



A Quantitative Analysis of China's Pharmacovigilance Policy Based on the PMC Index Model

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Abstract

Objective To study the current situation of China's pharmacovigilance system, and to provide some suggestions for the improvement of related policies. **Methods** A policy modeling consistency (PMC) index model of pharmacovigilance policy was constructed to quantitatively assess the samples of policies combining text mining. Then, the PMC surface was established to obtain the visualization results of China's pharmacovigilance policy samples, and their shortcomings were clearly analyzed by comparison. **Results and Conclusion** Forty-one percent of China's pharmacovigilance policies were rated as excellent, 54% as acceptable, and the overall evaluation was acceptable. But there is still some room for improvement. On the whole, there are problems of insufficient policy synergy, lack of policy incentives and constraints, and incomplete coverage of policy functions. It is recommended that China's pharmacovigilance policy system should be optimized by strengthening policy coordination, increasing policy incentives and constraints, and guiding multi-subjects to participate in coordination. These findings and recommendations can provide operational ideas for the system of China's pharmacovigilance policy.

Keywords: pharmacovigilance; PMC index model; policy evaluation; adverse drug reaction

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem. It is a new system in line with the actual situation in China ^[1]. Pharmacovigilance has an important impact on ensuring the safety and efficacy of medicines throughout their life cycle. It also keeps pace with international drug regulatory policies ^[2]. Pharmacovigilance was explicitly introduced in the "People's Republic of China Drug Administration Law" in 2019 ^[3]. However, at present, China's

pharmacovigilance system is not perfect and there is still room for improvement. Therefore, this study provides a quantitative analysis of pharmacovigilance policy by constructing a policy modeling consistency (PMC) index model and combining the characteristics of pharmacovigilance, so as to provide reference for the improvement of pharmacovigilance policy and better promote the development of pharmacovigilance system.

1 Selection of samples of pharmacovigilance policies in China

As policies can vary geographically in different regions, this study chooses pharmacovigilance policy documents issued by the central government. Based

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on the official website of the drug administration and the website of Chinese government, a total of 17

samples of pharmacovigilance policies were screened out (Table 1).

Table 1 Summary of samples of pharmacovigilance policy

No.	Policy	Release date	Issue number
P1	Measures for the Administration of Drug Registration	2020-01-22	State Administration for Market Regulation Order No.27
P2	Measures for the Supervision and Administration of Drug Production	2020-01-22	State Administration for Market Regulation Order No.28
P3	Issuance of the 14th Five-Year Plan for National Drug Safety and High-Quality Development	2021-12-30	No.64 [2021] of the National Medical Products Administration and other 8 various departments
P4	Implementing Opinions on Comprehensively Strengthening Capacity Building for Drug Regulation for General Office of the State Council of the People's Republic	2021-05-10	No.16 [2021] issued by the State Council
P5	Guidelines for Pharmacovigilance Inspections	2022-04-15	No.17 [2022] of the National Medical Products Administration
P6	Good Pharmacovigilance Practice	2021-05-13	No.65 of 2021 issued by National Medical Products Administration
P7	Regulations on the Supervision and Administration of the Main Responsibility for the Implementation of Drug Quality and Safety by Marketing Authorization Holders	2022-12-29	No.126 of 2022 issued by National Medical Products Administration
P8	Regulations on the Administration of Annual Reports	2022-04-12	No.16 [2022] of the National Medical Products Administration
P9	Measures for the Administration of Drug Inspection	2021-05-28	No.31 [2021] of the National Medical Products Administration
P10	Drug Administrative Department (2020)	2020-10-09	No.107 of 2020 issued by National Medical Products Administration
P11	Opinions on Further Strengthening the Monitoring and Evaluation System and capacity Building of Adverse Drug Reactions	2020-07-30	No.20 [2020] of the National Medical Products Administration
P12	Issues Related to the Promotion of the Pilot Marketing Authorization Holder System	2017-08-21	No.68 of [2017] of China Food and Drug Administration, Pharmaceutical Chemicals Management
P13	Notice of National Medical Products Administration on the Study and Publicity of Drug Administration Law of the People's Republic of China	2019-09-25	No.45 [2019] of National Medical Products Administration, Law
P14	Guidelines for the Collection and Reporting of Individual Case Safety Report	2018-12-21	No.131 of 2018 of the National Medical Products Administration
P15	Announcement of National Medical Products Administration on the Adjustment of Drug Clinical Trial Review and Approval Procedures	2018-07-27	No.50 of 2018 of the National Medical Products Administration
P16	Issuance of the 14th Five-Year Plan for Market Supervision Modernization Plan	2021-12-14	No.30 [2021] of State Council
P17	Announcement on the China Food and Drug Administration on the Application of the Level 2 Harmonisation for better health Guidelines	2019-11-22	No.10 of 2018 of China Food and Drug Administration



