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Investigating the current state of the Russian market for drugs treating infectious and inflammatory conditions of oral cavity and oropharynx to demonstrate the need for new drug development

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SUMMARY

Objective: to assess the relevance and commercial prospects of bringing to market a drug for the local treatment of infectious and inflammatory diseases of oral cavity and oropharynx.

Material and methods. The objects of the study were the drug nomenclatures in the State Register of Medicines, the Register of Medicines of Russia, as well as data from the Federal Service for Surveillance in Healthcare. The analysis of scientific publications in the field of marketing research of drugs, found in eLibrary.ru and PubMed/MEDLINE databases was carried out. For analyzing the structure and marketing research of drugs in the study group, specific methods of information retrieval, content analysis, description, data aggregation, ranking, data grouping method, system approach, as well as such methods of marketing analysis as determining the breadth and depth of the assortment, the renewal index, the vital importance index, SWOT analysis (strengths, weaknesses, opportunities, threats) were used.

Results. The assortment of drugs for the local treatment of oral cavity and oropharyngeal infectious and inflammatory diseases was structured by the nature of the active substance, type of dosage form, and country of origin. The main trends in the development of the market of drugs of this group were identified. An analysis of the range of drugs using marketing research methods made it possible to establish the breadth and completeness of the range. The calculated renewal and vitality indices confirmed the relevance of developing new drugs with the considered pharmacotherapeutic action.

Conclusion. The study revealed the main trends in the development of the market of drugs of the action in question. The SWOT analysis showed a possible strategy for developing and launching a new drug on the market.

KEYWORDS

Drug market, oral cavity and oropharyngeal diseases, marketing analysis, SWOT analysis.

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Authors' contribution

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Исследование современного состояния российского рынка лекарственных препаратов для местного лечения инфекционно-воспалительных заболеваний полости рта и ротоглотки с целью обоснования актуальности разработки нового лекарственного препарата

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РЕЗЮМЕ

Цель: оценить актуальность и коммерческую перспективу выведения на рынок лекарственного препарата (ЛП) для местного лечения инфекционно-воспалительных заболеваний полости рта и ротоглотки.

Материал и методы. Объектами исследования являлись номенклатуры ЛП Государственного реестра лекарственных средств, Регистра лекарственных средств России, а также данные Федеральной службы по надзору в сфере здравоохранения. Проведен анализ русскоязычных и англоязычных научных публикаций в области маркетинговых исследований рынка ЛП, найденных в базах eLibrary и PubMed/MEDLINE. Использованы специфические методы информационного поиска, контент-анализа, описания, агрегирования данных, ранжирования, метод группировки данных, системный подход, а также такие методы маркетингового анализа, как определение широты и полноты ассортимента, индекса обновления, индекса жизненной важности, SWOT-анализ (англ. strengths, weaknesses, opportunities, threats – сильные стороны, слабые стороны, возможности, угрозы).

Результаты. Ассортимент ЛП для местного лечения инфекционно-воспалительных заболеваний полости рта и ротоглотки структурирован по природе действующего вещества, виду лекарственной формы, стране происхождения препарата. Выявлены основные тенденции развития рынка ЛП данной группы. По результатам анализа ассортимента ЛП с применением методов маркетингового исследования установлены широта и полнота ассортимента. Рассчитанные индексы обновления и жизненной важности подтвердили актуальность разработки новых ЛП рассматриваемого фармакотерапевтического действия.

Заключение. Проведенное исследование позволило выявить основные тенденции развития рынка ЛП для местного лечения инфекционно-воспалительных заболеваний полости рта и ротоглотки. Выполненный SWOT-анализ показал возможную стратегию разработки и вывода на рынок нового ЛП.

КЛЮЧЕВЫЕ СЛОВА

Рынок лекарственных препаратов, заболевания полости рта и ротоглотки, маркетинговый анализ, SWOT-анализ.

