Review

Quantitative evaluation of traditional Chinese medicine registration management policy texts based on the PMC index model

Pan Chen, Shuling Wang*

School of Business Administration, Shenyang Pharmaceutical University, Shenyang 110016, China

Abstract

To systematically and quantitatively evaluate China's national-level traditional Chinese medicine (TCM) registration management policies, providing evidence for policy optimization. Eight core policy documents from 2008 to 2025 were selected. Text mining was conducted using ROSTCM 6.0 software to construct the Policy Management Capability (PMC) index model, which includes 9 primary and 31 secondary indicators. The PMC index for each policy was calculated, and a three-dimensional surface plot was generated for visualization. The overall average PMC score was 6.19, with the quality distribution exhibiting a "bottle-shaped" pattern. The "Drug Registration Management Measures" (2020) achieved the highest score of 7.50 (Excellent), while some technical guidance documents scored below 5.4 (Unsatisfactory). The policies generally performed well in terms of operability and content coverage but were deficient in policy evaluation, hierarchical structuring, and innovation incentives. The TCM registration management policies demonstrate a robust framework with imbalanced details. Dynamic evaluation and incentives for innovation need enhancement. Recommendations include systematic optimization of the system through improvements in post-market evaluation, enhanced incentive tools, and stronger policy coordination.

Keywords: traditional Chinese medicine registration management; PMC index model; policy evaluation; text mining; policy quantification

The management of traditional Chinese medicine (TCM) registration is a crucial aspect of China's pharmaceutical regulatory system and acts as a key policy tool for promoting the inheritance and innovative development of TCM. The detailed implementation of the "Healthy China 2030" Planning Outline [1] and the thorough application of the Law of the People's Republic of China on TCM have elevated the TCM industry's development to a national strategy. In recent years, pharmaceutical regulatory authorities have continuously pursued reforms in the review and approval system. Notably, the introduction of the new "Measures for the Administration of Drug Registration" [2] in 2020 has laid a new legal foundation for TCM registration management. Additionally, the 2023 Special Provisions on the Registration Management of TCMs [3] have marked the initial establishment of a registration management system for TCMs characterized by Chinese features. Its core aspect

These authors have no conflict of interest to declare.

*Author to whom correspondence should be addressed. Address:School of Business Administration, Shenyang Pharmaceutical University, Shenyang 110016, China.; Tel: +86-13998302138, E-mail: Lingyi50@163.com.

Received: 2026-02-02 Accepted: 2026-03-20

revolves around creating an evaluation evidence system that incorporates "TCM theory, human experience, and clinical trials", hereafter referred to as the "three-pronged approach." This system aims to honor the fundamental principles of TCM research and development and transform the extensive human experience gained from long-term clinical practice into scientifically validated registration evidence. It creates a pioneering approach uniquely suited to the specific nature of TCM drug development [4].

However, unlike chemical drugs, which have well-defined chemical compositions and relatively clear targets of action, TCM features a unique theoretical framework, a complex material basis, and a long history of clinical practice. These characteristics introduce special scientific and regulatory challenges during the registration review process [5]. Addressing these challenges depends on a coordinated, scientifically robust, and dynamically optimized policy framework. Presently, academic research on the regulatory management of TCM primarily centers on interpreting individual policies, addressing specific technical issues, or analyzing registration data statistically. There is a notable lack of research using systematic quantitative models to comprehensively assess the quality, internal structural consistency, and historical development patterns of the policy framework. The Policy Modeling Consistency (PMC) index model is an effective quantitative tool for evaluating policy texts. It uses a multidimensional indicator system to objectively score a policy's internal consistency and completeness and employs three-dimensional surface plots to visually depict its strengths and weaknesses. Consequently, this study bases its analysis on China's TCM registration management policies issued from 2008 to 2025. Using the ROSTCM 6.0 text mining software, it constructs a PMC index model and develops a quantitative evaluation system for China's TCM registration management policies. This system analyzes and assesses these policies, aiming to provide a scientific basis for the development and refinement of future TCM registration management policies in China.

1 Materials and methods

1.1 Policy sources

The policy texts for this study were sourced from documents related to TCM registration management that were publicly released by national-level drug regulatory authorities from 2008 to 2025. A systematic search was conducted using the keywords "TCM registration", "TCM re-registration", and "TCM review and approval" on the official websites of Peking University Law Database, the National Medical Products Administration (NMPA), the Center for Drug Evaluation (CDE) under the NMPA, and the National Administration of TCM. This initial search yielded relevant documents. Inclusion criteria included officially published public documents issued by central state agencies (e.g., the NMPA) featuring core policy content directly addressing management regulations, classification systems, application requirements, or review procedures for TCM registration. Exclusion criteria comprised regional policy documents; drafts for public comment, policy interpretations, or press releases; and duplicative content or non-comprehensive management documents. Following policy retrieval and review, 22 relevant TCM registration management policies were ultimately selected for inclusion in the study.

