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Reconciling Regulatory Governance and Communal Rights in Traditional Medicine: A Comparative Legal Study of Indonesia and Malaysia

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Abstract

Introduction: *The governance of traditional knowledge in traditional medicine raises a regulatory challenge: how can public health oversight be reconciled with the collective rights and customary practices of knowledge-holding communities? Indonesia and Malaysia provide a relevant comparative context because their regulatory frameworks differ in institutional organization and recognition of traditional medicine.*

Purposes of the Research: *This study examines and compares the legal governance of traditional knowledge in traditional medicine management in Indonesia and Malaysia, focusing on legal recognition, regulatory protection, customary law, and benefit-sharing.*

Methods of the Research: *The study employs normative legal research with a comparative and conceptual approach. It examines relevant legislation, regulatory instruments, legal doctrines, and scholarly literature to identify similarities, differences, and normative gaps in the two legal systems.*

Results of the Research: *The analysis indicates that traditional medicine governance in both jurisdictions prioritizes regulatory supervision and public health objectives, while the recognition of traditional knowledge as a collective legal entitlement remains insufficiently developed. Indonesia presents a fragmented regulatory framework, whereas Malaysia demonstrates more centralized institutional regulation. The study proposes a normative framework for integrating legal pluralism, regulatory accountability, and community-oriented protection. Its contribution lies in connecting traditional knowledge governance with the legal design of collective rights and equitable benefit-sharing.*

Keywords: Legal Pluralism; Traditional Medicine; Communal Rights.

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INTRODUCTION

Traditional knowledge related to traditional medicine constitutes a vital component of customary law and living law in many societies, particularly in developing countries such as Indonesia and Malaysia. For centuries, traditional medicine has been practiced, transmitted, and regulated through community-based norms rather than formal legal systems.[1] However, the increasing commercialization of traditional medicine has brought traditional knowledge into the domain of state regulation, intellectual property regimes, and modern health governance, often creating legal tension between customary law and statutory law. Previous studies on traditional medicine regulation have primarily focused

[1] Nicole Redvers et al., "*Indigenous Rights, Health and Traditional Medicine Systems*," *Bulletin of the World Health Organization* 103, no. 11 (2025): 722–29, https://doi.org/10.2471/BLT.24.292882.

on public health safety, product standardization, and administrative control.[2] Research in Malaysia emphasizes regulatory compliance, post-marketing surveillance, and clinical evidence requirements, while studies in Indonesia highlight cultural preservation and recognition of traditional medicine within national health policies. Other scholars have discussed the vulnerability of traditional knowledge to misappropriation and biopiracy, proposing intellectual property-based or sui generis protection mechanisms. Nevertheless, these studies tend to address regulatory or intellectual property aspects in isolation, without sufficiently examining how legal governance frameworks interact with legal pluralism and customary law. The main limitation of existing research lies in the lack of comparative legal analysis that integrates traditional knowledge as a manifestation of living law within modern regulatory systems. In particular, there is limited scholarly attention to how different governance models balance state control, public health objectives, and the protection of communal rights embedded in customary practices. This gap is significant, given that overly rigid regulation may marginalize traditional knowledge holders, while weak governance may expose traditional medicine to safety risks and commercial exploitation.

This article seeks to address these limitations by conducting a comparative legal analysis of Indonesia and Malaysia, focusing on the governance of traditional knowledge in traditional medicine management. By comparing two countries with similar cultural roots but different regulatory approaches, this study aims to identify structural strengths, regulatory gaps, and normative tensions within their legal frameworks. The novelty of this research lies in its legal pluralism perspective, positioning traditional knowledge not merely as an object of regulation but as a living legal system that requires sui generis governance. Accordingly, this article examines how traditional knowledge is recognized, protected, and managed within the legal systems of Indonesia and Malaysia, and evaluates the implications of these approaches for legal certainty, community rights, and sustainable development. The findings are expected to contribute to the development of a more inclusive legal governance model that harmonizes customary law and state regulation in the management of traditional medicine.