ИНФОРМАЦИЯ О СТАТЬЕ

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INTRODUCTION / ВВЕДЕНИЕ

Oral and oropharyngeal diseases continue to be one of the most common pathologies worldwide and the number of patients is increasing every year. According to the World Health Organization (WHO) report published at the end of 2022, about 3.5 billion people suffer from oral diseases [1]. According to statistics, every fourth person on the planet suffers from inflammatory diseases of the upper respiratory tract (in particular, oropharynx). In the Russian Federation (RF), these pathologies have a year-round character with seasonal exacerbations [2, 3].

To treat inflammatory diseases of the oral cavity and oropharynx, medicinal products drugs of both systemic and local action are used, and drugs for topical use with antiseptic and/or anti-inflammatory action are the leaders in sales both in volume (number of sold packages) and in value terms [4]. It should be noted that drugs used for topical treatment of the oral cavity and oropharynx belong to different groups according to different classifications (Anatomical Therapeutic Chemical Classification and International Classification of Diseases, 10th revision), although they have a complex effect.

Market analysis is required as a key source of information regarding the volume and growth rate of the market for a specific drug,

Highlights**What is already known about the subject?**

- ▶ The modern concept of treating patients with diseases of oral cavity and oropharynx is provision of timely, comprehensive and inclusive care, including means of prevention in various dosage forms
- ▶ The range of drugs for the treatment of oral and oropharynx diseases is represented mainly by oral forms, among which lozenges and orally dissolving tablets are the most common, due to local effects, patient compliance and effectiveness
- ▶ The variety of medicines is represented by drugs that contain both individual active pharmaceutical ingredients and their combinations with antibacterial, antiseptic, anti-inflammatory and antiviral effects (among them both natural and synthetic substances)

What are the new findings?

- ▶ For the first time, a structuring of the range of drugs registered in Russia was carried out by manufacturing countries, by dosage forms, and by the origin of the pharmacologically active substance
- ▶ A marketing study of drugs with action in question was performed in terms of breadth and completeness of the assortment, and the renewal and vitality indices were calculated

How might it impact the clinical practice in the foreseeable future?

- ▶ The presented information shows specialists the vector in the development of new drugs for the treatment of diseases of oral cavity and oropharynx
- ▶ Particular attention should be paid to the development of combined drugs with unique international nonproprietary names as the most promising from the point of view of complex pharmacotherapeutic action

Основные моменты**Что уже известно об этой теме?**

- ▶ Современная концепция лечения пациентов с заболеваниями полости рта и ротоглотки заключается в оказании своевременной, комплексной и всесторонней помощи, в т.ч. средствами профилактики в различных лекарственных формах
- ▶ Лекарственные препараты (ЛП) для лечения заболеваний полости рта и ротоглотки представлены в основном пероральными формами, среди которых леденцы и таблетки для рассасывания являются наиболее распространенными, что обусловлено местным воздействием, комплаентностью пациентов и эффективностью
- ▶ В состав ЛП входят как индивидуальные активные фармацевтические субстанции, так и комбинированные средства, обладающие антибактериальным, антисептическим, противовоспалительным и противовирусным действиями (среди них субстанции как природного, так и синтетического происхождения)

Что нового дает статья?

- ▶ Впервые проведена структуризация ассортимента ЛП, зарегистрированных на территории России, по странам-производителям, лекарственным формам и происхождению фармакологически активного вещества
- ▶ Выполнено маркетинговое исследование ЛП рассматриваемого действия по показателям широты и полноты ассортимента, рассчитаны индекс обновления и индекс жизненной важности данной группы ЛП

Как это может повлиять на клиническую практику в обозримом будущем?

