State Pharmacopoeia as the main quality standard of medicinal herbal raw materials and medicines in the PRC

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A significant difference in the drug policy of Russia and China is the attitude towards unofficial types of natural raw materials [9–13]. In particular, in the Russian Federation, only those drugs and types of raw materials that are included in the State Pharmacopoeia [4, 5] and the current (last) GR [6] are allowed for medical use. In the PRC, not only pharmacopoeial, but many other types are still widely used in traditional medical practice and for the production of traditional drugs (8980 of them are described in Jun Hua Beng Cao - "Modern Herbalist", created over 10 years by more than 500 specialists out of 60 research and educational institutions of China) [7, 8, 15–21]. These species are constantly being studied, including in a comparative aspect, and the most “worthy” of them are gradually being introduced into the Pharmacopoeia [9].

In the period between the next editions of the Pharmacopoeia, the so-called Standards of the Ministry (and not the State Standards, which include the Pharmacopoeia), that is, “intermediate” or “preparatory” (literal translation from Chinese) documents, are developed, introduced in the prescribed manner and are in effect. In addition, each province still has Local standards for those types of raw materials for which the State or Ministerial standards have not yet been developed [9]. At the moment, this situation is a historically conditioned compulsory measure, or the so-called “policy of the transition period,” providing the large population of the PRC with domestic drugs that have been used in traditional medicine for many hundreds of years and have proven their effectiveness and safety [9, 12, 13]. All these types of raw materials and drugs from it,

In accordance with the ideas existing in the Government (State Council) of the PRC, today the all-round distribution of drugs (MPs) of traditional Chinese medicine (that is, drugs of natural origin) is largely hampered by the lack of a sufficient level of their standardization.

Therefore, in the 21st century, the PRC pays special attention to the problem of standardization and state control of the quality of drugs and medicinal raw materials of natural origin. In this regard, in the early 2000s, China practically debugged the registration system for drugs of natural origin and dietary supplements [9]. At the same time, the system for registering raw natural raw materials is still in its infancy. To this end, the PRC has developed and is implementing a systematic approach to streamlining the use of raw materials for the production of drugs of natural origin. The most important aspect of this activity is the development of standardization methods and criteria for assessing the quality of raw materials and preparations. Inclusion of raw materials used in traditional medicine, in the number of official ones is carried out only after their comprehensive study in the historical and pharmacognostic aspects [9]. The most important tool in this process is the State Pharmacopoeia of the PRC (GF PRC) [1-3].

This study is devoted to a comparative analysis of the content and level of standardization of natural raw materials in various publications of the State Fund of the PRC (from 1953 to 2005). The study was carried out on the basis of the Institute of Chinese Materia Medica of the Chinese Academy of Traditional Medicine (Beijing, China), the Institute of Homeopathy and Naturotherapy of the Federal

scientific clinical and experimental center for traditional methods of diagnosis and treatment of Roszdrav (Moscow, Russia) and the Federal Service for Surveillance in Healthcare and Social Development (Moscow, Russia).

Organizational structure of the state system for the creation and approval of the Global Fund

PRC

The Pharmacopoeial Committee (FC) in China reports directly to the State Administration (GU) for the Control of Food and Drugs of the People's Republic of China. The functions of the FC include the development of projects of the GF of the PRC and State Standards for drugs and initial medicinal raw materials, as well as their submission for approval in accordance with the established procedure to the State Institution for Control of Food and Drugs.

There is a permanent executive body under the FC, which includes 24 specialized (profile) expert commissions of the FC, in which 312 specialists are constantly working.

The procedure for the development and publication of the State Fund of the People's Republic of China

Currently, the PRC State Fund is republished strictly once every 5 years, with a slight delay (about 1 year) being translated into English (there are no Russian versions).

The publication of the State Fund of the People's Republic of China began in 1953 with the participation of Russian specialists. The 1st 1-volume edition of the GF included all the drugs of traditional Chinese medicine and so-called "Western" medicine known at that time, but since 1963 (2nd edition) the GF of the PRC has already included 2 volumes. The first of them usually contains drugs of traditional Chinese medicine (drugs of natural origin), and the second - drugs of modern (so-called, "Western" medicine). This division was not accidental, since the level of drug standardization in volumes 1 and 2 was significantly different.