LITERATURE REVIEW

A. Traditional Knowledge as Living Law and Customary Law

Traditional knowledge has long been recognized as an integral part of customary law and living law within indigenous and local communities.[3] Scholars of legal pluralism argue that traditional knowledge operates through unwritten norms, collective ownership, and intergenerational transmission, making it distinct from state-centered legal systems. In the context of traditional medicine, traditional knowledge functions not only as cultural heritage but also as a normative system governing access, use, and transmission. In both Indonesia and Malaysia, traditional medicine practices continue to operate as living law within local communities, despite their increasing incorporation into formal regulatory regimes. Indonesia reflects a pluralistic legal landscape in which customary practices coexist

[2] Zuanji Liang et al., "Applying Regulatory Science in Traditional Chinese Medicines for Improving Public Safety and Facilitating Innovation in China: A Scoping Review and Regulatory Implications," *Chinese Medicine* 16, no. 1 (2021): 23, https://doi.org/10.1186/s13020-021-00433-2.

[3] Zuanji Liang 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," *Evidence-Based Complementary and Alternative Medicine* 2021 (2021): 1–16, https://doi.org/10.1155/2021/5833945.

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with administrative health regulations,[4] while Malaysia demonstrates a more centralized governance model that institutionalizes traditional medicine through statutory control. Existing literature emphasizes that ignoring customary law within these legal frameworks risks marginalizing community-based knowledge holders and transforming traditional knowledge into mere objects of market regulation, thereby undermining the sustainability and authenticity of traditional medicine systems.

B. Legal Regulation of Traditional Medicine

Research on traditional medicine regulation primarily focuses on public health protection, safety standards, and product quality control. In Indonesia, the regulatory framework adopts a tiered classification system that distinguishes traditional medicines based on levels of scientific validation, ranging from jamu to standardized herbal medicine and phytopharmaceuticals.[5] This approach reflects an attempt to integrate traditional knowledge into modern health governance while maintaining regulatory flexibility. However, the legal framework largely treats traditional medicine as a regulated product, with limited recognition of the customary norms governing its use and transmission. In contrast, Malaysian regulatory scholarship emphasizes a centralized administrative model characterized by mandatory product registration, licensing, and post-marketing surveillance under the authority of national regulatory agencies.[6] Malaysia's regulatory structure provides clearer legal certainty and enforcement mechanisms, yet it places traditional medicine firmly within a formal bureaucratic system.[7] Scholars argue that while such regulation enhances consumer protection, it may reduce the adaptive and community-based nature of traditional medicine practices. Comparative studies indicate that both regulatory models prioritize state control and public health objectives over the legal recognition of traditional knowledge as living law. Excessive formalization risks displacing customary governance mechanisms, thereby creating tension between regulatory compliance and the preservation of traditional medicine as a socially embedded practice within indigenous and local communities.

C. Protection of Traditional Knowledge and Sui Generis Approaches

Academic discourse on the protection of traditional knowledge consistently highlights the limitations of conventional intellectual property regimes. Patent and copyright systems are generally designed for individual authorship, novelty, and fixed expressions, making them ill-suited to protect communal, orally transmitted, and evolving traditional knowledge. In the context of traditional medicine, these limitations become more pronounced, as knowledge is collectively owned, culturally embedded, and governed by customary norms rather than exclusive legal rights. In Indonesia and Malaysia, legal protection of traditional knowledge remains fragmented and indirect.[8] Indonesia relies on

[4] Achmad Hariri and Basuki Babussalam, "Legal Pluralism: Concept, Theoretical Dialectics, and Its Existence in Indonesia," *Walisongo Law Review (Walrev)* 6, no. 2 (2024): 146–70, https://doi.org/10.21580/walrev.2024.6.2.25566.

[5] Andika Prawira Buana and Moch Andry Wikra Wardhana Mamonto, "The Role of Customary Law in Natural Resource Management: A Comparative Study between Indonesia and Australia," *Golden Ratio of Mapping Idea and Literature Format* 3, no. 2 (2023): 167–86, https://doi.org/10.52970/grmilf.v3i2.400.