- ▶ Представленная информация показывает специалистам вектор развития в области разработки новых ЛП для лечения заболеваний полости рта и ротоглотки
- ▶ Особое внимание следует уделить разработке комбинированных ЛП с уникальными международными непатентованными наименованиями как наиболее перспективным с точки зрения комплексного фармакотерапевтического действия

pharmacotherapeutic group or entire segment. Such information is needed at each stage of the life cycle of a product or organization, and it is the basis for the development of strategies to bring the drug to the market, methods of its promotion and budgets for marketing activities. In accordance with the above, this study was planned and executed.

Objective: to assess the relevance and commercial prospects of bringing to market a drug for the local treatment of infectious and inflammatory diseases of oral cavity and oropharynx.

MATERIAL AND METHODS / МАТЕРИАЛ И МЕТОДЫ**Objects of research / Объекты исследования**

The objects of the study were the nomenclatures of drugs in the State Register of Medicinal Products (GRLS) [5], the Russian Register of Medicinal Products (RLS) [6], as well as the data of the Federal Service for Supervision of Health Care (Roszdravnadzor) [7]. We analyzed Russian and English scientific literature in the field of drug marketing research found in eLibrary and PubMed/MEDLINE databases.

Methods of assortment analysis / Методы анализа ассортимента

The study of the drug market for local treatment of infectious and inflammatory diseases of the oral cavity and oropharynx was carried out in three directions: formation of the database for drugs of the considered pharmacological action, its subsequent characterization and marketing analysis.

The methods of information search, content analysis, description, data aggregation, ranking, data grouping and systematic approach

were used to analyze the nomenclature of drugs in GRLS and RLS [8–17].

Marketing research of the Russian market of drugs for local treatment of infectious and inflammatory diseases of the oral cavity and oropharynx was conducted by methods of determining the breadth and completeness of the assortment, update index, vital importance index, SWOT-analysis [8–17].

Coefficients of breadth and completeness

The coefficient of breadth (K_b) of the assortment was calculated by the formula:

$$K_b = S_a / S_b \times 100\%,$$

where S_a is actual assortment breadth (based on Roszdravnadzor data for 2022–2023); S_b is basic assortment breadth (based on data on actual registration certificates (RCs) of GRLS).

The completeness coefficient (K_c) of the assortment was calculated using the formula:

$$K_c = P_a / P_b \times 100\%,$$

where P_a is actual assortment breadth (based on Roszdravnadzor data for 2022–2023); P_b is basic assortment breadth (based on data on actual GRLS RCs).

As basic breadth and completeness we took the number of RCs of this group of drugs with a valid status, as actual breadth and

completeness – the number of RCs and trade names (TNs) (for the study of assortment completeness) of drugs of the studied pharmacotherapeutic effect, the TNs of which actually make up the turnover. The actual presence of drugs on the domestic market was determined by their presence in the Roszdravnadzor register for the period of 2022–2023.

Renewal index

To characterize the assortment renewal we used the renewal index (I_r), which was calculated according to the formula:

$$I_r = K_n / K_t \times 100\%,$$

where K_n is the number of international nonproprietary names (INNs) of drugs that received RCs for the first time (based on GRLS data); K_t is the total number of INNs that have valid RCs (based on data on current GRLS RCs).

The product range update in this segment was determined in the period from 2018 to 2023 (based on the date of RCs).

Vital importance index

To determine the proportion of drugs that are vital, essential and non-essential (VEN), VEN analysis was used to calculate the vital importance index (I_i) on a "formal" basis using the formula [18]:

$$I_i = K_i / K_t \times 100\%,$$

where K_i is the number of INNs included in the State Register of manufacturers' maximum selling prices for drugs included in the list of vital and essential medicinal products [19] among INNs of the group under consideration as of the date of the study; K_t is the total number of INNs of drugs with valid RCs (based on data on current RCs in the GRLS).

SWOT-analysis

SWOT analysis (strengths, weaknesses, opportunities, threats) is a classic method of identifying and planning the opportunities and threats that may arise during the development and introduction of a new drug into the market. All possible factors and threats that may arise during the development and introduction of a new drug into the market are divided into four specified categories.