Table 2 Evaluation variables of pharmacovigilance policy

Primary variable	Second level variable	Source or basis
X1 Policy nature	X1:1 Forecast	Modified from Estrada ^[6]
	X1:2 Regulation	
	X1:3 Recommendation	
	X1:4 Description	
	X1:5 Guiding	
X2 Policy timeliness	X2:1 Long term	Modified from Zhang YA, et al. ^[7]
	X2:2 Mid term	
	X2:3 Short term	
	X2:4 Current year	
X3 Incentive and constraint	X3:1 Talent incentives	Modified from Zhang YA, et al. ^[8]
	X3:2 Fiscal incentives	
	X3:3 Administrative approval incentives	
	X3:4 Laws and regulations	
X4 Life cycle	X4:1 Development period	Modified from Song DC, et al. ^[9]
	X4:2 Introduction period	
	X4:3 Growth period	
	X4:4 Maturity period	
	X4:5 Decline period	
X5 Policy evaluation	X5:1 Well founded	Modified from Zhang YA, et al. ^[8]
	X5:2 Clearly targeted	
	X5:3 Program science	
X6 Policy content	X6:1 Safety	Based on word frequency analysis
	X6:2 Adverse drug reactions	
	X6:3 Pharmaceutical marketing authorization holders	
	X6:4 Supervision	
	X6:5 Risks and benefits	
	X6:6 Other	
X7 Publishing agency	X7:1 General Office of the State Council	Modified from Zhang YA, et al. ^[7]
	X7:2 Ministry and commission	
	X7:3 Vice-ministry departments	
	X7:4 Other	
X8 Receptor	X8:1 Ministry	Modified from Zhang YA, et al. ^[7]
	X8:2 Vice-ministry departments	
	X8:3 Administration	
	X8:4 Province and municipalities	
	X8:5 County	
	X8:6 Other	
X9 Type	X9:1 Laws	Modified from Song DC, et al. ^[9]
	X9:2 Regulations	
	X9:3 Comments	
	X9:4 Notification	
	X9:5 Others	



2.2 Multiple input-output tables

Based on the above criteria, a multi-input-output table was created by assigning values to each sample

in turn (Table 3). The multi-input-output table provides a visual representation of the assignment of secondary indicators to each policy [7, 10].

Table 3 Multiple input-output table

Primary variable	Secon level variable	Primary variable	Secon level variable
X1	X1:1	X6	X6:1
	X1:2		X6:2
	X1:3		X6:3
	X1:4		X6:4
	X1:5		X6:5
X2	X2:1	X7	X6:6
	X2:2		X7:1
	X2:3		X7:2
	X2:4		X7:3
	X3:1		X7:4
X3	X3:2	X8	X8:1
	X3:3		X8:2
	X3:4		X8:3
	X4:1		X8:4
X4	X4:2	X9	X8:5
	X4:3		X8:6
	X4:4		X9:1
	X4:5		X9:2
	X5:1		X9:3
X5	X5:2		X9:4
	X5:3		X9:5

2.3 PMC index calculation

The PMC index for each variable of the pharmacovigilance policies enable the selected policies to be analyzed and compared. the PMC index is calculated as follows. Firstly, the variables are brought into a multi-input-output table (Table 4). Secondly, the secondary variables are assessed one by one against the criteria (Equation 1 and Equation 2). Thirdly, the value of each level of variable is calculated (Equation 3). Fourthly, the PMC index results are calculated (Equation 4).

$$X \sim N[0,1] \tag{Equation 1}$$

$$X = \{XR: [0 \vee 1]\} \tag{Equation 2}$$

$$X_t \left(\sum_{j=1}^n \frac{X_{tj}}{T(X_{tj})} \right) \quad t = 1, 2, 3, 4, 5, 6, 7, 8, 9, \dots \tag{Equation 3}$$

t = Primary variable, j = Secon level variable, n = Number of secondary variables under the same primary variable.

$$PMC = \left(X_1 \left(\sum_{i=1}^5 \frac{X_{1i}}{5} \right) + X_2 \left(\sum_{j=1}^4 \frac{X_{2j}}{4} \right) + X_3 \left(\sum_{k=1}^4 \frac{X_{3k}}{4} \right) + X_4 \left(\sum_{l=1}^5 \frac{X_{4l}}{5} \right) + X_5 \left(\sum_{m=1}^3 \frac{X_{5m}}{3} \right) + X_6 \left(\sum_{n=1}^6 \frac{X_{6n}}{6} \right) + X_7 \left(\sum_{o=1}^4 \frac{X_{7o}}{4} \right) + X_8 \left(\sum_{q=1}^6 \frac{X_{8q}}{6} \right) + X_9 \left(\sum_{r=1}^5 \frac{X_{9r}}{5} \right) \right) \tag{Equation 4}$$

The PMC index score of pharmacovigilance is divided into four levels. When the policy score is between 9.00 and 8.00, it indicates that the policy has perfect consistency. When the score is between 7.99 and 6.00, it indicates that the policy is excellent and has good consistency, but there is still room



for improvement. When the score is between 5.99 and 4.00, it indicates that the policy has acceptable consistency, but there is much room for improvement. When the score is between 5.99 and 4.00, the policy has acceptable consistency, but much room for optimization and further improvement is needed. If the score is 3.99 or below, it proves that the policy has low consistency and the policy is poor, and the shortcomings of the policy should be improved.