[6] Norazlina Abdul Aziz et al., "An Analysis of The Rights to Health and The Traditional & Complementary Medicine (TCM) Healthcare Services in Malaysia," *International Journal of Academic Research in Business and Social Sciences* 13, no. 4 (2023): Pages 1375-1391, https://doi.org/10.6007/IJARBSS/v13-i4/16705.

[7] Ji-Eun Park et al., "Twenty Years of Traditional and Complementary Medicine Regulation and Its Impact in Malaysia: Achievements and Policy Lessons," *BMC Health Services Research* 22, no. 1 (2022): 102, https://doi.org/10.1186/s12913-022-07497-2.

[8] Aan Eko Widiarto et al., "The Authority Relationship of Central and Local Governments in Forming Laws and Regulations: Between Indonesia and Malaysia," *Legality : Jurnal Ilmiah Hukum* 33, no. 1 (2025): 148–67, https://doi.org/10.22219/ljih.v33i1.36629.

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sectoral regulations related to health, culture, and biodiversity, while Malaysia emphasizes administrative control through health and regulatory statutes. Neither jurisdiction has adopted a comprehensive sui generis legal framework that explicitly recognizes traditional knowledge holders as collective legal subjects. As a result, traditional knowledge is often protected only insofar as it is transformed into regulated products, leaving the underlying customary governance structures legally unaddressed.[9] Scholars therefore advocate sui generis protection models that integrate principles of legal pluralism, prior informed consent, and equitable benefit-sharing. However, the literature reveals a significant gap in aligning such sui generis mechanisms with existing health regulations and governance structures.[10] In plural legal systems such as Indonesia and Malaysia, the challenge lies not merely in designing new legal instruments, but in harmonizing state regulation with living law to ensure that traditional knowledge protection supports both public health objectives and the rights of customary communities.

D. Research Gap

Despite growing academic interest in traditional knowledge and the regulation of traditional medicine, comprehensive comparative legal studies examining the governance of traditional knowledge in traditional medicine management between Indonesia and Malaysia remain limited.[11] Existing research predominantly addresses public health regulation or intellectual property protection in isolation, with insufficient integration of customary law, legal pluralism, and governance perspectives. Consequently, traditional knowledge is often analyzed as a regulated object rather than as living law embedded in community norms. This article addresses this gap by offering a structured comparative legal analysis that situates traditional knowledge within plural legal systems and modern regulatory governance frameworks.

METHODS OF THE RESEARCH

This article employs normative legal research, focusing on the analysis of legal norms governing traditional knowledge in the management of traditional medicine. A comparative law approach between Indonesia and Malaysia is applied, supported by statute and conceptual approaches. Legal materials are obtained through document-based research, including legislation, regulatory policies, international legal instruments, and relevant scholarly literature.[12] The analysis is conducted using qualitative legal reasoning to identify regulatory patterns, normative gaps, and governance models within plural legal systems.

RESULTS AND DISCUSSION

This section presents the research findings and their discussion in a descriptive, analytical, and critical manner. The analysis begins with an overview of the legal and

[9] Fathoni Fathoni et al., "Comparative Analysis of Environmental Permitting in Indonesia and Malaysia: Implications for National Strategic Projects," *Administrative and Environmental Law Review* 6, no. 1 (2025): 77–90, https://doi.org/10.25041/aelr.v6i1.4360.

[10] Maskun Maskun et al., "Legal Analysis of Reclaimed Wastewater Management in Indonesia: Reference to Malaysia and Singapore," *Water* 17, no. 10 (2025): 1416, https://doi.org/10.3390/w17101416.

[11] Rahmad Satria, "Legal and Institutional Frameworks for Managing Forest Resources: A Comparative Study of ASEAN Countries," *Jurnal Konseling Dan Pendidikan* 13, no. 1 (2025): 409–19, https://doi.org/10.29210/1143900.

[12] Nadine Ijaz and Heather Carrie, "Governing Therapeutic Pluralism: An Environmental Scan of the Statutory Regulation and Government Reimbursement of Traditional and Complementary Medicine Practitioners in the United States," *PLOS Global Public Health* 3, no. 8 (2023): e0001996, https://doi.org/10.1371/journal.pgph.0001996.

