

Situational analysis of the segment of the domestic drug market
herbal preparations in 2013 T.G.
Afanasyeva¹, N.B. Dremova², T.L. Kiseleva³
(¹Voronezh State University, ²Kursk State Medical
university, ³Research Institute of Nutrition, Russian Academy of Medical Sciences, Research Center "NO" Professional Association
naturotherapists ", Moscow)

A situational analysis of the segment of the domestic pharmaceutical market of medicinal
plant preparations in 2013
TG Afanasieva¹, NB Dremova², TL Kiseleva³
Voronezh state university (Voronezh, Russia),
²Kursk state medical university (Kursk, Russia),
³ RAMS Institute of nutrition, Scientific-research center of the "Professional Association of
Naturotherapists "(Moscow, Russia)

SUMMARY

A situational analysis of the segment of the domestic pharmaceutical market for herbal medicines in 2013 was carried out. Its quantitative and qualitative characteristics have been established. A comparative analysis was carried out with the results of a monitoring study of the same segment for the period 2006–2010. The tendencies of a decrease in the number of registered medicinal herbal preparations by 41.8% (compared to 2010) were revealed, mainly at the expense of domestic production funds. Presumably, this is due to the increased requirements for the quality of drugs during their planned re-registration by the Ministry of Health of Russia. The indicators of the assortment were determined according to various characteristics, incl. by country of origin, composition of active ingredients, raw materials, dosage forms, medical use, registration time in Russia.

Key words: officinal herbal preparations, herbal medicines, assortment, situational analysis, monitoring, pharmaceutical market, medicinal plant raw materials, dosage forms.

RESUME

We conducted a situational analysis of the segment of the domestic pharmaceutical market of medicinal plant preparations in 2013 and revealed its quantitative and qualitative characteristics. Then we conducted a comparative analysis of these characteristics with the results of the monitoring study of the same segment for the period 2006–2010. We have identified trends in reducing the number of registered medicinal herbal preparations by 41.8% (compared to 2010), mainly in domestic production facilities. Presumably this is due to increasing demands for quality products at their re-registration by The Ministry of Health (RF). We determined the range of indicators on various grounds: on the basis of the country of manufacture, composition of active ingredients, raw material sources, dosage forms, medical application, period of registration in Russia by The Ministry of Health. The present study allowed us to supplement the results of the earlier monitoring of the segment of herbal medicines in the domestic pharmaceutical market.

Keywords: officinal herbal preparations, herbal medicines, range of herbal preparations, pharmaceutical market, medicinal raw materials, dosage forms.

Previously, we monitored the development of the segment of official herbal medicinal products (LMP) in 2006–2010. [1]. The trends identified by us in the dynamics of quantitative and qualitative indicators, which have developed in the development of the range of medicinal products registered and approved for medical use in Russia, have made it possible to confirm the high mobility of the studied market segment.

The situational analysis method allows us to characterize the economic phenomenon at a certain date, identify problems and outline opportunities for their solution [2], therefore, we considered it appropriate to conduct a situational analysis of the LRP market segment for the most relevant specific period - 2013.

The purpose of this study is to study the characteristics of the assortment of official pharmaceutical products in the domestic pharmaceutical market in 2013.

Research object: electronic version of the State Register (GR) medicines for 9 months of 2013.

Research methods: content analysis, observation, systematization, grouping, variation statistics, ranking, structural, comparative, graphical analyzes. In the design of the study, we included the quantitative and qualitative characteristics of the breadth of the assortment, incl. the number (total) of medicinal products by production (domestic and foreign), by composition (monocomponent, complex), by the types of plant preparations included in the composition, by dosage forms (DF), pharmacotherapeutic action and registration time. The situational analysis was carried out according to the data of the LRP information array obtained as a result of the content analysis of the State Register on the basis of biologically active substances from plant materials (medicinal plants) contained in the LRP.

Research results

We have summarized the assortment breadth indicators for 2013 by the number of LPPs and their trade names (TN) in Table 1.