2.4 PMC surface construction

The PMC surface shows the advantages and disadvantages of any policy model in multidimensional coordinate space. It is constructed based on the results of the PMC matrix (Equation 5), which is a 3 × 3 matrix containing the individual results of all nine first level variables.

$$PMC = \begin{pmatrix} X1 & X2 & X3 \\ X4 & X5 & X6 \\ X7 & X8 & X9 \end{pmatrix} \quad (\text{Equation 5})$$

3 Analysis of the results of the PMC index model of pharmacovigilance policy

3.1 Analysis of the PMC index for samples of Chinese pharmacovigilance policies

Combined with the text mining method, the pharmacovigilance policies in Table 1 were brought into a multi-input-output table according to the running process of PMC index model. Then, it was calculated according to the formula to obtain the PMC index for each of the 17 samples of pharmacovigilance policies (Table 4). This resulted in a ranking of the samples (Table 5), yielding seven excellent policies, nine acceptable policies, and one poor policy.

Table 4 PMC index of pharmacovigilance policy PMC index

Policy number	X1	X2	X3	X4	X5	X6	X7	X8	X9	PMC index	Ranking
P1	0.80	1.00	0.75	1.00	1.00	1.00	0.25	0.67	0.20	6.67	2.00
P2	0.60	1.00	0.50	0.60	1.00	1.00	0.25	0.67	0.20	5.81	8.00
P3	1.00	0.75	0.75	1.00	0.67	0.83	0.50	1.00	0.20	6.70	1.00
P4	1.00	1.00	0.75	1.00	1.00	0.83	0.25	0.33	0.20	6.36	4.00
P5	0.80	1.00	0.25	1.00	1.00	0.83	0.25	0.17	0.20	5.50	11.0
P6	0.80	1.00	0.50	1.00	1.00	1.00	0.25	0.50	0.20	6.25	5.00
P7	0.80	1.00	0.50	1.00	1.00	1.00	0.25	0.50	0.20	6.25	5.00
P8	1.00	0.25	0.50	0.80	1.00	1.00	0.25	0.17	0.20	5.17	14.0
P9	0.80	1.00	0.25	0.80	1.00	0.83	0.25	0.17	0.20	5.30	12.0
P10	0.40	0.25	0.50	0.20	1.00	1.00	0.25	0.17	0.20	3.97	17.0
P11	1.00	0.75	0.50	1.00	0.67	1.00	0.25	0.17	0.20	5.53	10.0
P12	0.80	0.25	0.50	1.00	1.00	0.83	0.25	0.17	0.20	5.00	15.0
P13	0.60	0.25	0.50	0.8	1.00	0.83	0.25	0.33	0.20	4.77	16.0
P14	0.80	1.00	0.50	0.8	1.00	0.83	0.50	0.17	0.20	5.80	9.00
P15	0.60	1.00	0.50	1.00	1.00	0.83	0.25	0.67	0.20	6.05	7.00
P16	1.00	0.75	1.00	1.00	1.00	0.83	0.25	0.50	0.20	6.53	3.00
P17	0.60	1.00	0.00	1.00	1.00	0.83	0.25	0.33	0.20	5.22	13.0
Average value	0.79	0.78	0.51	0.88	0.96	0.90	0.28	0.39	0.20	5.69	



Table 5 Classification of PMC index evaluation levels

Score	9.00–8.00	7.99–6.00	5.99–4.00	< 3.99
Grading	Perfection	Excellent	Acceptable	Unhealthy
Policy level	–	P1, P3, P4, P6, P7, P15, P16	P2, P5, P8, P9, P11, P12, P13, P14, P17	P10

The results of the PMC index calculation for the samples of pharmacovigilance policies show that P3, “Issuance of the 14th Five-Year Plan for National Drug Safety and High-Quality Development”, has the highest score, while P10, “Drug Administrative Department (2020)”, has the lowest score. Among the 17 policies, there was no samples with a perfect rating, 40% of the samples scored an excellent rating, 53% were acceptable, and one policy had a poor rating, indicating that the existing pharmacovigilance policy system in China is not yet perfect and still needs to be optimized.

3.2 PMC surface plot analysis of pharmacovigilance policies

3.2.1 General analysis

Following the process of building the PMC index model, the analytical values of the PMC index for the 17 texts of pharmacovigilance policies were ranked

and analyzed according to the rating criteria in this study, which aimed to identify where optimizations could be made. The policy texts were ranked according to their PMC index scores, $P3 > P1 > P16 > P4 > P6, P7 > P15 > P2 > P14 > P11 > P5 > P9 > P17 > P8 > P12 > P13 > P10$.