1.2 Construction of the PMC index

1.2.1 Development of the indicator system

To distill the core focus of the policy, we initially utilized the content mining software

ROSTCM 6.0 to conduct text mining on the policy documents. This process identified high-frequency keywords (the top 50 as shown in Table 1) and generated a social network relationship diagram (as depicted in Fig. 1), providing empirical evidence for the construction of the indicator system.

Table 1 Frequently used terms in TCM registration management policies (partial list)

No.	Key term	Frequency	No.	Key term	Frequency
1	Drug	892	26	Institution	114
2	Clinical	589	27	Prescription	114
3	Trial	523	28	Implementation	106
4	Research	417	29	Regulations	106
5	Application	346	30	Permit	104
6	Shall	333	31	Modification	96
7	Register	325	32	Approval	95
8	TCM	296	33	Technology	95
9	Marketing	271	34	Compliance	93
10	Medicine	263	35	Ancient	92
11	Review	250	36	Based on	90
12	Preparation	245	37	Certificate	89
13	Quality	205	38	Herbal Medicine	88
14	Applicant	204	39	Inspection	87
15	Management	165	40	Sample	86
16	Process	157	41	Document	82
17	National	148	42	Compound	81
18	Standard	144	43	Procedure	80
19	Supervision	137	44	Authorization	76
20	Safety	135	45	Indications	76
21	Reporting	134	46	Administration	75
22	Center	121	47	New Drug	74
23	In accordance with	120	48	Verification	74
24	Instructions	119	49	Report	74
25	Classical	118	50	Function	73

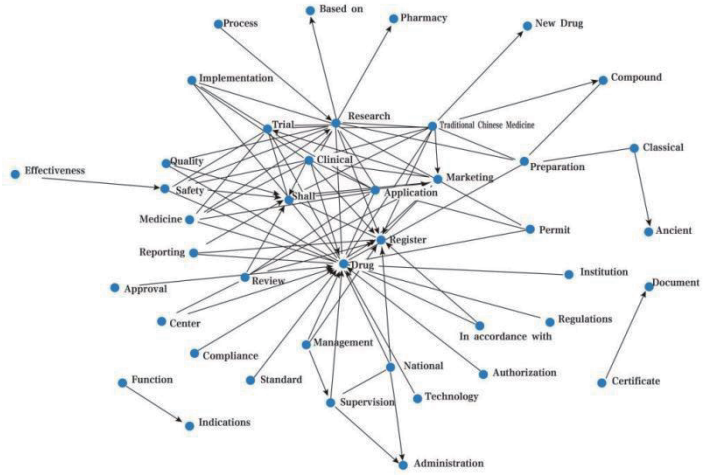


Fig. 1 Social network diagram of Chinese medicine registration management policy documents

To ensure the scientific rigor and rationality of the policy evaluation indicator system, this study was guided by Ruiz's "Omnia Mobilis" hypothesis [6]. Drawing on national-level policies governing TCM registration management and referencing variable design methodologies and frameworks proposed by relevant scholars [7-9], this study integrated the analysis results from ROSTCM 6.0 with the PMC model's universal framework. Consequently, an evaluation system consisting of 9 primary indicators and 31 secondary indicators was established, which aligns with the industry characteristics of TCM registration management policies, as detailed in Table 2.

Table 2 Evaluation framework for TCM registration management policy documents

Primary variable	Secondary variable	Secondary variable evaluation criteria
X1 Policy nature	X1-1 Forecast	Forward-looking statements on the development trends of TCM registration
	X1-2 Recommendations	Contains non-binding, advisory provisions or recommendations
	X1-3 Description	Objectively describe and define relevant concepts, definitions, scope, or current status
	X1-4 Mandatory	Mandatory provisions containing terms such as "must", and "shall not"
X2 Policy validity period	X2-1 Short-term (≤1 year)	Specify that its validity period shall be one year or less, or that it applies to temporary or pilot projects
	X2-2 Medium-term (1-5 years)	Specify that its validity period ranges from 1 to 5 years, or mark it as "trial implementation"
	X2-3 Long-Term (>5 years)	Specify that its validity period exceeds five years, or that no expiration date is specified

(to be continued)