Table 1

Indicators of the breadth of the range of herbal medicines in 2013
year

Показатели	Лекарственные растительные препараты		Торговые названия	
	Количество наименований	Доля, %	Количество наименований	Доля, %
Всего	2432	100,0	629	100,0
Отечественные	2110	86,8	415	66,0
Зарубежные	322	13,2	214	34,0
Состав				
Монокомпонентные	1717	70,6	–	–
Комплексные	715	29,4	–	–

Comparative analysis with the indicators of 2010 [1] allowed us to identify a trend towards a slight decrease in the number of registered LPPs. In particular, in comparison with 2010, the number of LPPs decreased by 1,749 positions, which is -41.8%. A detailed analysis based on the country of origin showed that such a decrease in the number of registered LPPs was due to domestically produced products:

3900 to 2100 positions (for 1800 positions, which is -53.8%). At the same time, the number of foreign-made LRPs increased from 281 to 322, i.e. by 41st position, or +14.6%.

Presumably, several reasons contributed to this significant decrease in the number of registrations of domestic LPPs. First, a significant number of LRS in the period 2011–2013. the registration period has expired. An in-depth analysis showed that the decrease in the number of items was mainly due to medicinal plant materials, which were not re-registered and disappeared from the list of the LRP and the State Register of Medicines [3], respectively. Secondly, due to the harmonization (tightening) of requirements for the quality of pharmaceutical products and the disappearance of a number of players from the market, documents for certain drugs were not even submitted for re-registration.

Comparative analysis with monitoring data from 2006–2010. indicates the following trends. The share of domestic LPPs decreased by -4.8%. Accordingly, the share of foreign countries increased by the same amount - from 8.4% to 13.2%. Similarly, the share of consumer goods decreased from 78.9% to 66.0% (by -12.9%), and this was reflected in the increase in the share of foreign consumer goods to 34.0% (according to the monitoring data of 2006–2010, there were 21.1 %). The established trends can be explained by the above factors. Analysis of the range of medicinal products based on the composition of formulations showed that, compared to 2010, the share of complex medicinal products increased significantly: from 18.9% to 29.4% (+ 10.5%). The same decrease is noted in the segment of monocomponent LPP: from 81.1% to 70.6% (-10.5%). In absolute quantitative terms, both of these indicators tend to decrease, in particular, monocomponent - from 3391 (2010 to) up to 1717 (2013), i.e. by 1674 positions (- 49.4%); multicomponent - from 790 (2010) to 715 (2013), i.e. by 75 positions (-9.5%). Table 2 shows the results of the analysis of the assortment of LRP according to the country of origin.

As follows from the data table. 2, among foreign countries that represent LRP on the Russian market, as in the years of monitoring [1], Germany is in the lead. Its share in the assortment structure even increased, both in terms of quantity (from 97 to 125 items) and in relative terms: from 32.7% to 38.8%. The shares of the LRP in Slovenia (from 7.4% to 9.3%) and Ukraine (from 6.7% to 7.8%) increased. The shares in other countries decreased slightly, for example, India (from 9.8% to 8.1%), France (from 6.4% to 3.4%), Belarus (from 4.7% to 3.4%) , Poland (from 6.7% to 3.1%). A total of 9 countries indicated in table. 2, accounts for 81.7% of positions in the structure of the number of foreign-made LRPs. The share of other countries (21) is 18.3% (Fig. 1).

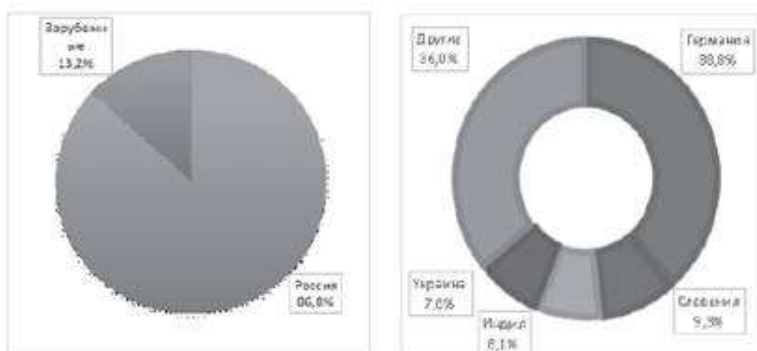
Table 3 shows the types of medicinal plants, which are raw materials for obtaining official medicinal products, as of 2013. In total, 242 plant species were found. Then, according to the criterion "raw source for the production of 50 or more LRS," we identified only 20 plants, while in 2010 there were 40. In the ranking of the frequency of occurrence in LRS formulations, the location of plants varies within the first 10–15 positions. For example, in 2010, valerian took 1st place in the list of plants included in the formulation of the LRP, mint - the second, calendula - the third. In 2013, licorice moved to the first place, valerian - to second, and mint - to third. Another 8 medicinal plants are raw materials for obtaining 40–48 LRP: immortelle flowers (48), leaves and / or flowers of coltsfoot (44), fruits of pungent pepper (44),