Overall, the mean value of the PMC index for the 17 policies is 5.69, which is a good grade. Plotting the PMC surface shows (Fig. 2) that the PMC surface of pharmacovigilance policies is smoother in the region from Y1 to Y2 on the vertical axis, but having a downward trend in the Y3 region. This indicates that the internal consistency of pharmacovigilance policies is not high enough in terms of the average of the 17 policies. Besides, the policies are not developed in a balanced manner across internal aspects. However, this may be due to the fact that agency (X7) and type (X9) are indicators of a single nature, and therefore the structure of China's pharmacovigilance policy is relatively reasonable.

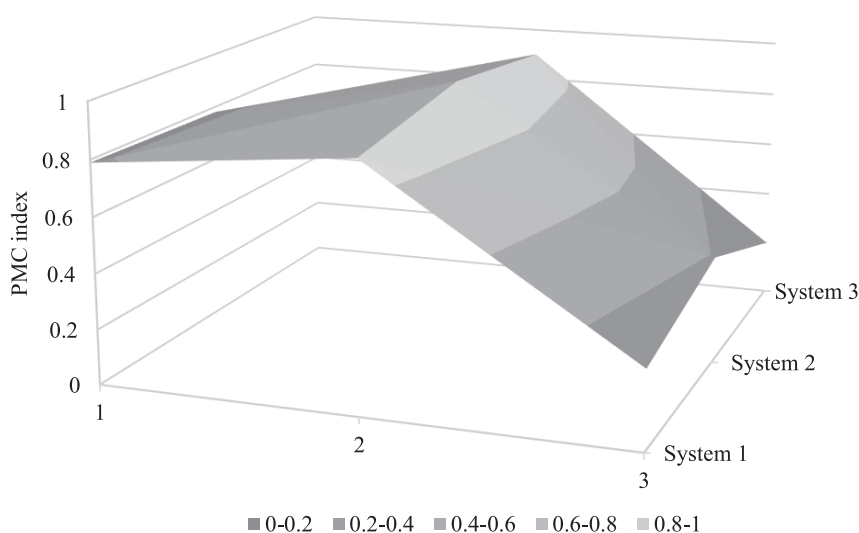


Fig. 2 Overall PMC surface of the pharmacovigilance policy

Specifically, the mean values of indicators X_4 (life cycle), X_5 (policy evaluation) and X_6 (policy content) are greater than 0.8, which is a more satisfactory result. The mean values of X_1 (policy nature) and X_2 (policy timeliness) are 0.79 and 0.78, which are also relatively good. The result of X_3 (incentive and constraint) is 0.51, which is acceptable. However, the mean values of X_7 , X_8 and X_9 are lower, which is less satisfactory. According to the mean value, the suggested order of improvement is X_9 - X_7 - X_8 - X_3 - X_2 - X_1 - X_4 - X_6 - X_5 . This indicates that China's pharmacovigilance policy is generally comprehensive and can cover the whole life cycle of drugs, which has adequate basis, clear objectives, rigorous programs and relative stability. However, there are insufficient incentive and constraint conditions, a single issuing body, and poor policy impact.

3.2.2 Detailed analysis

The PMC index of P3 (“Issuance of the 14th Five-Year Plan for National Drug Safety and High-Quality Development”) has a score of 6.7, ranking first with an excellent rating. This policy scores higher than average in five aspects. Among them, X_1 (policy nature), X_4 (life cycle) and X_8 (receptor) score high. The policy combines the nature of prediction, regulation, suggestion, description and guidance, planning the development of the whole life cycle of medicines, and makes clear the work schedule of drug regulatory authorities at all levels of. A slight deficiency is that the policy lacks scientific and specific implementation plan (Fig. 3).

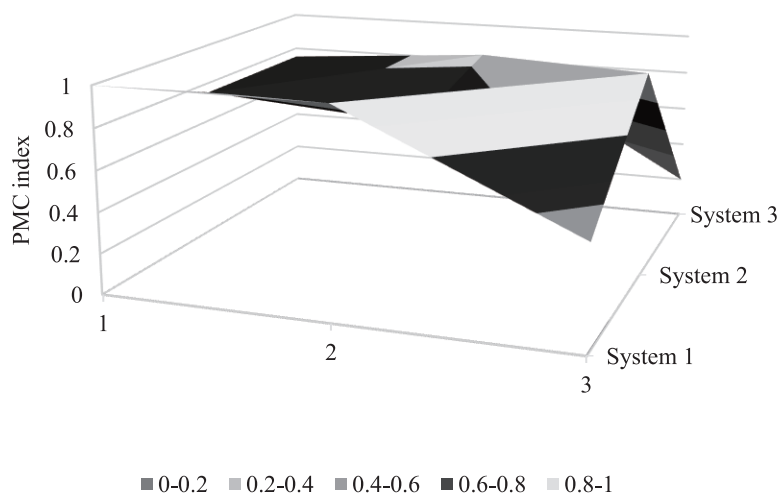


Fig. 3 P3-PMC surface diagram

The PMC index score for P1 (“Measures for the Administration of Drug Registration”) is 6.67, with an excellent rating. The policy scores higher than average for all tier 1 indicators except X_7 , with X_3 and X_8 having relative strengths. The policy motivates or constrains the operation of drug

registration management in many ways, including financial and taxation, administrative approval, laws and regulations, which also clearly implements pharmacovigilance by drug regulatory authorities at all levels of when conducting drug registration management (Fig. 4).