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institutional frameworks governing traditional knowledge and traditional medicine in Indonesia and Malaysia. Presenting this preliminary mapping is important to provide contextual clarity before examining each country's governance model in detail. The comparison highlights how different legal traditions and regulatory priorities shape the recognition, protection, and management of traditional knowledge within plural legal systems.[13] To support the analysis, Table 1 summarizes the key regulatory features of traditional medicine management and traditional knowledge governance in both countries.

Table 1. Legal and Institutional Frameworks Governing Traditional Knowledge and Traditional Medicine

Aspect	Indonesia	Malaysia
Primary regulatory authority	National Agency of Drug and Food Control (BPOM)	National Pharmaceutical Regulatory Agency (NPRA)
Legal basis of traditional medicine	Health Law and sectoral regulations	Medicines and public health regulations
Classification of traditional medicine	Jamu, Standardized Herbal Medicine, Phytopharmaceuticals	Registered traditional medicines
Recognition of traditional knowledge	Cultural heritage and customary practices	Administrative and regulatory recognition
Role of customary law	Implicit and fragmented	Minimal
Governance orientation	Pluralistic but decentralized	Centralized and administrative

Source: Author's analysis based on national legislation, regulatory policies, and scholarly literature.

A. Legal Governance of Traditional Knowledge in Indonesia

The findings indicate that Indonesia recognizes traditional knowledge as part of cultural heritage and living law, particularly through health and cultural regulations governing traditional medicine. The legal framework classifies traditional medicine into several categories based on levels of scientific validation, reflecting an effort to integrate traditional practices into the national health system. However, traditional knowledge holders are not explicitly positioned as legal subjects with collective rights. Governance remains fragmented, as protection norms are dispersed across health law, intellectual property law, and sectoral regulations.[14] This condition weakens legal certainty and limits benefit-sharing mechanisms for indigenous and local communities. From a legal pluralism perspective, Indonesian regulation symbolically acknowledges customary practices but prioritizes state-centered regulatory control in implementation.[15] As a result, traditional knowledge is governed more as an object of administrative supervision than as a living legal system embedded in community norms.

B. Legal Governance of Traditional Knowledge in Malaysia

Malaysia has established one of the most structured legal frameworks for traditional and complementary medicine in Southeast Asia. The primary legal instrument is the Traditional

[13] Kamrul Hossain and Rosa Maria Ballardini, "Protecting Indigenous Traditional Knowledge Through a Holistic Principle-Based Approach," *Nordic Journal of Human Rights* 39, no. 1 (2021): 51–72, https://doi.org/10.1080/18918131.2021.1947449.

[14] Tatiana Andia and Nitsan Chorev, "How to Study Global Lawmaking: Lessons from Intellectual Property Rights and International Health Emergencies," *Annual Review of Law and Social Science* 19, no. 1 (2023): 215–34, https://doi.org/10.1146/annurev-lawsocsci-111522-091304.

[15] Azza Elnaiem et al., "Global and Regional Governance of One Health and Implications for Global Health Security," *The Lancet* 401, no. 10377 (2023): 688–704, https://doi.org/10.1016/S0140-6736(22)01597-5.

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and Complementary Medicine Act 2016 (Act 775), which provides a statutory basis for regulating traditional medicine practices and practitioners.[16] This Act mandates the registration and certification of traditional and complementary medicine practitioners under the supervision of the Traditional and Complementary Medicine Council, operating within the Ministry of Health Malaysia.

The governance framework was further strengthened by the Traditional and Complementary Medicine Regulations 2021, which came into force in 2021 and detail administrative procedures, licensing requirements, and enforcement mechanisms. These regulations aim to ensure professional accountability, standardization of practice, and consumer safety. From a regulatory standpoint, this model offers legal certainty and institutional clarity. In relation to traditional medicine products, Malaysia places regulatory oversight under the National Pharmaceutical Regulatory Agency (NPRA).[17] Traditional and herbal medicines are categorized as natural products and are subject to mandatory registration, safety evaluation, and post-marketing surveillance. Recent regulatory data indicate that thousands of traditional and herbal products have been registered under this system, reflecting the government's emphasis on administrative control and consumer protection. However, despite its regulatory effectiveness, the Malaysian legal framework provides limited recognition of traditional knowledge as a form of customary law or living law. Traditional knowledge is treated primarily as a component of public health governance rather than as a communal legal entitlement. The absence of explicit legal mechanisms for recognizing collective ownership and benefit-sharing raises concerns regarding the long-term protection of traditional knowledge holders, particularly indigenous and local communities.