table 2

Producing countries of herbal medicinal products presented

on the Russian pharmaceutical market in 2013

№ пп	Страна- производи- тель	2013г.		
		Количество позиций ЛРП	Доля, %	
			К общему количеству	К общему количеству зарубежных ЛРП
1	Россия	2110	86,8	
2	Зарубежные	322	13,2	
	Итого:	2432	100,0	
2.1	Германия	125		38,8
2.2	Словения	30		9,3
2.3	Индия	26		8,1
2.4	Украина	25		7,8
2.5	Нидерланды	15		4,7
2.6	Франция	11		3,4
2.7	Беларусь	11		3,4
2.8	Польша	10		3,1
2.9	Китай	10		3,1
2.10	Другие	59		18,3



Rice. 1 Structure of the MPC segment by producer countries (2013 g.)

The remaining 214 plant species (excluding 20 and 8 species) are sources for the production of 1 to 39 LRS.

Similar to monitoring (2006-2010 biennium), distribution on For pharmacotherapeutic groups and groups of ATC classification, we carried out in accordance with the indicated codes in the GR [3]. A total of 2432 LRP were classified by us in 54 pharmacotherapeutic groups. Table 4 shows the most significant groups in terms of the number of LRS.

As follows from the data in Table 4, the priority pharmacotherapeutic groups in the range of LRP retain their positions, that is, expectorant, sedative, diuretic LRP and a number of other groups dominated the range of LRP in 2006–2013.

Analysis of the structure of the LRP segment by types of dosage forms is presented in table.

5.

From the data table. 5 it follows that it forms an assortment of LRP, mainly crushed medicinal plant raw materials in packs, bags, filter bags, briquettes. If we sum up its share with solid LF, then their total share will be 70.6%. V

In 2010, this total share was equal to 64.6%, i.e. in 2013 it grew by 6.0%. The share of liquid formulations decreased from 30.5% (2010) to 25.8% (2013); there is also a slight decrease in the proportion of soft DFs in the assortment (from 4.9% to 3.5%).

Table 3

Dominant in frequency of occurrence in formulations of officinal plants
drugs types of medicinal herbal raw materials (GR, 2013)

№ пп	Лекарственное растение	Кол-во ЛРП	№ пп	Лекарственное растение	Кол-во ЛРП
1	Корни солодки (голая, уральская)	191	11	Трава чабреца	85
2	Корневища с корнями валерианы	183	12	Листья эвкалипта	82
3	Листья мяты перечной	169	13	Листья подорожника	80
4	Цветки ромашки аптечной	146	14	Плоды шиповника	80
5	Цветки календулы	138	15	Корни алтея	78
6	Трава пустырника	118	16	Листья крапивы	66
7	Цветки и/или плоды боярышника	114	17	Трава душицы	62
8	Трава и/или цветки тысячелистника	105	18	Кора крушины	59
9	Трава зверобоя	96	19	Корневища аира	51
10	Листья шалфея	87	20	Листья и/или плоды сенны	51

Table 4

Pharmacotherapeutic groups dominating in the nomenclature of medicinal
herbal preparations (2013)