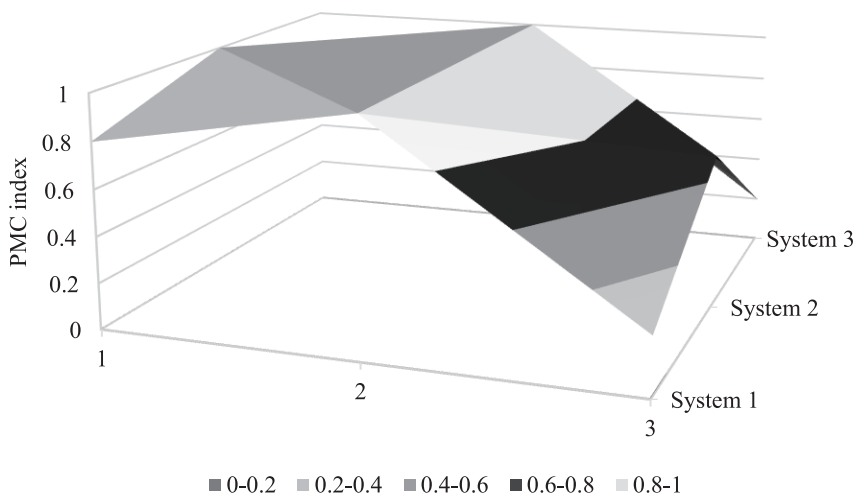


Fig. 4 P1-PMC surface diagram

P16 (“Issuance of the 14th Five-Year Plan for Market Supervision Modernization Plan”) scores 6.53, indicating that it is an excellent policy. Five of the policy’s indicators are higher than average, with *X1* and *X3* having the most significant strengths. This policy is a five-year plan, so it is multiple in nature, and it is the only policy in the sample that contributes to the modernization of

drug market regulation through incentives such as regulating market order, strengthening talent cultivation, and improving the financial and taxation system. However, this policy focuses less on pharmacovigilance. Therefore, such policies should be developed in the area of pharmacovigilance to guide the direction of drug regulation (Fig. 5).

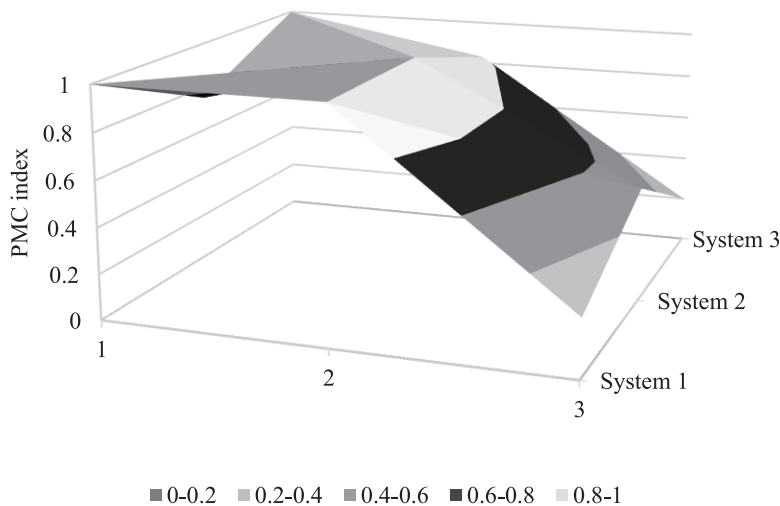


Fig. 5 P16-PMC surface plan

P4 (“Implementing Opinions on Comprehensively Strengthening Capacity Building for Drug Regulation for General Office of the State Council of the People’s Republic”) scores 6.36, indicating that it is an excellent policy. The values of

the first five indicators of this policy are all greater than the average, and all score higher, with a longer timeframe, a detailed basis for policy formulation, clear development goals, and a more scientific and rigorous program. However, its shortcoming is that



the content is not sufficient, lacking provisions related to risk benefit assessment. It is recommended to be

more comprehensive and to explore all aspects of drug regulatory capacity building in depth (Fig. 6).