In the case of SWOT-analysis of a drug with a new unique INN, it is necessary to take into account the impact of opportunities and threats in both the internal and external environment. The factors of the internal environment of the studied object (which the object itself can influence) include the uniqueness of the composition of the drug and indications for use, contraindications, dosage form, convenience of use, etc. The factors of the internal environment of the studied object (which the object itself can influence). The factors of external environment (which the object itself cannot influence, but these factors influence the object from the outside) include compliance of doctors and patients to the new drug and dosage form, availability of substance for drug production, changes in the economic sphere, etc.

SWOT-analysis was conducted in three stages:

- (1) identification of external and internal factors of the object;
- (2) evaluation and ranking of the identified factors;
- (3) determination of the development strategy of the object.

Statistical analysis / Статистический анализ

Processing of the study results was carried out in Office Excel 2019 program (Microsoft, USA). The results are presented in the form of

graphs and charts, recommendations for expanding the range of drugs of the studied pharmacotherapeutic action are given.

RESULTS AND DISCUSSION / РЕЗУЛЬТАТЫ И ОБСУЖДЕНИЕ

Characteristics of drug assortment / Характеристика ассортимента ЛП

In order to analyze the range of drugs for local treatment of infectious and inflammatory diseases of the oral cavity and oropharynx, we formed a database of the studied group of drugs with valid RCs, the indications for use of which include the possibility of use for local treatment of infectious and inflammatory diseases of the oral cavity and oropharynx. In addition, on the basis of Roszdravnadzor data, we identified those RCs for which drugs were introduced into civil circulation during the last two years (2022 and 2023).

Registered names

The study of the range of drugs as of July 2023 showed that 425 active RCs with 80 INNs were registered in the territory of the RF. Moreover, the study of the dynamics of drug registration depending on the type of INN (botanical, chemical substance origin or combination of pharmacologically active substances of both botanical and chemical origin) shows that over the last 10 years there is a tendency to register drugs whose active substances are of chemical origin (Fig. 1). In addition, two periods in which there is a jump in the number of registered drugs, namely from 2008 to 2011 and from 2021 to 2022, are clearly demonstrated.

A detailed study of the formed database of RCs showed that in the period from 2008 to 2011, a series of drugs with INN "amylmethacresol + dichlorobenzyl alcohol" (have combined antiseptic action), as well as drugs with the above INN and supplemented with ascorbic acid (vitamin C), levomenthol (has a distracting effect) or lidocaine (has a local anesthetic effect) were registered in the RF. The whole line of these drugs is registered under TNs Strepsils®, Strepsils® with vitamin C, Strepsils® with menthol and eucalyptus, Strepsils® Express (registration certificate holder (RCH) and manufacturer: Reckitt Benckiser Healthcare International Ltd., Thailand). These preparations have proved to be effective antiseptic agents for topical application, are widely prescribed by doctors and used by patients.

During the same period, a series of no less well-known drugs with INN gramicidin C, which is an antibiotic, as well as combinations of "gramicidin C + cetylpyridinium chloride" (antibiotic + antiseptic agent) were registered in the RF, "gramicidin C + oxybuprocaine + cetylpyridinium chloride" (antibiotic + antiseptic agent + local anesthetic agent), the best known of which are registered under TNs Grammidin®, Grammidin® NEO, Grammidin® with anesthetic (RCH and manufacturer: Valenta Pharm JSC, Russia). These drugs are available in the form of tablets for resorption, and later the line will include tablets for resorption for children and sprays for topical application.

In the period from 2008 to 2011, plant-based drugs manufactured by Krasnogorsklexredstva JSC and Firma Zdorovye LLC (Russia) were registered, containing as pharmacologically active substances apothecary chamomile flowers, sage leaves, eucalyptus twig leaves and calendula flowers.