Continued Table 2

Primary variable	Secondary variable	Secondary variable evaluation criteria
X3 Policy function	X3-1 Heritage Preservation	Explicitly propose supporting the registration of TCM knowledge, including classical formulas from ancient texts
	X3-2 Encouraging Innovation	Explicitly encourage the research, development, and market launch of new TCM products
	X3-3 Regulatory Standardization	Aiming to systematically standardize the entire process of TCM development, registration, and production
	X3-4 Streamlined Approval	Establish simplified or expedited review and approval procedures for specific circumstances
X4 Policy content	X4-1 Registration Classification	Clearly list the specific classifications for TCM registration
	X4-2 Application Documentation	Specify technical requirements for the pharmaceutical, clinical, and other research data required for the application
	X4-3 Review and Approval Process	Specify the specific steps and time limits for accepting registration applications, conducting technical reviews, performing on-site inspections, and granting administrative approvals
	X4-4 Lifecycle Regulation	Clearly stipulate requirements for post-marketing changes, adverse reaction monitoring, and reevaluation
X5 Policy evaluation	X5-1 Evaluation Criteria	Define specific evaluation indicators and methods for the efficacy and safety of TCM
	X5-2 Dynamic Adjustment Mechanism	Establish mechanisms for updating drug labels and modifying registration certificates based on new evidence
	X5-3 Re-evaluation	Require periodic reevaluation of the efficacy or safety of marketed TCM
X6 Policy level	X6-1 Law/Administrative Regulation	Issued by the National People's Congress or State Council, constituting a law or administrative regulation
	X6-2 Ministry Regulation/ Normative Document	Issued by ministries such as the NMPA, constituting a national departmental regulation or normative document
	X6-3 Technical Guidance Principles	Issued by technical bodies such as the CDE, constituting specific technical guidelines
X7 Policy subject	X7-1 Marketing Authorization Holder	Directly regulate the obligations of marketing authorization holders and research and development institutions
	X7-2 R&D Institutions	The policy content primarily impacts and applies to TCM research and development institutions
	X7-3 Medical Institutions	The role of medical institutions in collecting clinical experience with TCM for human use, developing formulations, or conducting clinical trials
	X7-4 Regulatory and Technical Institutions	Guide and regulate the work of drug regulatory, review, and testing agencies

(to be continued)

Continued Table 2

Primary variable	Secondary variable	Secondary variable evaluation criteria
X8 Policy tools	X8-1 Regulatory Constraints	Employing mandatory administrative measures such as approvals, permits, inspections, and penalties
	X8-2 Incentive-Based	Employing incentive measures such as priority review, conditional approval, and data protection
	X8-3 Information & Service-Oriented	Employ guidance and service measures such as issuing guidelines and disclosing information
X9 Policy operability	X9-1 Clear Procedures & Timelines	Clear specifications for the steps and specific timeframes of key processes
	X9-2 Specific Technical Requirements	Provide clear and actionable descriptions of the technical requirements for the research
	X9-3 Clear Responsibility Assignment	Clearly define the boundaries of responsibilities and authorities among all parties, including applicants, holders, and regulators

1.2.2 Constructing a multi-input-output table

A multi-input-output table is a multidimensional quantitative data analysis framework designed for predefined variables [10]. Based on the configuration of each indicator variable in the aforementioned TCM registration management policies, a multiple input-output table was constructed, as shown in Table 3.

Table 3 Input-output table for TCM registration management policies

Primary variable	Secondary variable
X1	X1-1, X1-2, X1-3, X1-4
X2	X2-1, X2-2, X2-3
X3	X3-1, X3-2, X3-3, X3-4
X4	X4-1, X4-2, X4-3, X4-4
X5	X5-1, X5-2, X5-3
X6	X6-1, X6-2, X6-3
X7	X7-1, X7-2, X7-3, X7-4
X8	X8-1, X8-2, X8-3
X9	X9-1, X9-2, X9-3

1.2.3 Calculation of the PMC index

After constructing multiple input-output tables, that is, obtaining the assignment data for all secondary variables within the policy texts, the calculation phase of the PMC index begins. This step is aimed at transforming fragmented indicator evaluations into a comprehensive quantitative score that measures the internal consistency and completeness of each policy holistically. The

computational process adheres strictly to the general methodology for the PMC index model proposed by Estrada and is conducted in two distinct stages.

First, the primary variable score for each policy across nine dimensions is calculated. This score represents the policy's performance level on a specific dimension, as calculated with the following equation:

$$X_i = \frac{\sum_{j=1}^{n} X_{ij}}{n} (i=1,2,...,9) \quad (1)$$

where denotes the assignment value (0 or 1) of the th secondary variable under the -th primary variable, where *n* represents the total number of secondary variables contained within that primary variable. This equation calculates the arithmetic mean to standardize the binary evaluation results of secondary variables into continuous primary variable scores (0 to 1).

