anecdotal/ traditional legitimacy	Traditional/cultural healing	Cambodia, Ethiopia, Tuvalu, Tonga, Nepal
Hybrid Harmonizer	Definitions draw on WHO or regional models, blending traditional, scientific, and regulatory language. Systems are in transition, with partial standards and variable integration of traditional use, safety, and manufacturing requirements.	Partial pre-market standards; GMP or safety-focused	Traditional use documentation; partial bibliographic or safety data	Traditional use or supportive health claims	Bangladesh, Cuba, Egypt, Ghana, Kenya, Malaysia, Nigeria, Philippines, South Africa, Rwanda, Tanzania, Uganda, Zambia, Jordan
Therapeutic Claim-Gated Model	HTMs lack therapeutic recognition unless they meet drug criteria. Structure/function or wellness claims are permitted as dietary supplements, but therapeutic intent triggers full drug regulation.	Regulated as dietary supplements unless therapeutic claims are made	None for supplements; full clinical evidence for drug claims	Structure/function and nutrient claims allowed for supplements; full therapeutic claims only if approved as drug	United States of America

Definitions Can be Reactive or Proactive

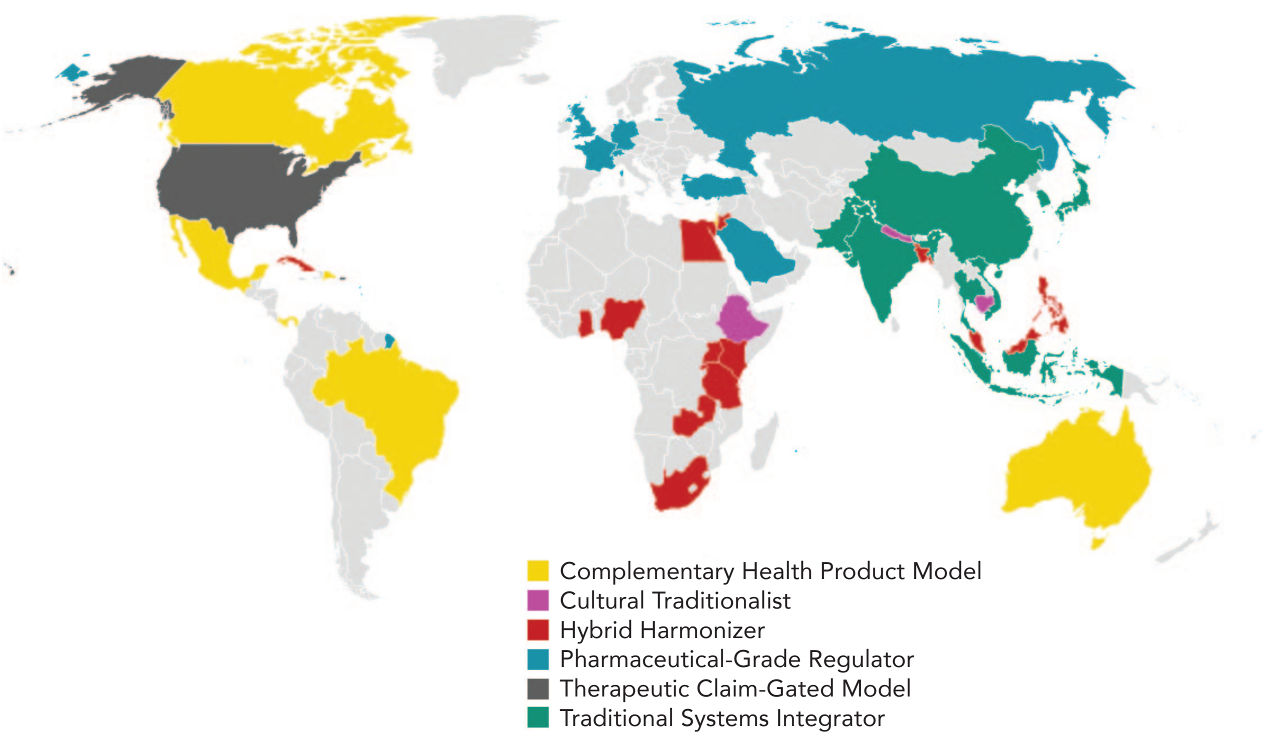
Definitions serve as both mirrors and shapers of regulatory intent. In some countries, HTMs definitions are reactive, based on cultural practices, traditional healing systems, and indigenous knowledge. These definitions emerge in response to existing practices, formalizing what is already practiced and in use rather than reinterpreting it to fit a regulatory model. Often, they aim to legitimize or preserve indigenous systems rather than create new classifications. For example:

