# Research on Differences in Traditional Chinese Medicine Regulatory Legal Regimes within China's Dual Legal Regions and Compliance Strategies for Cross-Jurisdictional Circulation

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**Abstract: Against the backdrop of the Greater Bay Area and global industrial layout, disparate legal norms governing traditional Chinese medicine apply across China's separate legal jurisdictions. Such institutional divergences create tangible obstacles to the international circulation of TCM products. This study systematically analyzes the TCM governance legal frameworks covering legislative standards, market access, quality supervision and distribution regulation, identifies the root causes of institutional discrepancies between domestic legal zones, and sorts out compliance risks and institutional frictions emerging in inter-jurisdictional TCM trade and exchange. Drawing on existing policy practices represented by the Announcement of the Guangdong Provincial Drug Administration on Simplifying Registration and Approval Processes for Marketed Proprietary Chinese Medicines from the Special Administrative Regions, this paper explores targeted compliance pathways for inter-jurisdictional TCM circulation that adapt to varied local legal regimes and industrial development demands. It further puts forward legal references to deepen cross-jurisdictional regulatory collaboration, advance coordinated high-quality development of the TCM industry within the Greater Bay Area, and facilitate the standardized global development of traditional Chinese medicine.**

**Keywords: Traditional Chinese Medicine Regulation; Legal Framework; Cross-Border Compliance**

## 1. Introduction

Traditional Chinese medicine(TCM) is part of what is special about Chinese ancient culture and is very competitive and unique for the Guangdong Hongkong Makao region. It forms good basis for cross border exchange on this area and thus promotes more coordinated integration of TCM sector in region. But with industrial cooperation among all parties in Greater Bay Area going well forward, problems like regulatory frameworks between areas being uneven; getting into the market is tough; things don't line up when compared to others; regulations aren't always working together smoothly, following rules has its own risks too; these are all stopping those two-way flows - one direction has Chinese medicines and traditional Chinese medicine items while another way moves related medical examination services. In order to solve these problems, this paper makes an exhaustive analysis of the main difference between TCM regulatory legal system of both regions, the challenges of compliance during the process of trans-border circulation are analyzed, scientific ways to make the trade comply can be found through this study so that better cooperation among regulation departments may take place alongside better development of the TCM sector.

## 2. Differences in the Legislative Frameworks of Traditional Chinese Medicine Regulatory Systems between Mainland China and Hong Kong

### 2.1 Differences in Legal Sources and Legislative Systems

Legal framework of main land of China's TCM regulations, based on written laws and the Constitution, special laws, administrative regulations, departmental rules, local rules and so on, interconnection among them at various levels, it has developed an orderly legislative frame work with strong logicality and uniform standards.Traditional Chinese Medicine Law + Drug Administration Law = basis for overseeing industries; China Pharmacopoeia & relevant drugs reg = supplementary support.It has now created an up-from-the-top down-uniform

 

standardized law for regulating TCMD over-all in every part of China and each part in China has its own way that it follows the same standard law set out for TCMD. On the other hand,hong kong,a common law area,makes use of written provisions backed up by cases as its main body of law with the principal source of authority coming from the Traditional Chinese Medicine ordinance (cap 549). Supporting legislation such as Import And Export Ordinance is there too.There is no single overarching hierachical legislative framework and local adaptations are emphasized over centralized legislation as is typical in Mainland China.

### 2.2 Differences in Regulatory Authorities and Division of Powers and Responsibilities

Traditional Chinese medicine(TCM) regulationinMainlandChinaadoptacentralandunifiedmanagementmodelthroughmultidepartmentscooperationwithdutiesclarifiedandscaledhierarchysystemized. The National Administration of Traditional Chinese Medicine supervises the development strategy of the industry and supervises and controls different TCM diagnosis and treatment; drug regulatory authority ensures the whole-process quality control, including researching, developing, registering and producing as well as selling medicinal herbs; market supervision system does specific checks for industry price and running rules; but local regulation organizations from all over regions shoulder jurisdiction obligations across every little spot, building a nation-wide interconnected managing system. TCM regulation in Hong Kong is headed by TCM Regulation Office of the Department of Health, in coordination with TCM Management Committee made up of TCM Management Group and TCM Practitioner Management Group that manage herbal medicines and practitioners respectively.And structure, in which there's one boss, no hierarchy on the land, lots of local bosses..