Next, the overall Policy Management Index (PMC) for the policy is calculated. This index is a composite measure of the policy's performance across its nine dimensions, reflecting its overall quality. The calculation formula is as follows:

$$\text{PMC} = \sum_{i=1}^{9} X_i \quad (2)$$

As the theoretical maximum value of each primary variable score is 1, the PMC index theoretically ranges from 0 to 9. Ultimately, the PMC index is categorized into four levels based on the classification proposed by Ruiz Estrada [11]. These categories are as follows: Unqualified: between 0 and 5.39; Qualified: between 5.4 and 6.29; Good: between 6.3 and 7.19; Excellent: between 7.2 and 9.

The higher the score, the more balanced and comprehensive the policy performance across all evaluated dimensions, and the greater its internal consistency. Specific grade classifications are presented in Table 4.

Table 4 PMC index grading classification

PMC index range	Level
[7.2, 9]	Excellent
[6.3, 7.19]	Good
[5.4, 6.29]	Qualified
[0, 5.39]	Fail

1.2.4 Construction of PMC surface diagrams

To more clearly and intuitively present the strengths and weaknesses of TCM registration management policies across various dimensions, a three-dimensional surface plot should be generated based on the results of the PMC index calculation. A 3×3 matrix can be constructed using the nine primary variables identified in this study, as shown in:

$$\text{PMC Matrix} = \begin{bmatrix} X1 & X2 & X3 \\ X4 & X5 & X6 \\ X7 & X8 & X9 \end{bmatrix} \quad (3)$$

2 Results

2.1 Selection of policy evaluation subjects

To ensure the authority, systematic nature, and timeliness of the evaluation, this study selected eight core policy documents issued by the NMPA and its subordinate technical institutions between 2008 and 2025. These documents are critical for guiding the registration management of TCM and thus serve as the subjects for evaluation. The selection process was based on several criteria: Initially, the "Measures for the Administration

of Drug Registration" and its accompanying "Special Provisions on the Administration of TCM Registration" were identified as the foundational institutional framework. Subsequently, regulations tailored for the peculiarities of TCM, such as the "Supplementary Provisions on the Administration of TCM Registration" and targeted provisions for the simplified registration of "ancient classic formulas" were included. Additionally, essential technical guidance from the CDE was incorporated to cover the practical aspects of registration review. These policies encompass a range of departmental regulations, normative documents, and technical guidelines, covering the entire spectrum from overarching principles to detailed regulations, and from registration categories to processing and review steps. Collectively, they constitute a comprehensive and representative set that systematically reflects the development and current state of the TCM registration management system in China. Details of specific policies are presented in Table 5.

Table 5 Summary of eight TCM registration management policies for evaluation

Policy code	Policy title	Issuance date/year	Issuing authority
P1	Notice on Issuing Supplementary Provisions for the Registration Management of TCMs	2008	State Food and Drug Administration
P2	Announcement on Issuing Simplified Registration Approval Management Provisions for Compound Preparations of TCMs Based on Ancient Classic Formulas	2018	NMPA
P3	Measures for the Administration of Drug Registration	2020	State Administration for Market Regulation
P4	Pharmaceutical Data Requirements for Communication Meetings During New TCM Drug Research (Trial)	2020	Drug Evaluation Center, NMPA
P5	Notice of the NMPA on Issuing the Classification of TCM Registration and Requirements for Application Materials	2020	NMPA
P6	Technical Guidance Principles for Pharmaceutical Research of TCM Compound Preparations Managed According to the Catalog of Ancient Classic Formulas (Trial)	2021	Drug Evaluation Center of the NMPA
P7	Announcement on the Release of the "Special Provisions on the Registration Management of TCMs"	2023	NMPA
P8	Notice on the Release of the "Guidance on Acceptance and Review of TCM Registrations (Trial)"	2025	Drug Evaluation Center of the NMPA

2.2 Overall evaluation of the policy PMC index

Based on the PMC index model, the eight policies were quantitatively evaluated. Table 6 elucidates the PMC index, quality grade, ranking, and concavity index for each policy.