In total, the PRC State Fund has undergone 8 editions in its history: 1953 (1), 1963 (II), 1977 (III), 1985 (IV), 1990 (V), 1995 (VI), 2000 (VII), 2005 (VIII) ... To date, 7 of them have been translated into English. The translation began in 1963 and continues to this day with a slight lag behind the original Chinese edition. Below we present the dynamics of standardization of drugs and raw materials in the State Fund of the People's Republic of China in 8 editions.

The dynamics of standardization of drugs of natural origin (traditional Chinese medicine) and raw materials

The 1st edition (1953) contained 531 names of objects, of which: 289 drugs of traditional Chinese medicine, 215 drugs of "western" medicine, 2 antibiotics and 25 biological drugs. The structure of the drugs of traditional Chinese medicine included fatty oils (65 types), medicines of animal origin (13 items) and 211 complex formulations for the manufacture of drugs of traditional Chinese medicine in pharmacies. Herbal medicines and MPs were absent.

The 2nd edition (1963) contained 1310 object names. The 1st volume included 645 objects related to traditional Chinese medicine, of which 197 were prescriptions for complex drugs, and 446 were natural raw materials, including plant origin. Volume 2 contained 667 drugs of "Western" medicine.

The 3rd edition (1977) differed significantly from the previous ones, since for the first time it contained plant extracts, as well as national (Mongolian, Tibetan and some regional Chinese) types of natural raw materials (882 items) and prescriptions for ready-made complex drugs (270 items, taking into account national prescriptions). The 2nd volume of this edition contained 773 drugs of "western" medicine. Thus, a total of 1925 items were included in both volumes.

4th edition (1985), in turn, differed from 3rd edition in fewer objects

- both volumes contained 1489 titles in total. In China, this is explained by the fact that the 3rd edition, which was being prepared during the years of the Cultural Revolution, contained a significant amount of drugs of traditional Chinese medicine and natural raw materials with unproven efficacy and safety. Therefore, during the preparation of the 4th edition, such objects were excluded from it and sent for further study in order to "obtain scientifically confirmed information." Thus, the 1st volume included 713 objects of traditional Chinese medicine (506 types of raw materials and 207 prescriptions of complex drugs), and the 2nd - 776 names of drugs of "Western medicine".

Since the 5th edition (1990), the PRC SP has been republished regularly every 5 years. This edition contained a total of 1,751 items, of which 976 were "Western" drugs (2nd volume), and 784 belonged to traditional Chinese medicine (1st volume) - 509 types of raw materials and 275 complex formulations of finished drugs.

The 6th edition of the State Fund of the People's Republic of China (1995) already contained 2375 objects. Of these, 920 belonged to traditional Chinese medicine (522 types of raw materials and 398 drugs), but the number of so-called "modern" or "Western" drugs increased dramatically (1455). Among the latter, in addition to synthetic drugs, antibiotics and biological drugs (serum, vaccines), auxiliary materials, radioactive drugs and so-called "biochemical" drugs (isolated from animal organs and purified, for example, insulin), were for the first time included.

For inclusion in the 7th edition (2000) in the FC of the People's Republic of China, 562 articles out of 2375 that were present in previous editions were revised (in accordance with international requirements for normative documentation). In addition, 399 new articles were included in both volumes, and obsolete ones were excluded. In total, the 1st volume included 992 articles on drugs and raw materials of traditional Chinese medicine, and the 2nd - 1699 modern drugs.

The last, 8th edition of the State Pharmaceutical Organization of the People's Republic of China (2005) consists of 3 volumes and includes a total of 3214 names of drugs and raw materials. The 1st volume contains 1146 types of raw materials and drugs of traditional Chinese medicine, 154 articles are completely new, 453 are revised, and the rest are identical to the previous edition. The 2nd volume of the State Fund of the PRC contains 1967 names of modern drugs, of which 327 are new, and 522 are revised. 3rd volume, where all biological and so-called. “Biochemical” drugs include 101 items, of which 44 articles are new, and 57 are revised.

We summarized the quantitative data obtained as a result of this study in Table 1.