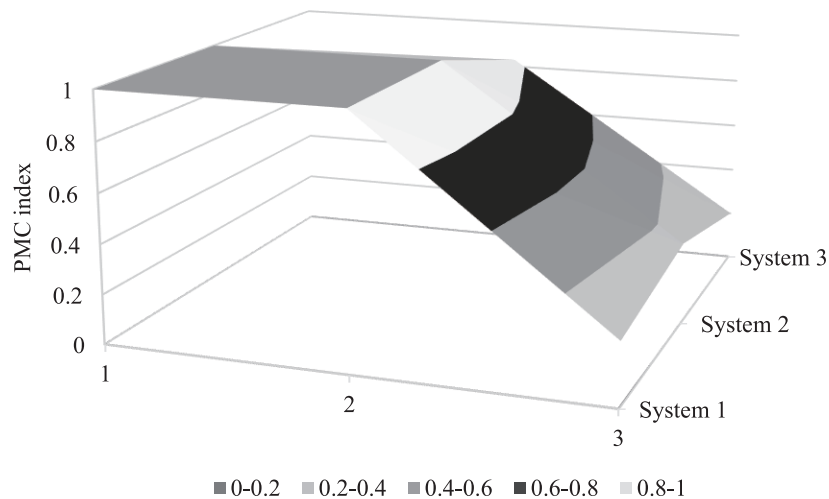


Fig. 6 P4-PMC surface plan

P6 (“Good Pharmacovigilance Practice”) and P7 (“Regulations on the Supervision and Administration of the Main Responsibility for the Implementation of Drug Quality and Safety by Marketing Authorization Holders”) are both excellent policies with a score of 6.25. X2 and X4 have clear advantages. Firstly, these policies are more comprehensive, covering all aspects related to

pharmacovigilance. Secondly, these policy have a long statute of limitations, so the program is rigorous and can be more stable. The disadvantage is that these policies have fewer incentives and constraints. If more support in terms of human resources training and financial and taxation policies are given, it would ensure smoother implementation of these polices (Fig. 7).

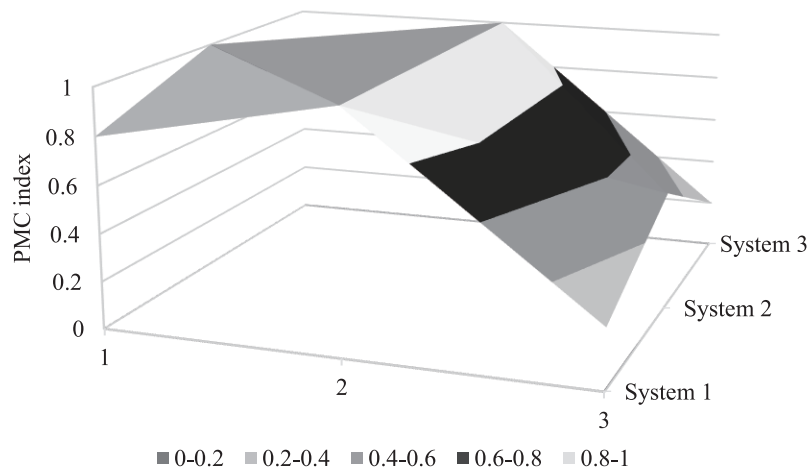


Fig. 7 PMC surfaces of P6 and P7

The PMC index of P15 (“Announcement of National Medical Products Administration on the Adjustment of Drug Clinical Trial Review and Approval Procedures”) has a score of 6.05 and is

classified as excellent. The values of four indicators of the policy X2, X4, X5 and X8 are higher than the average, with X2 and X8 having a significant advantage. This policy has long duration and therefore



it is more stable, which has a wider scope of action and clarifies where the responsibilities of drug supervision and management departments at all levels

lie. However, this policy lacks a certain guiding nature and does not play a leading role in pharmacovigilance (Fig. 8).

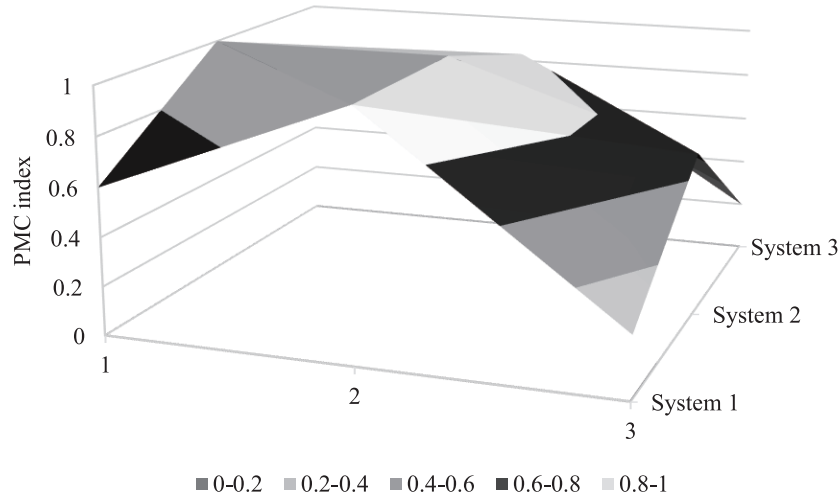


Fig. 8 P15-PMC comprehensive diagram

The PMC index of P10 (“Drug Administrative Department (2020)”) is 3.97, with a poor evaluation grade, and it is ranked at the end. Only two indicators, X5 and X6, are higher than average. This policy is sufficiently well founded, its objectives are clear, the program is rigorous and it can include enough pharmacovigilance-related topics, which means