Table 6 PMC index, ranking, policy level, and concavity index for 8 TCM registration management policies

Policy	X1	X2	X3	X4	X5	X6	X7	X8	X9	PMC index	PMC level	Rank	Deficit index*
P1	0.50	0.33	1.00	1.00	0.33	0.67	0.75	0.67	1.00	6.25	Qualified	5	2.75
P2	0.50	0.33	0.75	1.00	1.00	0.67	0.50	1.00	1.00	6.75	Good	4	2.25
P3	0.50	0.67	1.00	1.00	0.67	0.67	1.00	1.00	1.00	7.50	Excellent	1	1.50
P4	0.50	0.67	0.75	1.00	1.00	0.33	1.00	1.00	0.67	6.92	Good	3	2.08
P5	0.50	0.33	0.50	0.75	0.00	0.33	0.75	0.33	1.00	4.50	Fail	8	4.50
P6	0.50	0.33	0.50	0.75	0.33	0.33	0.75	0.33	1.00	4.83	Fail	6	4.17
P7	0.50	0.67	1.00	1.00	0.67	0.33	1.00	1.00	1.00	7.17	Good	2	1.83
P8	0.50	0.67	0.25	0.75	0.00	0.33	0.75	0.33	1.00	4.58	Fail	7	4.42

Note: *Deficit index=9 - PMC index, used to visually reflect the gap between policy implementation and an "ideal" state. A higher index indicates more shortcomings.

2.2.1 Overall scores and grade distribution

The average PMC index for the eight policies was 6.19, with an overall quality rating of "Good", although there were notable variations among individual policies. Specifically, policy P3 received an "Excellent" rating, policies P2, P4, and P7 were rated "Good", policy P1 was considered "Passing", while policies P5, P6, and P8 were deemed "Failing". This resulted in a "barrel-shaped" distribution, with a concentration of middling scores and fewer policies at the extreme ends of the scale. The difference in scores between the highest-ranked policy P3 and the lowest-ranked policy P5 was 3.0 points, highlighting significant disparities in the quality of policy texts. This disparity underscores the coexistence of a strong framework alongside weaker implementation rules within the TCM registration management policy system.

2.2.2 Analysis of scores for indicators at all levels

From the analysis of first-level variables, it is evident that performance across various dimensions is inconsistent. The scores for Policy Operability (X9, 0.96), Policy Content (X4, 0.91), Policy Subject (X7, 0.81), and Policy Tools (X8, 0.83) were relatively high, indicating that these policies are clear in terms of requirements, comprehensive in content, have well-defined responsible entities, and effectively utilize a variety of tools. In contrast, Policy Level (X6, 0.46), Policy Evaluation (X5, 0.50), Policy Nature (X1, 0.50), and Policy Validity Period (X2, 0.50) exhibited lower scores, representing the primary areas of weakness. Particularly, Policy Evaluation (X5) and Policy Level (X6) received the lowest mean scores, suggesting that there is significant scope for improvement in evolving post-market evaluation mechanisms and enhancing the standing of certain documents, especially technical guidelines.

2.3 Visual analysis of policy structures based on PMC surface diagrams

To elucidate the structural characteristics and internal equilibrium of various policies across multidimensional evaluation indicators, this study has created PMC surface diagrams for each policy (Figs. 2-9). These surface plots utilize the X and Y axes to establish a coordinate plane for the nine primary variables, while the Z axis represents the score of each variable. The peaks and valleys on these surfaces intuitively indicate the policy's strengths and weaknesses, respectively, and the general flatness of the surface reflects the degree of coordination within the policy's internal structure.