- Cambodia and Nepal (Cultural Traditionalist Model) define traditional medicines in terms of ancestral knowledge and local customs, reflecting organic integration of tradition into health frameworks.
- India's AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy) defines "classical" formulations based on authoritative Ayurvedic texts, institutionalizing ancient practices without requiring scientific revalidation. (Traditional Systems Integrator)

In contrast, some developed countries define HTMs proactively, intentionally crafted to fit existing legal, scientific, or market structures:

- Canada (Complementary Health Product Model) categorizes HTMs as "Natural Health Products" (NHPs), a classification established in 2004 to oversee an expanding market for supplements and natural remedies.
- The United States (Therapeutic Claim-Gated Model) classifies most HTMs as dietary supplements under DSHEA (1994), a legislative decision that shaped the market and allowed manufacturers to bypass pre-market

Figure 2.
Global Map of the DART-HTM Framework



approval if they do not make therapeutic claims.

These examples show that while some nations often codify tradition, others reshape or constrain traditional product definitions to align with modern legislative priorities. Definitions are not just descriptors of HTMs but instruments that determine how and whether these products are regulated.

Some definitions are reactive—preserving traditional approaches; others are proactive—reshaping product use to fit modern systems.

HTM Regulatory Pathways: A Solution or A Compromise

Across frameworks, countries have adopted alternate regulatory pathways to balance honoring traditional practices with enforcing modern standards. These models, formally codified or functionally emergent, aim to preserve access to historic products while introducing scrutiny for novel or higher-risk claims.

- In Canada (Complementary Health Product Model), products may qualify for market authorization under the NHP framework by providing evidence of traditional use. However, those making substantial therapeutic claims or involving added complexities require more rigorous review, including safety and efficacy data.
- Malaysia (Hybrid Harmonizer Model) allows registration based on evidence of traditional use and basic quality parameters. Modern herbal products, especially those closer to pharmaceuticals, require comprehensive documentation, including clinical data or advanced GMP compliance.
- Thailand (Traditional Systems Integrator) maintains a two-tier model, distinguishing between traditional formulations under the Thai Traditional Medicine scheme and modern herbal products requiring extensive dossiers. This variation reflects both cultural integration and regulatory risk management

These examples demonstrate the broad applicability of alternate pathways across regulatory philosophies. **Table 2** summarizes their implementation in selected countries, distinguishing

Table 2.
Alternate Regulatory Pathways for HTMs in Selected Countries

Country	Regulatory Path "A"	Regulatory Path 'B'	Trigger For Transition
CANADA	Natural Health Product (NHP)	Drug Approval Pathway	Type of claim or level of complexity
MALAYSIA	Traditional Medicine Notification	Herbal Medicinal Product Registration	Potency/type of claim/scientific complexity
THAILAND	Thai Traditional Medicine Registration	Modern Herbal Product Registration	Classification (traditional vs. modern) and dosage form
AUSTRALIA	Listed Medicine (AUST L)/ (AUST L(A))	Registered Medicine (AUST R)	Type and strength of claim; risk profile of ingredients or indications

between traditional-use routes and more stringent frameworks. While pragmatic in reconciling traditional legitimacy with regulatory control, such systems also create gray areas in enforcement and classification. Their success relies on clear definitions, strong governance, and transparent criteria for when a product transitions from one track to another.

Where Product Ends and Practice Begins: The Regulatory Blind Spot

In many countries, particularly those within the Cultural Traditionalist, Hybrid Harmonizer, and, to some extent, Traditional Systems Integrator archetypes, herbal and traditional medicines are not merely products; they are embedded within the act of healing itself. The definitional boundaries in these contexts are intentionally broad or culturally grounded, reflecting the lived realities of traditional health systems. However, this convergence of product and practice creates significant regulatory challenges that existing frameworks often struggle to address. In South Africa and Ghana, for example, traditional healers are permitted to dispense preparations without requiring formal market authorization, further blurring the boundary between regulated product and the act of healing.