The study of the formed database of drugs registered from 2021 to 2022 allowed us to conclude that during this period several RCs for drugs with INN benzidamine (non-steroidal anti-inflammatory drug) in the dosage forms of spray or solution for topical use were registered at once. The original drug with INN benzidamine is the well-established Tantum® Verde (RCH and manufacturer: Aziende Kimike Riunite Angelini Francesco A.C.R.A.F. S.p.A., Italy). At the same time,

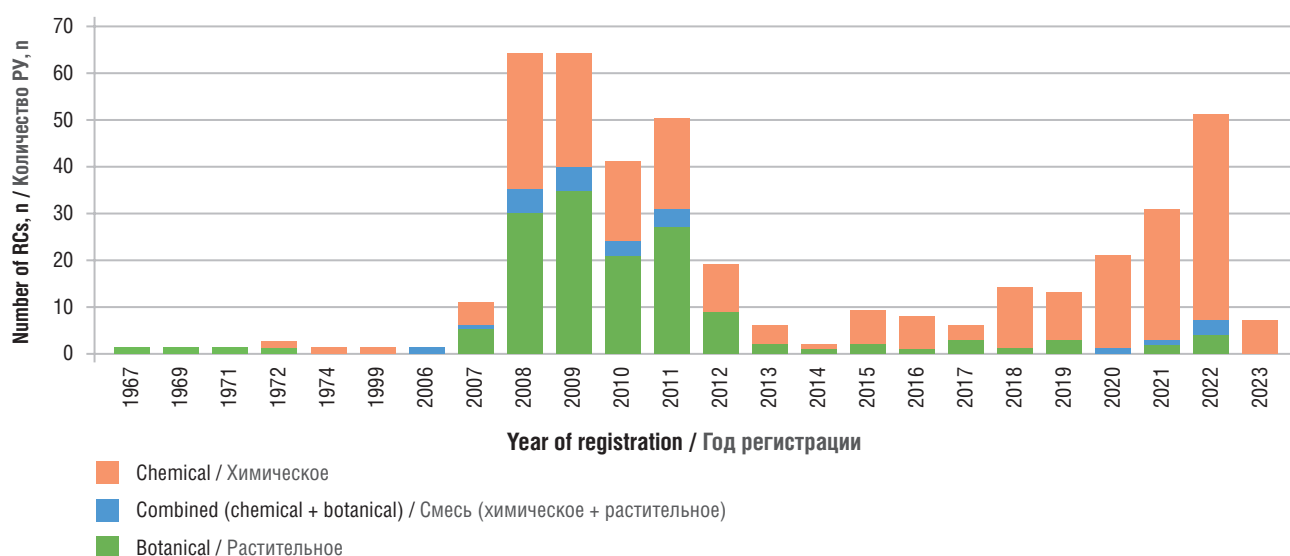


Figure 1. Dynamics of registration of drugs used for local treatment of infectious and inflammatory diseases of oral cavity and oropharynx, depending on the origin of the active substance.

RC – registration certificate

Рисунок 1. Динамика регистрации лекарственных препаратов, применяемых для местного лечения инфекционно-воспалительных заболеваний полости рта и ротоглотки, в зависимости от происхождения действующего вещества.

РУ – регистрационное удостоверение

several drugs with the combinations "benzydamine + chlorhexidine" and "benzydamine + cetylpyridinium chloride" (both are non-steroidal anti-inflammatory agent + antiseptic) appeared. In addition to the above INNs, during this period several analogs of drugs with INN benzildimethyl-myristoylamino-propylammonium were registered, the most well-known INN is Miramistin® (RCH: LLC Infamed, Russia; manufacturer: Infamed K LLC, Russia).

Producing countries

Analysis of countries-manufacturers of drugs for local treatment of infectious and inflammatory diseases of the oral cavity and oropharynx showed that drugs of this pharmacotherapeutic action are represented on the domestic market by 29 manufacturers, among which the top 10 manufacturers produce 94% of drugs with current RCs (**Fig. 2**). The analysis of GRLS data showed that the largest number of RCs (81%) were issued for drugs, the country of origin of which is Russia. Moreover, the ratio of registered drugs of foreign origin to drugs of Russian origin changed annually, and starting from 2018 the share of registered domestic drugs began to increase sharply, which may be associated with the support of national manufacturers under the import substitution program.