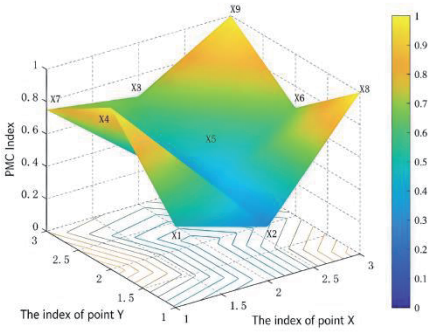


Fig. 2 PMC surface diagram for policy P1

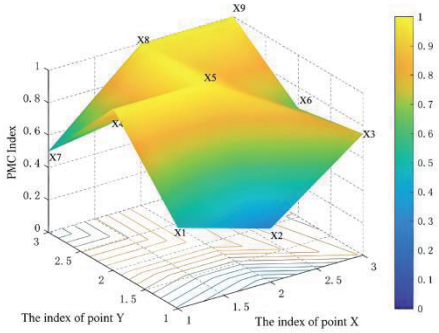


Fig. 3 PMC surface diagram for policy P2

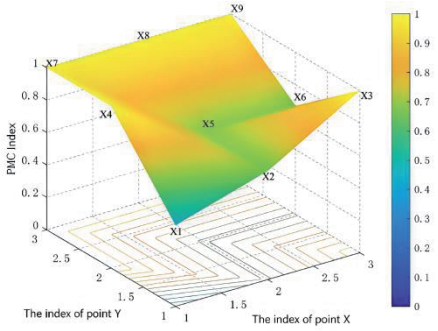


Fig. 4 PMC surface diagram for policy P3

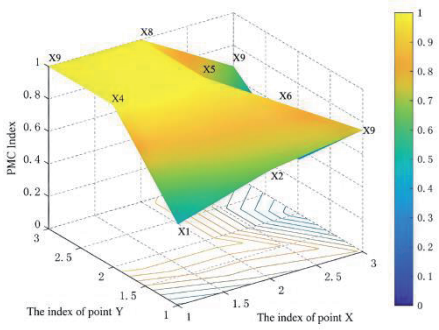


Fig. 5 PMC surface diagram for policy P4

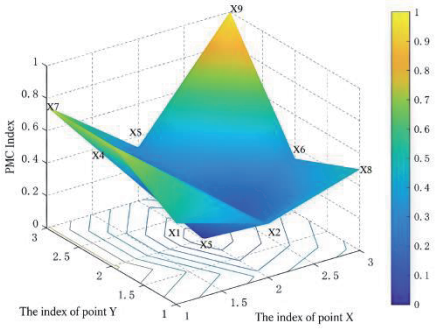


Fig. 6 PMC surface diagram for policy P5

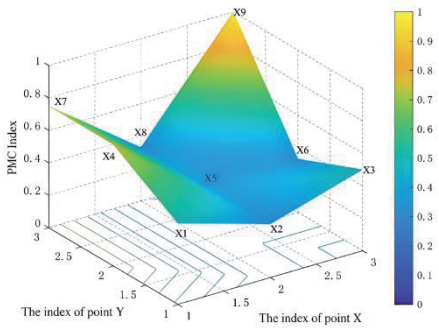


Fig. 7 PMC surface diagram for policy P6

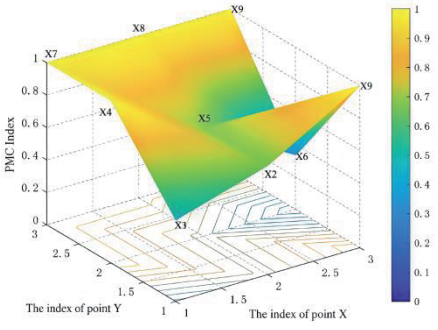


Fig. 8 PMC surface diagram for policy P7

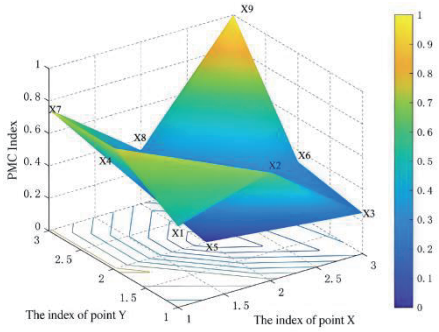


Fig. 9 PMC surface diagram for policy P8

2.3.1 Surface characteristics of high-score policies

Policies categorized as "Excellent" and "Good" (P3, P7, P4, P2, P1) feature comparably flat yet elevated PMC surfaces. Among these, P3 and P7, as the highest-scoring comprehensive regulations, demonstrate the most robust surfaces. With the exception of the invariant score in Policy Level (X6) due to its static nature, the surfaces maintain high elevations, particularly in the areas of X4, X7, X8, and X9, with only minor depressions at Policy Nature (X1) and Policy Evaluation (X5), denoting a pronounced structural advantage. As specialized policies, P2 and P4 exhibit excellence in specific functional dimensions. Nevertheless, they reveal noticeable depressions at single points, such as Policy Subject (X7) or Policy Level (X6), indicating targeted audiences and limited scope within an effectiveness hierarchy typical of specialized documents.

2.3.2 Surface characteristics of low-score policies

Policies deemed non-compliant (P5, P6, P8) display PMC surfaces characterized by significant undulations and deep structural depressions. The surface topography of these policies is notably similar, with each forming deep canyons in the regions of Policy Evaluation (X5), Policy Level (X6), and Policy Function (X3). Specifically, P5 and P8 have a score of zero on X5, resulting in a cliff-like depression. This distinctly underscores that while such policies may function as specific technical guidelines or specialized requirements with clearly defined operational procedures, they lack in overarching functional design, enduring evaluation mechanisms, and authority.

2.3.3 Comparison of typical policies

To further delineate the structural differences between policies, this section compares the PMC curves of the highest-scoring policy, P3, and the lowest-scoring policy, P5. The PMC curve of P3 resembles a solid, slightly undulating plateau, contrasted sharply by P5's curve, which resembles an isolated peak with localized collapses. The stark height disparity between these two policies is particularly evident in dimensions such as X5 and X6. This comparison powerfully illustrates that while a high-quality policy may not achieve exemplary scores across all dimensions, it displays well-coordinated functional aspects without significant structural flaws. Conversely, low-quality policies often suffer from severe deficiencies in one or more dimensions, drastically reducing their overall effectiveness.