## 3. Differences in Core Regulatory Systems for Traditional Chinese Medicine between Mainland China and Hong Kong

### 3.1 Differences in Traditional Chinese Medicine Registration and Approval Systems

When registering and approving traditional Chinese medicines on the mainland part of China, there is always the same rule that applies to all parts, such as the medicinal materials, ready-to-use medicines, cut-up medicines, hospital-made preparations etc., so it's like having similar process when applying for them approved.All domestic as well as foreign imported TCM should meet clinical trial, quality check, technique assessment and so forth stipulated through Drug Registration Administration Method in line with the relative standards in the China Pharmacopoeia.Only use of traditional classics will be given the simpler kind of licensing procedure, which has very high industrial admission requirements and follows a specific set of rules for granting approvals.Hong Kong uses classified registration for its TCM supervision and has prepared Chinese medicines, medicinal herbs, and Chinese medicine formula granules as three different types of products.Local prepared chinese medicines are put into simplified and official records, no need for trials;only quality and safety related documents needed.The barrier to entry is lower compared to the Mainland part of China, there's much more focus on localization in terms of getting approvals as opposed to the very strict registration setup found within the Mainland region of China.

### 3.2 Differences in Quality Standard Control of Traditional Chinese Medicine

The Mainland's quality control for Traditional Chinese medicines(TCMs) relies mostly upon the *Chinese Pharmacopoeia*, which provides a foundation with other elements including production origin tracking, distinctive properties, important ingredients amounts, heavy metals, insecticides left overs, and many more.Detailed and count-able one-stander all over stages of production,processing, transportation, and testing of tcm. [1]Secondly, China Mainland has also built a TCM track-and-trace systems, require medicinal material and prepared TCM products all should have verifiable origins, trackable destinations; it must follow complete quality controls from beginning till end, no exceptions made here.On the contrary, there is no special nation-wide standard system set up by Hong Kong on the TCM Quality Control. Its management basically follows general guidelines as well as some regulations in Mainland Pharmacopoeia which mainly check harmful impurities and poisonous parts.Specific required constraints on the active ingredient portion of it as well as how things need to be done at the processing end or that you have to be

 

able to prove where your starting material came from - those specifics aren't in there either which is just making it way looser and less exacting of rules that we're getting to go by so far as I can tell - still doesn't have everything tied into an overarching number system to keep us all on par.

## 4. Current Compliance Challenges in the Cross-Border Circulation of Traditional Chinese Medicine

### 4.1 Inconsistent Regulatory Standards Lead to Compliance Conflicts.

Both regions have different regulations about the standard of quality,registration of tcm & practice, it leads to the first reason for difference among cross border tcm distribution. And as far as Chinese Patent Medicines being allowed inside Hongkong are also different than what is approved on the Chinese mainland, so they won't really be allowed in right away. Simplification measures mentioned in "Hong Kong-Macao Traditional Chinese Medicine Guidelines" applies only to topicals Chinese patent medicines, the rest like oral tablets and herbs decocting still need finish the total mainland's registration process. TCM products following mainland rules do not comply with Hong Kong local and impurity control, so they can't sell on the Hong Kong side. This no common standard is required that we must re-qualify in each direction, which adds to our corporation and makes them take longer and prevents usual trade between borders.

### 4.2 The Inadequate Mutual Recognition Mechanism for Qualifications Creates Barriers to Market Circulation.

Mutual recognition on qualification of practicing and producing/testing Traditional Chinese Medicine(TCM) on Mainland vs. HongKong is somewhat limited with somewhat vague definition thus creating some hindrance to cross border circulation. The qualifications for TCM practitioners between these two areas are not fully compatible: Hong Kong's TCM practitioners can't work directly on the mainland, and when mainlanders go to Hong Kong, they need extra local exams, which limits how much TCM diagnosis and treatment service moves across regions. Industry wise, certifications under GMP of Hong Kong based TCM manufacturer along with the test report from inspecting organization has no full recognition on main land; in a similar fashion qualifications of TCM processing & tracing of mainland are also not recognized by Hong Kong authority. It requires cross border product requalification and inspection, making it complicated and risky for cross border distribution [3].