C. Comparative Legal Governance of Traditional Medicine Products in Indonesia and Malaysia

Traditional medicine represents a form of living law rooted in customary knowledge and long-standing social practices. In both Indonesia and Malaysia, traditional medicine is not merely a health commodity but also a cultural expression transmitted across generations.[18] However, when such traditional knowledge enters the modern market, it becomes subject to state regulation, particularly in relation to consumer safety, licensing, and market supervision. This section examines the comparative legal governance of traditional medicine products in Indonesia and Malaysia, focusing on regulatory authorities, licensing mechanisms, and recent legal developments over the last three years. In Indonesia, traditional medicine products such as jamu, standardized herbal medicine, and phytopharmaceuticals are regulated primarily by the National Agency of Drug and Food Control.[19] The legal governance model emphasizes product-based regulation, where traditional knowledge is indirectly acknowledged through product classification rather than explicitly protected as collective intellectual or customary rights. BPOM has progressively implemented a risk-based licensing approach to simplify registration while

[16] Norazlina Abdul Aziz et al., "A Comparative View on the Traditional and Complementary Medicine (TCM) Regulation in Malaysia and China," *Environment-Behaviour Proceedings Journal* 9, no. SI17 (2024): 169–74, https://doi.org/10.21834/e-bpj.v9iSI17.5442.

[17] Goh Cheng Soon, "Regulatory Challenges In Uplifting Traditional Malay Medicine In Malaysia", *International Journal of Allied Health Sciences* 5, no. 5 (2021): 2312-2321.

[18] Yeni Indriyani et al., "Socio-Culture and Health Problem Factors on Traditional Medicine Use among Indonesian Adult: A Cross-Sectional Analysis from National Survey," preprint, March 27, 2023, https://doi.org/10.1590/SciELOPreprints.5769.

[19] Tiara et al., "Legal Protection Analysis of Consumers Against Traditional Medicines Containing Pharmaceutical Chemical Substances in Digital Markets," *Journal of Law, Politic and Humanities* 5, no. 5 (2025): 3644–54, https://doi.org/10.38035/jlph.v5i5.1922.

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maintaining safety standards, reflecting Indonesia's effort to balance cultural heritage preservation with public health governance.[20] Malaysia adopts a relatively centralized and structured regulatory model through the National Pharmaceutical Regulatory Agency (NPRA).[21] All traditional and natural medicine products must be registered and obtain a valid MAL number before being marketed. Additionally, Malaysia distinguishes itself by regulating not only products but also practitioners through the Traditional and Complementary Medicine Act 2016 (T&CM Act). Although the Act focuses on practitioners rather than product ownership of traditional knowledge, it represents a formal state recognition of traditional medical practices as part of the national health system.

Recent regulatory developments (2022–2025) indicate diverging governance trajectories. Indonesia continues to expand the quantity of registered traditional medicine products, supported by regulatory simplification and ASEAN harmonization initiatives. Malaysia, on the other hand, has introduced new regulatory categories allowing traditional and natural products to carry modern therapeutic claims, signaling an adaptive approach to innovation while retaining strict registration requirements. From a pluralism perspective, both countries demonstrate a state-centric legal pluralism, where customary practices are accommodated within formal legal frameworks but are not fully autonomous. Traditional knowledge functions as living law socially, yet legally it is transformed into an object of administrative regulation rather than a subject of customary rights.