3 Conclusions and recommendations

3.1 Conclusions

This study investigated eight core national-level policies on TCM registration management, which were issued between 2008 and 2025. A quantitative evaluation was conducted using the PMC index model. These selected samples cover a complete cycle from initial exploration to system maturity. The types of documents evaluated include departmental regulations, normative documents, and technical guidance principles. Focusing on key aspects of TCM registration, this collection forms a representative and comprehensive sample set that systematically illustrates the structure and evolution of the policy framework. Based on a model-driven systematic analysis, three primary conclusions were drawn:

(1)The policy system displays a fundamental structural characteristic where a "robust framework" coexists with "imbalanced implementation details", resulting in a "bottle-shaped" divergence in overall quality. Analysis

using the PMC index shows that the internal quality of China's TCM registration management policy system is not uniform but exhibits a marked "bottle-shaped" distribution. The highest-level institutional frameworks, exemplified by the "Measures for the Administration of Drug Registration" in 2020 (P3, 7.50 points) and the "Special Provisions on the Administration of TCM Registration" in 2023 (P7, 7.17 points), have reached an excellent level of systematicness and completeness, indicating the maturity of the macro-level structure. However, specific key implementation regulations intended to operationalize this framework, such as the "Classification and Documentation Requirements for TCM Registration" in 2020 (P5, 4.50 points) and the "Guidelines for Acceptance and Review of TCM Registration Applications" in 2025 (P8, 4.58 points), are considered substandard due to their limited policy functionality and the absence of effective evaluation mechanisms. This structural tension between a robust framework and inadequate implementation rules is the most pronounced characteristic of the current policy system, highlighting bottlenecks in the transition from macro-level design to micro-level implementation.

(2) The development of policy clearly adheres to an "evolutionary spiral-shaped ascent," with enhancements in quality demonstrating a non-linear, wave-like progression. Within the broader context of policies, such as the 2019 Opinions on Promoting the Inheritance and Innovative Development of TCM, a chronological analysis of eight pivotal policies elucidates their developmental trajectory. Phase I (2008-2017): Exploration and Foundation-Laying. Represented by the 2008 Supplementary Provisions (P1), which scored 6.25 points, this phase involved initial experiments in balancing regulatory oversight with the unique characteristics of TCM, thereby setting the foundation for later reforms. Phase II (2018-2020): Innovation and Reconstruction. The 2018 Announcement on Classic Prescriptions (P2), scoring 6.75 points, introduced a streamlined pathway for approvals, and the 2020 revised Measures for Drug Registration Administration (P3) represented a fundamental restructuring of the registration management system. This period witnessed the prolific issuance of various supporting regulations (e.g., P4, P5, P6), leading to quality variation through trial and error. Phase III (2021-2025): Integration and Deepening. The 2023 Special Provisions (P7) marked the peak of this phase, systematically incorporating previous practical experiences and lessons learned, with maturation of policy concepts. The newly released 2025 Acceptance Guidelines (P8) signifies the forefront of ongoing operational optimization. This evolutionary process underscores that policy refinement is not instantaneous but occurs as a continuous spiral of iteration through "exploration, trial and error, and integration".

(3)The lack of dynamic evaluation mechanisms and diminished incentive functions are common deficiencies that limit the effectiveness of policies. An in-depth analysis of key variables shows that although various policies perform adequately in dimensions X9 and X4, two dimensions reveal pervasive weaknesses: firstly, Policy Evaluation (X5, mean 0.50) often lacks comprehensive, closed-loop designs for re-assessing the effectiveness of marketed TCMs based on real-world evidence and implementing dynamic adjustments; secondly, the sub-item "encouraging innovation" within Policy Function (X3) is insufficiently addressed in some specific provisions, and the application of incentive tools (X8) needs to be enhanced. These deficiencies are not simply gaps in text but reflect broader challenges that current policies face in propelling the TCM industry towards standardized development and high-quality innovation.