that there are no problems with the formulation of the policy itself. The main problem is that this policy is only valid until 2020 and is therefore not predictive or guiding. Moreover, this policy is only for the production phase of medicines and does not cover the whole life cycle of medicines (Fig. 9).

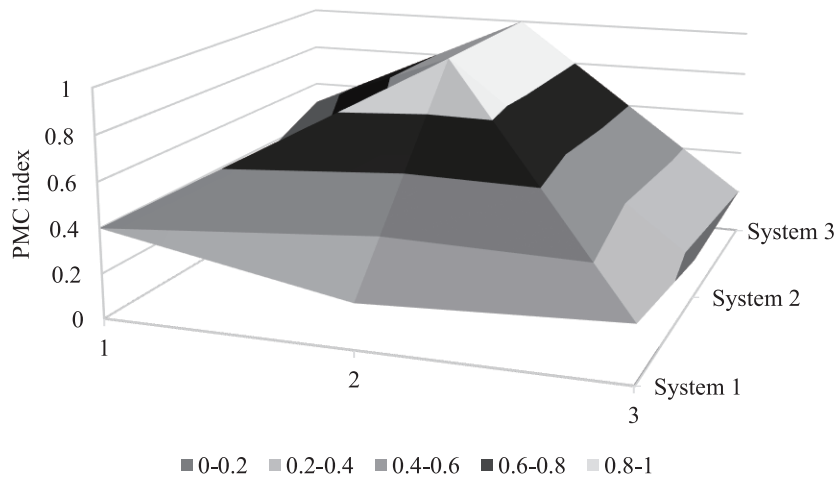


Fig. 9 P10-PMC surface plan

The rest of the policies are good, and their formulation is more or less flawed, either because the incentives and constraints are not strong, or the

programs are not rigorous enough, or the policies are not comprehensive enough and need to be further improved. In terms of policy evaluation ratings,



there are no perfect policies, 41% of the policy texts are evaluated as excellent, 54% are evaluated as acceptable and 5% are relatively poor, indicating that most of the pharmacovigilance policies promulgated in China are of acceptable quality. Therefore, there is still much room for improvement.

3.2.3 Results

From the above analysis, the following three deficiencies of China's pharmacovigilance policy are identified: insufficient policy synergy, lack of policy incentives and constraints, and incomplete coverage of the scope of policy effects.

As can be seen from the PMC index, the value of X7 (Publishing Agency) is 0.28, with a relatively single policy issuing agency, indicating that there is insufficient joint issuance between pharmacovigilance policy departments, and they lack communication and coordination mechanisms and channels. Although there is legal compulsion such as the "Drug Administration Law" and normative documents such as quality management norms, it is clear that the existing pharmacovigilance policies in China do not constitute a system and there is a lack of guidelines to guide the implementation of each process^[11].

The mean value of the PMC index for X3 (Incentive and Constraint) is 0.51, a low score, which indicates the lack of incentives or constraints in China's pharmacovigilance policy to ensure its reasonable implementation. Some binding conditions such as penalties for holders who fail to comply with pharmacovigilance requirements are increased in various ways, from the imposition of fines, confiscation of marketing authorizations and market recalls, to limit the occurrence of non-compliance by holders.

The mean value of the PMC index of X8 (receptor) is 0.39, and some of the policies are formulated in a way that involved the role of targets including ministries and commissions of the State Council, agencies directly under the State Council, and national and local drug authorities. But there are also a large proportion of policies that fail to fully

cover the role of pharmacovigilance policies, which cannot fully mobilize the enthusiasm of various subjects.

4 Discussion and recommendations

4.1 Establishing policy synergy mechanisms

From the comparison of pharmacovigilance policies in various countries and the calculation results of the PMC index, it can be seen that China's pharmacovigilance policies are issued by a single institution. There are few jointly issued policies, indicating that there are insufficient joint issuances between pharmacovigilance policy departments and a lack of communication and coordination mechanisms and channels. Moreover, the composition system of China's pharmacovigilance policy is not sound enough to form a complete system, and the synergy is insufficient.

It is suggested that China can develop more comprehensive guidelines^[12] to promote pharmacovigilance and form a complete system. For example, the government should strictly regulate the process of collecting clinical data by pre-marketing companies. Besides, the scope and strength of adverse reaction monitoring should be strengthened. Then, it should clarify the reporting process and how to tap risk signals to reduce the risk of new drugs^[13]. A life-cycle pharmacovigilance policy system that is in line with China's actual situation should be formed to achieve an effective interface between the systems. At the same time, a pharmacovigilance committee can be established to standardize the process of handling regular and emergency risks.