Table 1

Dynamics of quantitative indicators of drugs and raw materials in eight editions of the State Fund PRC

Издание ГФ КНР		Общее кол-во ЛС и исходного сырья в данном издании, шт	Кол-во ЛС и исходного сырья традиционной медицины	
№	год		шт	% от общего кол-ва ЛС и сырья
1	2	3	4	5
I	1953	531	289	54,42
II	1963	1310	645	49,24
III	1977	1925	1152	59,84
IV	1985	1489	713	47,88
V	1990	1751	784	44,77
VI	1995	2375	920	38,74
VII	2000	2691	992	36,86
VIII	2005	3214	1146	35,66

From the data in Table 1, it can be seen that the number of pharmacopoeial monographs (PCs) on drugs of natural origin and raw materials in absolute terms increased from 289 (1953) to 1146 (2005), but their relative number compared to the number of PCs per ton .n. "Modern" or "western" drugs are steadily decreasing.

Chinese experts explain this for several reasons, including the desire of Chinese manufacturers to produce expensive synthetic drugs and substances, the quality of which meets international standards and which are in demand abroad. Traditional Chinese medicine drugs, even with a modern level of standardization, are sold mainly in the domestic market and bring incomparably lower profits.

At the same time, medicinal raw materials of natural origin, as well as modern extraction preparations based on it, are in good demand both in the domestic and foreign markets. Despite this, the relative amount of raw materials in the structure of official drugs is also decreasing, since rare protected species of plants and animals are gradually disappearing from the prescriptions of traditional medicine, and attempts to scientifically substantiate the effectiveness of some traditionally used species do not always lead to positive results. In addition, in recent years in the PRC, budgetary funding is mainly allocated for the development of modern standardized drugs of natural origin and dietary supplements "with proven efficacy", created on the basis of the experience of traditional Chinese medicine, which are competitive in the world market of over-the-counter drugs.

The continuing purposeful study of local natural sources of raw materials in the PRC made it possible to substantiate in the State Council the need to intensify work on the cultivation of many types of raw materials and the production of plant mass based on the cell culture of medicinal plant raw materials (MP). In connection with the increase in the range and volume of preparations for cultivated medicinal plant raw materials and raw materials obtained using cell technologies, the Chinese FC is discussing the need to introduce a mandatory indication of the origin of this or that raw material in the PRC GF. In the latest edition of the GF of the PRC, there is not a single PS on medicinal plant raw materials or medicinal products obtained from raw materials grown using cellular technologies. Nevertheless, not only in the domestic market, but also abroad, Chinese-made drugs and dietary supplements from Cordiceps cinensis raw materials grown using cell technologies are very actively sold. Explain

This is due to the fact that in the PRC today there is no legal basis for the mandatory registration of medicinal raw materials. To date, such an indication is required only on the label of a specific drug or medicinal product.

Thus, the GF of the PRC is currently the main document regulating the quality of medicines and raw materials, including those of natural origin, and serves as the basis for the introduction of a standardization system for raw materials and products of natural origin in the PRC. At the same time, the PRC GF is constantly improving.

Improvement of criteria and norms for assessing the quality of medicinal vegetable raw materials in the State Fund of the People's Republic of China

The process of increasing the level and quality of standardization of medicinal products of natural origin and raw materials began to develop especially actively over the past 30 years. For example, such an important section of standardization as microscopic examination of raw materials began to be included in the State Pharmacopoeia of the People's Republic of China only since 1977 [10, 11], but in the 1995 Pharmacopoeia there are already 239 complex preparations, which are powders from plant, animal and mineral raw materials (a also their mixtures), had a microscopic description.

In 1986, the Atlas of drawings of the anatomical structure of raw materials and preparations from it was released, and in 1999 the Institute for Medicinal Medicine Standardization under the State Council of the People's Republic of China published an Atlas of photographs of the microscopic structure of raw materials powders and 10 preparations [15]. This Atlas is currently the official supplement to the PRC Pharmacopoeia. A similar Atlas of photographs for identifying raw materials by external signs was released in 1998. It already includes 1138 species of producing plants and animals [18].