№ п/п	Фармакотерапевтическая группа	ЛРП	
		Кол-во	Доля, %
1	Отхаркивающие	257	10,6
2	Седативные	212	8,7
3	Диуретические	109	4,5
4	Слабительные	86	3,5
5	Общетонизирующие	79	3,3
6	Кардиотонические	74	3,0
7	Спазмолитические	73	3,0
8	Желчегонные	66	2,7
9	Противовоспалительные	58	2,4
10	Вяжущие	57	2,3
11	Антисептические и противовоспалительные	53	2,2
12	Антисептические	48	2,0
13	Стимуляторы аппетита	39	1,6
14	Гемостатические	34	1,4
15	Иммуностимулирующие	31	1,3
16	Поливитаминовые	30	1,2
17	Другие фармакотерапевтические группы	1126	46,3

Table 5

The structure of the range of medicinal products by types of dosage forms (2013)

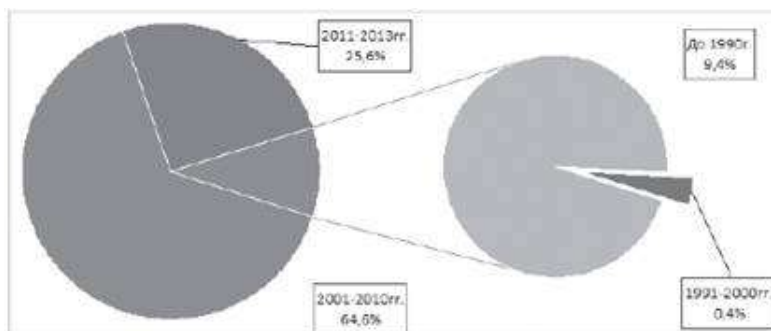
№ п/п	Тип лекарственной формы	ЛРП	
		Кол-во	Доля, %
1	Сырье лекарственное растительное измельченное в различных типах упаковки	1240	51,0
2	Твердые	477	19,6
3	Жидкие	626	25,8
4	Мягкие	86	3,5
5	Спреи	3	0,1
Всего		2432	100,0

Chronological analysis of data on the dates of issuance of registration certificates for LPP is presented in table. 6 and fig. 2.

Table 6

Chronological dynamics of registration of herbal medicinal products in
RF (until 2013)

№ п/п	Период регистрации ЛРП	ЛРП	
		Кол-во	Доля, %
1	До 1990 г.	229	9,4
2	1991–2000 гг.	10	0,4
3	2001–2010 гг.	1571	64,6
4	2011–2013 гг.	622	25,6

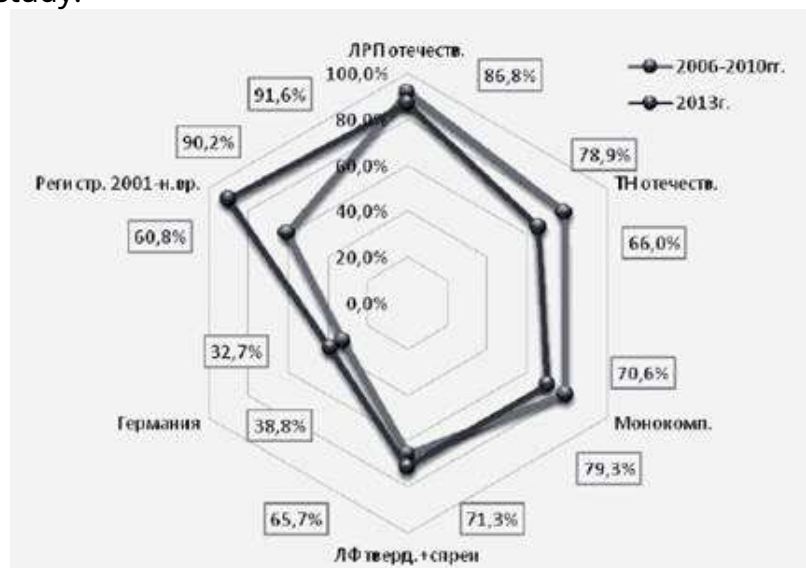


Rice. 2. Chronological structure of registration of LPR in the Russian Federation (2013)

As follows from the above data, in the assortment of LPRs in 2013 are represented mainly LPRs registered for the first time or again in the period from 2001 to the present - 90.2%. There are only 239 items (9.8%) of the drugs that were registered before 2001. Comparative analysis with monitoring data from 2006–2010, showed that the share of LPP with registration before 2001 was 39.2% (during the monitoring period), but now it has decreased by 4 times and amounted to only 9.8%. The share of LPR registered later than 2000 also changed significantly - it increased from 60.8% to 90.2%.