4.2 Increasing policy incentives and constraints

The mean score of 5.1 on the PMC Index of X3 (Incentive and Constraint) shows that this policy is not formulated with appropriate incentives, and the penalties and constraints are not strong enough in terms of content to mobilize the initiative for policy implementation.



4.2.1 Talent incentives

Pharmacovigilance is an emerging discipline with a high hiring threshold, which has reached a level of thirst for relevant talent. Currently, there is a shortage of people in the pharmacovigilance management in China, and the lack of professionalism of the existing practitioners should be solved as soon as possible^[14]. Talent cultivation can therefore be proposed as an incentive policy to mobilize the initiatives. The education sector should also be linked to improve the pharmacovigilance education system by adding pharmacovigilance-related courses in universities.

4.2.2 Financial and tax incentives

There are a few systematic studies on the costs of pharmacovigilance management in China^[15]. These studies have small sample sizes and cannot assess the economic burden of pharmacovigilance. In the US, the cost of ADR regulation is as high as \$30 billion per year^[16], so the cost of pharmacovigilance is huge and can therefore be subsidized in policy, with tax breaks to reduce the economic cost of the activities undertaken by companies, thus motivating holders to implement appropriate pharmacovigilance policies.

4.2.3 Penalty constraints

China's "Drug Administration Law" only stipulates that "if a post-marketing study or post-marketing evaluation of a drug is not conducted in accordance with the provisions, the person shall be ordered to rectify the situation within a certain period of time and shall be given a warning. If the person fails to rectify the situation after a certain period of time, a fine of not less than 100 000 yuan but not more than 500 000 yuan shall be imposed". Because the penalties are only warnings and fines, they are relatively light and have little deterrent effect on the holder. For violations that may occur in the course of pharmacovigilance, a variety of penalties such as property penalties, honorary penalties and qualification

penalties should be formulated and adopted. Besides, the corresponding policies should also increase penalties, such as suspension of sales and withdrawal of marketing authorization in serious cases, which will increase the motivation of enterprises to implement the requirements of pharmacovigilance in accordance with them and to implement the main responsibility of holders for drug safety^[17].

4.3 Guiding the collaborative participation of multiple parties

Currently, the activities of the various pharmacovigilance departments in China are carried out separately in different departments, but there is no effective coordination mechanism. Moreover, the level of medical care and regulatory capacity varies from province to province, and the inter-provincial regulatory mechanism is not perfect, which makes the implementation of the pharmacovigilance system more difficult^[18, 19]. China should improve the organizational system of pharmacovigilance, clarify the responsibilities and working procedures of each department, and establish a coordination mechanism between them to achieve effective communication for the pre- and post-marketing drug risk management.

A third-party pharmacovigilance coordinating organization can also be established in the management of companies and the implementation of pharmacovigilance^[19]. Special channels for reporting adverse drug reaction information to the public could be set up, and suggestions for adverse drug reactions could be reported regularly in hospitals, pharmacies or communities to encourage individuals to deliver adverse reactions in a timely manner^[20]. Consideration may also be given to establishing a system for compensation for damage caused by adverse drug reactions and improving the specific content of the conditions and scope of compensation, which can encourage patients to take the initiative to report adverse reactions. These ways can promote the establishment of a collaborative participation of multiple subjects of pharmacovigilance in China.



5 Summary

China's pharmacovigilance policy system is still in its early stages of construction and is not well developed, with fragmented policies and little synergy between them. In order to improve the pharmacovigilance policy system, it is particularly important to conduct evaluation studies on it. In this study, we analyze the actual situation of China's pharmacovigilance policy system using the PMC index model, based on the specific policies at the national level, and make some suggestions for the subsequent optimization of the policy.

The results show that of the 17 pharmacovigilance policies selected for the evaluation, there were no policies rated as perfect. 41% are rated as excellent, 54% are rated as acceptable, and 5% are rated as poor. Overall, the development of pharmacovigilance policies in China is acceptable, but there is a lack of strong linkages between the policies, and some of the policies suffer from a lack of long-term planning. This study therefore proposes three paths for policy optimization. Firstly, we should establish a policy synergy mechanism. Secondly, we can increase the policy mechanism and constraints, and thirdly, we should guide the collaborative participation of multiple parties. Due to the limitations of the research methodology and sample selection, this paper is still far from reflecting the utility of the entire policy system, and many of the research findings need further verification.

As an internationally accepted drug regulatory system and a basic system of China's "Drug Administration Law", pharmacovigilance should adhere to the principle of risk management, full process control and social co governance. We can draw on advanced international experience, while giving full play to the advantages of our system, to improve the pharmacovigilance system and promote scientific regulation of medicines.

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