The need to publish this publication was due, among other things, to one of the most important pharmacognostic problems in the PRC - the absence of clear legal restrictions for many types of raw materials in terms of harvested producing plants. In particular, as a result of the last census of producing species for obtaining medicinal raw materials of natural origin (which lasted 10 years), 12807 of their names were described (11146 species of plant, 1581 of animal and 80 of mineral origin). At the same time, it was found that often the procurement of the allegedly the same type of raw material in different provinces of the PRC is carried out from different representatives of the same botanical genus [10, 11].

For example, from more than 20 species of the genus Rheum described in the PRC [17-21], included in the pharmacopoeia and allowed to procurement only 3 of them, belonging from a taxonomic point of view to the group Palmatum: Rh. palmatum, Rh. tanguticum, Rh. officinale[2, 18, 19, 21]. Nevertheless, in a number of provinces continue to record cases of receipt of raw materials procured from other representatives of this genus at the points of acceptance. Such raw materials are now usually rejected at the stage of receipt from collectors on the basis of the results of luminescence microscopy, since comparative scientific studies have shown that the transverse sections of the roots of three officinal species have a reddish-brown luminescence, and all others - blue [2].

Numerous cases were recorded when raw materials procured from completely different types of producing plants, even belonging to different families, came under one Latin name, since in various ancient herbalists in China the same type of raw material (or medicine) was procured from different types of plants. having, respectively, different Chinese names in different provinces of the country [17, 20, 21].

For example, under the guise of a pharmacopoeial plant Potentilla genesis in several provinces of Chinaabout 20 species of various plants with different Latin names, chemical composition and types of action were procured. According to Professor Xie Zong-wan, this problem is relevant for about 300 types of plant materials out of 500 that are considered the most commonly used in China today.

That is why such great attention in the PRC is paid to the issues of standardization of raw materials and the development of criteria for assessing their quality as necessary conditions for the inclusion of producing plants, animals and minerals (as well as raw materials from them) in the official list.

The 2000 edition of the Chinese Public Fund [2] included 784 FS for raw materials of plant, animal and mineral origin and 509 FS for preparations of natural origin. Each of them has a mandatory "standard for the name" (literal translation from Chinese), i.e. reliable name in Latin and Chinese (hieroglyphs and English transcription) languages. All of them are also considered “fully established” (literal translation from Chinese), and their effectiveness is fully proven, since one of the main tasks of the Pharmacopoeia Committee of the PRC is to create a modern pharmacopoeia that meets world requirements in the field of standardization and includes only reliably effective types of raw materials and preparations.

As a result of this policy of the Pharmacopoeia Committee, for example, from the Pharmacopoeia of the PRC was excluded Licosporum, taken with 2nd century BC (from the time of the Khan dynasty), and instead appearedAlepia, recognized as more effective in action (according to the resultsphytochemical, pharmacological and clinical studies). Such examples are becoming more and more in connection with the implementation of environmental protection measures in relation to medicinal plants, for which more effective analogues in action have been found [10, 11].

Taking into account the importance of the relationship between the two countries, in the Russian Federation, studies were carried out on a comparative study of the PRC GF of different years (from 1990 to 2000), and an attempt was made to track the dynamics of the process of streamlining the use of drugs of natural origin (and raw materials) and increasing their level. standardization. Studies carried out on the basis of the Pharmaceutical Institute of the Academy of Traditional Chinese Medicine of the Main Directorate of Traditional Chinese Medicine and Pharmacology of the PRC (Beijing) and the Federal Scientific Clinical and Experimental Center for Traditional Diagnostic and Treatment Methods of the Ministry of Health of the Russian Federation (Moscow) made it possible to establish the following [26, 27].

The introduction of the developed systematic approach allowed for 10 years (from 1990 to 2000) to increase the number of official types of raw materials in the PRC by 31 names (38 pharmacopoeial monographs (FC) were added and 7 types of raw materials were excluded from the Pharmacopoeia). The number of producing species of plants, animals and minerals increased from 709 to 735 (by 26 species).