In settings where herbal preparations are made at the point of care, such as during a patient visit to a traditional healer, enforcing the standardized manufacturing protocols typical in pharmaceutical regulation becomes difficult. Good Manufacturing Practice (GMP), by design, assumes an industrial production model: validated processes, fixed formulations, and reproducible conditions. These assumptions do not hold in contexts where diagnosis, preparation, and administration are interwoven. In China, most major hospitals have a TCM department, which typically maintains its own "secret" hospital formulas developed from clinical expertise. Addressing issues of quality in such environments may require alternative approaches to GMP.

Likewise, in contexts where traditional products are freshly prepared, vary by healer, and may circulate outside formal markets, pharmacovigilance systems designed to monitor safety become nearly unworkable, primarily because they rely on batch traceability, defined ingredient profiles, and established distribution channels. In these circumstances, adverse event reporting is unlikely, and even when reported, it may be impossible to attribute an outcome to a specific product or ingredient.

This overlap of product and practice has important implications:

- It exposes a regulatory blind spot in frameworks that attempt to treat all herbal medicines as commodified, isolatable goods. **Figure 3** illustrates how product regulation and traditional healing practices intersect but lack formal oversight
- It complicates harmonization efforts, particularly when international bodies (e.g., WHO, ICH) promote standards that assume a clear separation between production and clinical use.

Some definitions of HTMs encourage the application of pharmaceutical-style regulatory models, while others – especially those routed in healing traditions – challenge these assumptions. This variation is captured in the DART-HTM framework, especially among the Traditional Systems Integrator and Cultural Traditionalist archetypes, where product and practice increasingly overlap. Recognizing this distinction is critical to developing systems that safeguard public health while respecting cultural practices.

Toward a Global Dialogue on Definition and Oversight Policy

Definitions are not passive descriptors but active levers that shape regulatory structure, market access, and cultural legitimacy. In the DART-HTM framework, definitional choices influence what is regulated, how enforcement is applied, and the implications for safety, efficacy, and innovation.

The WHO's approach to global harmonization emphasizes standardized technical requirements and collaborative regulatory networks to promote safety and accessibility (WHO, 2019). As global interest in HTMs grows, the challenge extends beyond regulation to the question of who has the authority to define them.

This raises questions:

- Do regulatory definitions reflect the political and cultural identities of nations?
- Should the power to define HTMs rest solely with national regulatory authorities and ministries of health?
- To what extent should traditional medicine councils, healer associations, and cultural institutions contribute to this process?

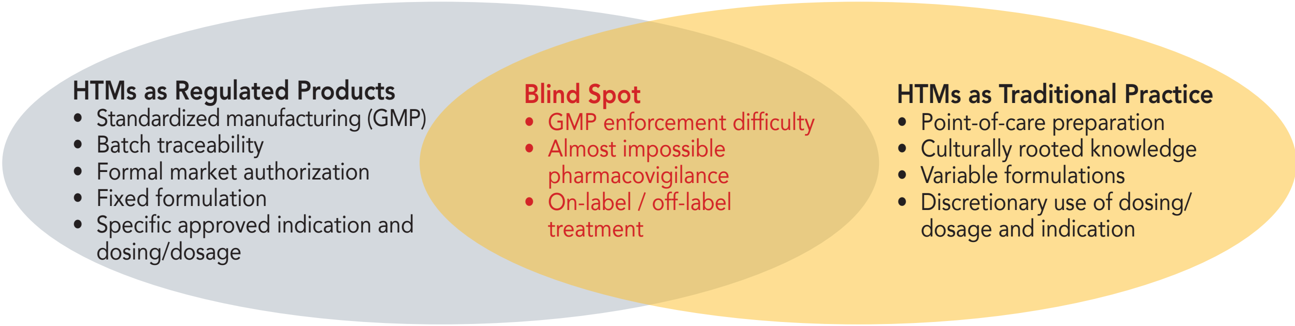
Without aligned criteria, international cooperation on HTMs will remain fragmented.