## 5. Compliance Optimization Pathways for Cross-Border Circulation of Traditional Chinese Medicine between Mainland China and Hong Kong

### 5.1 Strengthen the Alignment of Core Regulatory Standards

In line with those demands that require coordinated advancement of the traditional Chinese medicance industry within Greater Bay Area, we need step-by-step to harmonize or unify major supervision standard between the 2 areas so that there will not have any circulation barriers resulting due to the difference of those standards.As far as it is concerning quality standards for traditional Chinese medicines, take the lead and reach each other to agree on these through the infrastructure built upon our country's pharmacopeia, using Hong Kong's experiences gained through adapting itself into global compliance systems in their tests; this would then be used to create some new testing standards on herbal medicines as well as processed medical concoctions which work on a common basis. It makes more sense to make sure things like what metals might harm you, poisons left over from sprays, and figuring out how many active parts something has - they all have to follow rules at the same time first. For example, transitional index could refer to the world recognized standard but with considerations for localities; so that same produce tested in different part of area would have equal result upon inspections done there.Existing policies under the Hong Kong - Macao Traditional Chinese Medicine Agreement must be improved, with time, the simple registration and approval requirements for topical prepared medicines should be extended to other oral prepared medicines having a long track record of conformity and established history of being safe and stable in Hong Kong.

### 5.2 Improve the Compliance Mechanism for Mutual Recognition of Qualifications Between Both Parties

Create an ordered, categorized structure on both

 

sides for acknowledgment of TCM degrees to get rid of different kinds of blocks to the flow of workers, goods, and companies, so that the regions' resources will be properly divided up.Talent area : The interoperable should include the two areas, TCM practitioners in both areas have qualifications and should have easy way to register cross border practice qualification. Both parties must recognize the other party's licensed to practice credentials, ongoing education history, and in-person care outcome records; similar stipulations need to be applied when writing down medical files, issuing prescriptions and making reports about bad things that happen because of treatment, which would help lower repeated tests and certification efforts.

### 5.3 Establish a Regular Cross-Border Regulatory Cooperation Framework

Mainland and Hong Kong should develop long term cross border regulation for TCM which will be good for comprehensive regulation in all aspects of TCM's production, transportation and use so we could achieve full coverage and no disruption.From those two regions, the regulatory bodies ought to have created data exchange routes through the means of particular pipes and websites, making sure that new news on stuff being signed off by product registration offices as well as the outcome of checks about stuff, any time that somebody misbehaves themselves on the internet or has something bad to warn people against getting involved. Standardize the product traceability code can allow tracing from beginning of the life cycle(raw material to use), it will be able to find out immediately after finding out what batch is affected, find who is responsible, and recall if there's any problem with the product (ref: 4). Cross border enforcement needs uniform standards, set procedures jointly processing offenses.Both parties sign mutual enforcement agreements on how to refer cases between us, do joint investigations into these things, decide what constitutes proof in such matters and determine penalties in such situations so there can be no confusion over which court will handle the matter or whether this would just be another round of enforcing penalties for doing something already punished elsewhere within one entity [5].

## 6. Epilogue

Legal systems and regulatory methods in mainland China and Hong Kong are very different and both have separate ways they handle laws for Traditional Chinese Medicine. Different legislative structure and approval process, as well as quality controls, professionalism practising management causes problems like different kind of standards for distribution, difficulties recognizing other place's work as good enough, not coordinating regulations, making it hard for everyone in bay area to help out tcm industry develop together. Need to find main difference in their two regulating systems, meet up when doing operation on different countries' law, show way of standardizing, making other people believe about being recognized, more working together to take care of laws. Next step: deepen legal cooperation, improve cross-border compliance system for TCM, strike a balance between safety supervision and industrial growth, promote standardized and sustainable cross-border flow of TCM products, and advance it towards high-end globalization.

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