As an example, the dynamics of the number of types of medicinal plant raw materials included in the Pharmacopoeia of the People's Republic of China by morphological groups is given (Table 2).

table 2

The number of types of medicinal plant materials in the publications of the Pharmacopoeia of the People's Republic of China 1990 and 2000

№ п/п	Название морфологической группы сырья	Год издания фармакопеи КНР				Названия вновь включенных в 2000 году видов ЛРС	Названия Исключенных в 2000 году видов ЛРС
		1990 [2]		2000 [3]			
		абс.	%	абс.	%		
1.	Bulbus	6	1,6	7	1,8	Bulbus Hupehensis	-
2.	Cortex	16	4,3	16	4,1	-	-
3.	Exocarpium	3	0,8	3	0,8	-	-
4.	Flos	21	5,7	21	5,3	-	-
5.	Fructus	64	17,3	66	16,8	Fructus Schisandrae Chinensis, Fructus Schisandrae Sphenantherae*; Fructus Sinopodophylli	-

6.	Folium	15	4,0	17	4,3	Folium et Cacumen Murrayae, Folium Ginkgo, Folium Ginseng (+3)	Folium Digitalis (-1)
7.	Herba	59		60		Herba Moslae	-
8.	Lignum	4		4		-	-
9.	Radix	80		88		Radix Astragali Preparata, Radix et Caulis Acanthopanacis senticosi, Radix Ginseng Rubra, Radix Glycyrrhizae Preparata, Radix Hedysari Preparata, Radix Liriopes, Radix Quinquefolii, Radix Rehmaniae, Radix Zanthoxyli	Radix Acanthopanacis Senticosi
10.	Ramulus	4		4		-	-
11.	Rhizoma (Rhizoma et Radix)	50		57		Rhizoma Acori ca-lami, Rhizoma Dry-opteris Crassirhizomae, Rhizoma et Radix Baphicacanthis Cusiae, Rhizoma et Radix Notopterygii, Rhizoma Fago-pyri Dibotruis, Rhizoma Pinelliae Preparatum, Rhizoma Zingiberis Preparatum	Rhizoma Acori Tatarinowii
12.	Semen	49		51		Semen Arecae Preparatae, Semen Euryales	
	Итого:	371	100	394	100	+ 23	

* These columns indicate the percentage of the sum of all types of medicinal plant materials analyzed in this table, included in the Pharmacopoeia of the PRC in 1990 and 2000. editions respectively.

* * In the 1990 edition [1], only one type of medicinal plant raw material is designated - Fructus Schisandrae, instead of which in 2000 [2] 2 types of raw materials were included in the pharmacopoeia with the specification of the specific name of the producing plant.

From the data in Table 2, it can be seen that, as a percentage of the total number of types of medicinal plant raw materials, by 2000 the number of barks, flowers, fruits, herbs, twigs, seeds decreased with an increase in the number of bulbs, leaves, roots and rhizomes. In addition, attention is drawn to the significant dominance in the Chinese Pharmacopoeia (in relative terms) of such types of raw materials as fruits (17.3 and 16.8%), herbs (15.9 and 15.2%), rhizomes (13, 5 and 14.4%), seeds 13.2 and 12.9%), roots 21.6 and 22.3%, respectively, in 1990 and 2000) [10, 11].

In general, the number of all producing species (plants, animals and minerals) has increased in the PRC Pharmacopoeia over 10 years from 709 to 735 (by 26 species). But the positive dynamics is not so much the number of official species of producing plants and raw materials as the level of their standardization (Table 3).

In particular, if in the Pharmacopoeia of the People's Republic of China in 1990 [1], the quality of raw materials was assessed mainly by external signs and qualitative reactions, then the last Pharmacopoeia (2000) [2] provides for mandatory microscopic examination and highly desirable determination in raw materials quantitative content of biologically active

substances (BAS), including using modern methods of analysis: GLC, HPLC, high-voltage horizontal electrophoresis, capillary electrophoresis, modern modifications of TLC and other methods.

At the same time, the structure of the FS based on raw materials of natural origin in the Chinese Pharmacopoeia gradually became more complicated and became completely analogous to that in the USSR State Fund of the XI edition [4, 5]. In particular, FS for plant raw materials, for example, in the latest edition have the following structure:

- the name of the raw material (in Chinese and in English transcription, in Latin),
- the name of the producing plants,
- external signs of raw materials,
- microscopy,
- qualitative reactions,
- numerical indicators,
- method of quantitative determination,
- indicator of the content of the determined BAS or the amount of BAS,
- the applied dose and the nature of the drug action in accordance with the theory of traditional Chinese medicine [2].