3.2 Recommendations

3.2.1 Promote the coordinated optimization of "framework-specific rules" to eliminate bottlenecks in policy implementation

To address the structural imbalance between the top-level institutional framework and implementation rules, it is recommended to strengthen the systematic review and coordinated design of the policy system. Regulatory authorities should conduct regular systematic evaluations of current TCM registration management policies, clarifying the hierarchical relationships and coordination points between core regulations such as "Measures for the Administration of Drug Registration" and "Special Provisions on the Registration Management of TCM", along with various technical guidance documents. In formulating support rules, it is crucial to align functions with the higher-level framework to ensure that key dimensions, such as Policy Function (X3) and Policy Evaluation (X5), are fully reflected in the technical guidelines. This approach helps prevent implementation deviations caused by the disconnect between strong frameworks and weak rules. Furthermore, policy interpretations and implementation guides should be issued to enhance stakeholders' understanding and application capabilities of the policy system.

3.2.2 Improve the policy iteration mechanism to drive the spiral optimization of the system

To sustain and enhance the positive trajectory of policy development, it is recommended to establish a regular mechanism for evaluating and providing feedback on the outcomes of policy implementation. Encouraging the use of quantitative tools, such as the PMC index model, to conduct periodic assessments of the scientific rigor, coordination, and practical impact of key policies can help identify strengths and weaknesses at each stage of the policy evolution. Regulatory authorities might consider setting evaluation milestones post-policy release to proactively collect industry feedback and implementation data. This would form a closed-loop process of "formulation-implementation-evaluation-revision". Such a mechanism enables the policy system to respond promptly to technological advancements and industrial demands, thus achieving continuous optimization from exploration to integration and further refinement.

3.2.3 Refine dynamic evaluation and incentive mechanisms to address shortcomings in policy functionality

To address common weaknesses in Policy Evaluation (X5) and Encouraging Innovation (X3-2), the focus should be on two key areas: Firstly, strengthen the post-market dynamic evaluation mechanism by accelerating methodological research and pilot applications for re-evaluating the efficacy of TCM. Exploring pathways that link label revisions and registration certificate updates based on real-world evidence can fill evidence gaps in the full lifecycle regulatory loop. Secondly, refine the institutional design of innovation incentives. Within core policy frameworks, further clarification of eligibility criteria and procedures for incentive measures such as priority review and conditional approval is necessary. Collaboration with relevant departments to study substantive incentive tools, such as additional tax deductions for R&D expenses and extended data protection periods, can transform the orientation towards innovation into predictable institutional arrangements.

References

[1] Central Committee of the Communist Party of China, State Council. The Central Committee of the Communist

Party of China and the State Council Issue the "Healthy China 2030" Planning Outline. (2016-10-25) [2025-12-10]. http://www.gov.cn/xinwen/2016-10/25/content_5124174.htm.

[2] State Administration for Market Regulation. Measures for the Administration of Drug Registration (Order No. 27 of the State Administration for Market Regulation). (2020-03-30) [2025-12-10]. https://www.nmpa.gov.cn/zhuanti/ypzhcglbf/ypzhcglbfzhcwj/20200330180501220.html.

[3] National Medical Products Administration. Special Provisions on the Registration Management of Traditional Chinese Medicines. (2023-02-10) [2025-12-10]. https://www.nmpa.gov.cn/xxgk/fgwj/xzhgfxwj/20230210173401120.html.

[4] Lu Y, Lu Y, Li G, et al. Reflections and Practices on New Traditional Chinese Medicine Drug Development Under the "Three-Combination" Model. Chin J Tradit Chin Med, 2025, 50: 1994-2000.

[5] Liu C, Chen S, Xiao X, et al. Quality Markers (Q-Markers) in traditional Chinese medicine: A New Concept for Product Quality Control. Chin Herb Med, 2016, 47: 1443-57.

[6] Ruiz M, Yap F, Nagaraj S. Beyond the ceteris paribus assumption: modeling demand and supply assuming Omnia Mobilis. Int J Economic Res, 2008, 5: 185-94.

[7] Lu L, Li Z. Evaluation of China's Long-Term Care Insurance Policy Texts Based on the PMC Index Model. China Health Serv Manag, 2025, 42: 996-2004.

[8] Tang Z, Li B, Li Q, et al. Quantitative Evaluation of China's Medical Insurance Fund Supervision Policies: An Analysis Based on the PMC Index Model. China Health Serv Manag, 2025, 42: 531-7.

[9] Gao W, Wang S. Quantitative Evaluation of the "Dual Channel" Management Policy for Nationally Negotiated Drugs Based on the PMC Index Model. Chin Pharmacy, 2024, 35: 2335-9.

[10] Zhang Y, Zhou Y. Identification and Quantitative Evaluation of New Energy Vehicle Subsidy Policy Instruments. China Popul, Resour and Environ, 2017, 27: 188-97.

[11] Estrada MAR. Policy modeling: Definition, classification and evaluation. J Policy Model, 2011, 33: 523-36.