Table 2. Comparative Legal Governance of Traditional Medicine Products (Indonesia and Malaysia)

Aspect	Indonesia	Malaysia
Regulatory Authority	National Agency of Drug and Food Control	National Pharmaceutical Regulatory Agency (NPRA), Ministry of Health
Main Legal Framework	Food and Drug Control Agency Regulations on Traditional Medicines; Health Law; ASEAN harmonization instruments	Drug Registration Guidance; Traditional and Complementary Medicine Act 2016
Product Categories	*Jamu*, Standardized Herbal Medicine, Phytopharmaceuticals	Natural Products (traditional medicine, health supplements)
Licensing / Registration System	Mandatory Food and Drug Control Agency distribution permit prior to market circulation	Mandatory registration with NPRA and issuance of MAL number
Approximate Registered Products (Recent Data)	Over 15,000 traditional medicine products; limited number of phytopharmaceuticals (2023–2024)	Hundreds of natural products registered annually; cumulative registrations in the thousands
Practitioner Regulation	No unified national licensing system for traditional medicine practitioners	Mandatory practitioner registration under the T&CM Act

[20] Widha Dianasari and Mardiati Nadjib, "Supervision Of Traditional Medicines Containing Undeclared Substance: Analysis Of Indonesian Fda Monitoring Data For 2012 - 2021," *Journal of Indonesian Health Policy and Administration* 7, no. 1 (2022): 196, https://doi.org/10.7454/ihpa.v7i1.5858.

[21] Swee Kheng Khor, Esther Pei Wei Chua, and Caroline Fried. "Sustainability and resilience in the Malaysian health system." *Center for Asia-Pacific Resilience and Innovation (CAPRI) 2 (2024).*

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Aspect	Indonesia	Malaysia
Recognition of Traditional Knowledge	Implicit cultural recognition; no explicit legal protection as collective customary rights	Practice recognized institutionally; traditional knowledge not framed as proprietary legal rights
Recent Regulatory Developments (Last 3 Years)	Risk-based licensing, regulatory simplification, increased ASEAN alignment	Introduction of "natural products with modern claims" category (2024)
Governance Orientation	Product-focused administrative regulation	Product and practitioner-focused regulation

Source: *Comparative analysis of Indonesian BPOM and Malaysian NPRA regulatory frameworks (2022–2025).*

The comparison reveals that while both Indonesia and Malaysia formally regulate traditional medicine within modern legal systems, neither jurisdiction fully integrates customary law principles into the legal ownership or governance of traditional knowledge.[22] Traditional medicine remains legally positioned as a regulated commodity rather than a manifestation of collective cultural rights. This condition highlights an unresolved tension within legal pluralism: the coexistence of living law practices and state administrative law without substantive recognition of indigenous or customary epistemologies. Accordingly, this comparative governance model demonstrates that legal protection of traditional medicine in Southeast Asia is still predominantly oriented toward consumer safety and market control, rather than toward legal pluralism that empowers traditional knowledge holders.

CONCLUSION

This comparative study demonstrates that the governance of traditional knowledge in traditional medicine in Indonesia and Malaysia remains primarily structured around state regulatory objectives, particularly product oversight, practitioner regulation, and public health protection. However, the two jurisdictions require more systematic examination of how traditional knowledge holders are recognized and protected within these regulatory frameworks. Indonesia's regulatory landscape reflects the interaction of cultural recognition, sectoral regulation, and customary practices, while Malaysia's framework provides a more centralized institutional structure for traditional and complementary medicine. These differences should not be equated automatically with overall legal effectiveness, as the protection of traditional knowledge requires separate assessment of collective rights, legal recognition, and enforcement mechanisms. The principal normative implication is the need to connect traditional medicine regulation with a clearly defined framework for protecting traditional knowledge holders. Such a framework should address the legal status of collective rights, conditions for authorized use, institutional responsibilities, and equitable benefit-sharing. Any proposed sui generis approach must be developed through specific legal mechanisms and assessed against existing national legislation. This study is limited by its reliance on normative legal materials and does not establish the practical experiences of traditional knowledge-holding communities. Further research should therefore examine the implementation of legal protections and the perspectives of relevant communities and regulatory institutions.

[22] Dwi Tatak Subagiyo et al., "An Overview of Legal Measures to Prevent and Protect Unreasonably the Use of Traditional Medicine in Indonesia," *Journal of Law and Sustainable Development* 11, no. 11 (2023): e1782, https://doi.org/10.55908/sdgs.v11i11.1782.

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