Table 3

Dynamics of the level of standardization of medicinal raw materials of natural origin in State Pharmacopoeia of the People's Republic of China

№ п/п	Сравниваемые показатели	Год издания фармакопеи КНР		Увеличение количества ФС
		1990	2000	
1.	Количество ФС, имеющих раздел “Качественные реакции”	417	602	В 1,4 раза
2.	Количество ФС, имеющих раздел “Количественное определение”	17	308	В 18,1 раза

This study was carried out even before the official approval in the Russian Federation of "Quality Standards for Medicines: Basic Provisions" (OST 91500.05.001-00 / Date of introduction 03/01/2000 / Approved by Order of the Ministry of Health of the Russian Federation No. 82 of 02/29/2000) [14] and the latest publication of the State Fund of the People's Republic of China (2005). A more modern comparative study of the latest edition of the PRC GF and OST was carried out by us in 2007.

Comparative analysis of the requirements for quality assessment criteria medicinal plant materials in the Russian Federation and China

Requirements for the criteria for assessing the quality of medicinal plant materials in the Russian Federation are determined by OST 91500.05.001-00 “Quality standards for medicinal products. Basic Provisions "(Date of introduction 03/01/2000 / Approved by Order of the Ministry of Health of the Russian Federation No. 82 dated 02/29/2000), and in the PRC - by the State Pharmacopoeia of the PRC. A comparative analysis of the requirements is easy to carry out on the basis of tabular data based on the specified regulatory documents of the two countries (table 4). Analysis of the data in Table 4 allows us to state that today the requirements for the criteria for assessing the quality of medicinal products in China and the Russian Federation are similar. However, the Pharmacopoeia of the People's Republic of China does not regulate the content of ash, insoluble in a 10% solution of hydrochloric acid, in the section "Numerical indicators"; the presence of permissible impurities: crushed raw materials, particles of raw materials that have changed color, other parts of raw materials, not subject to procurement; organic and mineral impurities.

Nevertheless, the latest edition of the Chinese Pharmacopoeia (2005) in terms of the requirements for the criteria for assessing the quality of medicinal plant raw materials is as close as possible to

similar requirements for medicinal plant raw materials in our country. This fact can serve as a good basis for cooperation between Russia and the PRC in the field of registration and circulation of medicines of natural origin and raw materials for their production. Thus, the GF of the PRC is currently the main document regulating the quality of medicines and raw materials, including those of natural origin, and serves as the basis for the introduction of a standardization system for raw materials and products of natural origin in the PRC. At the same time, the PRC State Fund is constantly improving [28].

Table 4

Criteria for assessing the quality of medicinal plant materials in the Russian Federation and China

№ п/п	Критерий оценки качества	Наличие в	
		ОСТ 91500.05.001-00	ГФ КНР
1.	Название ЛРС на национальном и латинском языках	+	+
2.	Область применения ЛРС	+	+
3.	Название производящих растений и семейства на национальном и латинском языках	+	+
4.	Внешние признаки сырья	+	+
5.	Микроскопия, иллюстрирована микрофотографией или рисунком	+	+
6.	Качественные и/или гистохимические реакции	+	+
7.	Числовые показатели: - количественное содержание БАВ - потеря в массе при высушивании - зола общая - зола нерастворимая в 10% растворе кислоты хлористоводородной - допустимые примеси: измельченного (ситовой анализ), частицы сырья, изменившие окраску, другие части сырья, не подлежащие заготовке; органическая примесь, минеральная примесь	 + + + + +	 + + + - -
8.	Микробиологическая чистота	+	+
9.	Упаковка цельного и измельченного сырья	+	+
10.	Маркировка цельного и измельченного сырья	+	+
11.	Срок хранения	+	+
12.	Срок годности	+	+
13.	Фармакологическая группа	+	+

Conclusion

Thus, a balanced, purposeful policy of the State Council of the People's Republic of China in the sphere of circulation (and, in particular, standardization) of traditional drugs and raw materials has led to tangible positive results in providing the population with effective and safe drugs of natural origin. The existing experience in increasing the level of standardization of raw materials and traditional drugs, the timely setting of the relevant tasks and scientifically substantiated solution to them in a planned manner made it possible to transfer the problem of developing drugs of natural origin in the PRC to a qualitatively new level on a national scale.

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