It is this fact that confirms our assumption that the number of registered LPRs (according to 2013 data) has decreased, mainly due to the expiration of the registration period for a significant number of LPRs. Our informational and analytical comparative study allows us to build the contours of the pharmaceutical market segment - LRP in 2013 and 2006–2010. (fig. 3). In fig. 3 it can be seen that the contours of the assortment in relative units for the main

indicators repeat each other with some difference in the direction of decreasing or increasing, which confirms the presence of certain trends that we identified in the course of this study.



Rice. 3. Contour of the LRP assortment (according to data on 2013 and 2006–2010).

The discussion of the results

In the last decade, there has been a trend towards a significant increase in the assortment of the target segment of the pharmaceutical market for pharmaceutical products. At the same time, the registering authorities pay great attention to the quality of LPR, therefore, with the tightening of requirements for manufacturers, obsolete, ineffective and inappropriate LPRs are removed from production and "leave" the market. excluded from the range. This fact has led to a slight decrease in the breadth of the assortment.

A gratifying fact is the conquest of priority positions in the assortment of both LPP and their consumer goods by domestic products. This testifies to the capabilities of our procurement organizations and domestic enterprises to meet the demand of the population in the LPP of certain groups, especially since our raw materials are recognized by experts as of high quality. Moreover, it is generally accepted that the most effective for the patient / consumer are LRS made from raw materials collected in the region of residence of a person (the so-called principle of "treat by area") [4].

If during the monitoring period 2006–2010. there was a tendency of growth in the structure of the assortment of the share of monocomponent LDP (made from raw materials of one plant), then in recent years the share of multicomponent (complex) standardized herbal medicines has been increasing. The tendency of the presence of consumers' preferences for the intake of RLP in convenient types of dosage forms, in particular, solid (tablets, capsules, filter bags, etc.), is confirmed, which is expressed in the predominance of the share of these LRP in the assortment structure.

When analyzing the formulations and pharmacotherapeutic groups of RLP, there is a tendency to maintain priority positions in the ranking of medicinal plants and RLP used in the treatment and prevention of the most common diseases, in particular, the upper respiratory tract (expectorant), the cardiovascular system, the nervous and immune systems, and the digestive organs. and etc.

The obtained results of the situational analysis

allow

supplement

information base of the monitoring results of the studied segment of the pharmaceutical market for medicinal products, as well as to trace further trends in the development of its assortment.

conclusions

1. As a result of the conducted situational analysis of the LRP segment of the domestic pharmaceutical market (2013) established the qualitative and quantitative characteristics of its state at the beginning of the second decade of the twenty-first century.

2. During the study period, a tendency towards a decrease in the breadth of the LRP assortment was revealed. by 41.8%, mainly due to domestically produced products. A significant number of medicinal products were not re-registered due to the expiry of the term of state registration. There is a tendency for monocomponent LRS to decrease by -49.4%. Chronological dynamics have shown that 90.2% of registration certificates for LPPs present on the modern Russian market were issued in the period 2001–2013.

3. The species composition of plants that are dominant raw materials has been determined. sources of official LRP. Priority pharmacotherapeutic groups have been identified that have retained their positions in the DRP market from 2006 to the present (expectorant, sedative, diuretic DRP). The structure of the assortment is dominated by solid dosage forms that are in the greatest demand among consumers of medicinal products.

4. The tendency of mobility of the LRP segment of the domestic pharmaceutical market in 2013 in the process of comparative analysis with the results of monitoring 2006–2010. A slight decrease in the parameters of the segment is presumably due to the reasons for the current market situation and the state's concern for the quality of medicinal products and drug supply to the population.

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Author's address

D. farm. D., prof. Kiseleva T.L., Director of the Research Center, President of the Professional Association of Naturotherapists, Leading Researcher, Research Institute of Nutrition, Russian Academy of Medical Sciences.

KiselevaTL@yandex.ru

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