In India and China, traditional systems are part of national health strategies, giving institutional weight to classical knowledge. In contrast, other jurisdictions define HTMs through modern pharmacology, often marginalizing non-Western epistemologies. These approaches reflect regulatory priorities, geopolitical dynamics, and the tension between scientific modernity and ancestral knowledge.

Future-Proofing Definitional Models

As global trade and innovation in HTMs expands, questions arise about whether current classification models can address emerging realities. Hybrid therapies, integrative healthcare systems, and AI-generated phytomedicine formulations are testing definitions based only on botanical composition or conventional risk profiles.

Figure 3.
Intersecting Realms of Traditional Practice and Product Regulation



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Toward a Baseline Global Framework

One potential pathway forward is to establish a global baseline for HTM definitions. A shared framework with minimum criteria could support mutual recognition across regulatory systems without imposing uniformity. The DART-HTM Framework provides a starting point by grouping countries according to definitional logic, offering a neutral map for dialogue.

Such a framework might include:
- Core parameters such as region-specific traditional use, source materials, and therapeutic intent
- Flexibility for countries to integrate system-specific details

The goal is interoperability, creating a structure that respects sovereignty while fostering cooperation, transparency, and trust. The regulatory archetypes outlined here could serve as a starting point for these conversations.

Beyond Technical Consensus: Cultural and Institutional Dimensions

Progress toward global coherence in HTM oversight will require:
- The recognition of cultural impact and experience
- The validity of diverse knowledge systems
- Institutional design that accommodates both traditional and modern paradigms

The central challenge is to redefine what it means to define an HTM in a way that serves public health while honoring cultural pluralism in an interconnected world. The DART-HTM framework is one approach to addressing this challenge.

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References

Asase, A.A. (2023) 'Ghana's herbal medicine industry: Prospects, challenges and ways forward from a developing country perspective', *Frontiers in Pharmacology*, 14. doi:10.3389/fphar.2023.1267398.

European Medicines Agency (EMA) (2009) *Human regulatory: overview. Herbal Medicinal Products, European Medicines Agency (EMA)*. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/herbal-medicinal-products (Accessed: 05 August 2025).

Jackson, E. (2012) *Law and the regulation of medicines* [Preprint]. doi:10.5040/9781474200776.

Lakshmi, J.K. et al. (2014) 'Cultural consonance, constructions of science and co-existence: A review of the integration of traditional, complementary and alternative medicine in low- and middle-income countries: Figure 1', *Health Policy and Planning*, 30(8), pp. 1067–1077. doi:10.1093/heapol/czu096.

Office of Dietary Supplements (ODS) (2021) *Office of dietary supplements - dietary supplement health and education act of 1994, NIH Office of Dietary Supplements*. Available at: https://ods.od.nih.gov/About/DSHEA_Wording.aspx (Accessed: 05 August 2025).

World Health Organization (WHO) (2001) *Legal status of traditional medicine and complementary/alternative medicine: A worldwide review, World Health Organization. Institutional Repository for Information Sharing*. Available at: https://iris.who.int/handle/10665/42452 (Accessed: 05 August 2025).

World Health Organization (WHO) (2013) *Who traditional medicine strategy: 2014-2023, World Health Organization. Institutional Repository for Information Sharing*. Available at: https://iris.who.int/handle/10665/92455 (Accessed: 05 August 2025).

Additional Reading

Josephine Ozioma, E.-O. and Antoinette Nwamaka Chinwe, O. (2019) 'Herbal medicines in African Traditional Medicine', *Herbal Medicine* [Preprint]. doi:10.5772/intechopen.80348.

Lim, T. et al. (2022) 'Traditional Khmer medicine and its role in wildlife use in modern-day Cambodia', *Journal of Ethnobiology and Ethnomedicine*, 18(1). doi:10.1186/s13002-022-00553-5.

Liu, W.J. (2010) 'Introduction to traditional herbal medicines and their study', *Traditional Herbal Medicine Research Methods*, pp. 1–26. doi:10.1002/9780470921340.ch1.

Sung, S.-H. et al. (2020) 'Current status and future perspective of external herbal dispensaries preparing traditional herbal medicine in South Korea: The first national-wide survey results', *BMC Complementary Medicine and Therapies*, 20(1). doi:10.1186/s12906-020-03094-0.