Dosage forms

Drugs used for topical treatment of infectious and inflammatory diseases of the oral cavity and oropharynx were represented by the following dosage forms (**Fig. 3**):

- liquid dosage forms (concentrate for preparation of solution for topical application, oil, tincture, solution for topical and external application, spray for topical application, extract, emulsion for inhalation and external application);
- hard dosage forms (lozenges, tablets for solution for topical and external use, orally dissolving tablets, powder for preparation of solution for topical and external use);
- soft dosage forms (gel for topical use, dental gel, liniment, paste for external use);
- medicinal plant raw materials (crushed plant raw materials).

Liquid dosage forms (58.73%) occupied the largest share among the dosage forms of preparations of the studied group, among which solutions accounted for 44.98% and sprays for 28.52%. The second place was occupied by solid dosage forms (23.35%), among which 67.68% were in the form of orally dissolving tablets. Oils have a minimal share in this segment (0.4%).

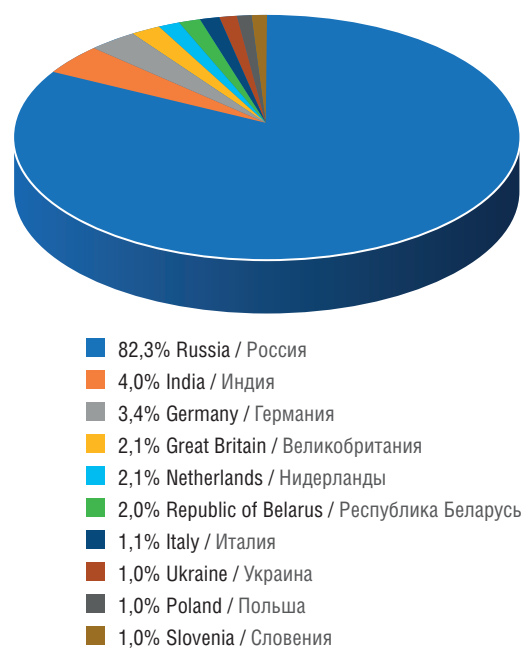


Figure 2. Structure of the range of finished dosage forms used for topical treatment of infectious and inflammatory diseases of oral cavity and oropharynx by producing countries (top 10 countries by the number of active registration certificates)

Рисунок 2. Структуризация ассортимента готовых лекарственных форм, применяемых для местного лечения инфекционно-воспалительных заболеваний полости рта и ротоглотки по странам-производителям (топ-10 стран по количеству действующих регистрационных удостоверений)

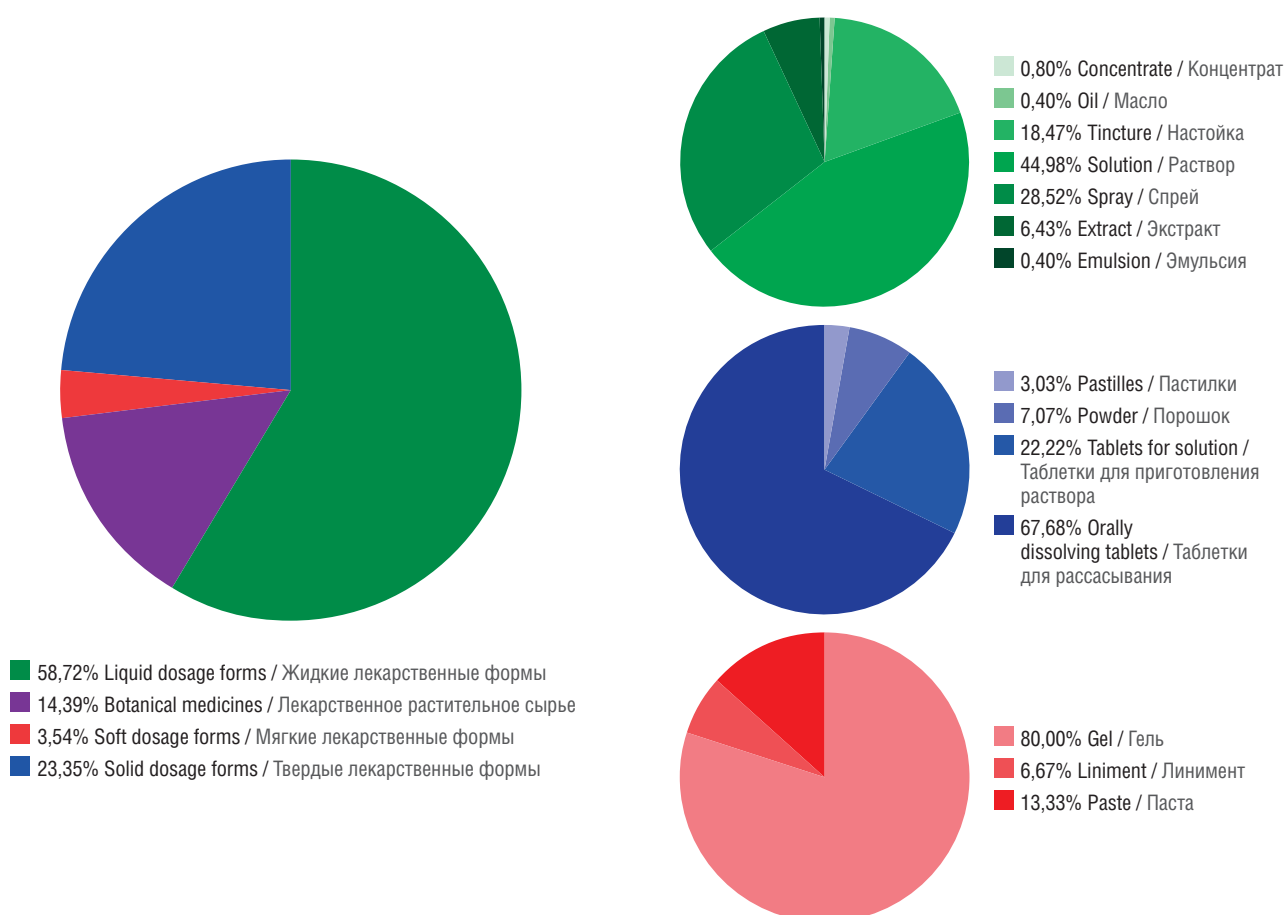


Figure 3. Structure of the range of drugs used for local treatment of infectious and inflammatory diseases of oral cavity and oropharynx, by dosage forms

Рисунок 3. Структуризация ассортимента лекарственных препаратов, применяемых для местного лечения инфекционно-воспалительных заболеваний полости рта и ротоглотки, по лекарственным формам

Origin of substance

The most interesting results were shown by the study of the origin of substance of the considered drugs (pharmacologically active substances of botanical, chemical origin or a mixture of substances of both botanical and chemical origin). The generated database consisted of 80 INNs. In order to improve the convenience of information processing and its relevance (we considered drugs involved in the turnover), 25 INNs were singled out from all the presented INNs of the studied drugs according to the number of active RCs (accounting for 80% of all active RCs of the considered pharmacotherapeutic effect) (Fig. 4).

The analysis revealed that 57.78% of the tested drugs have an active ingredient of chemical origin, with benzydamine (18.65%), chlorhexidine (16.58%) and nitrofurazone (15.03%) being the most common components. The drugs, the active ingredients of which are botanical components, most often include extracts of chamomile (*Matricaria chamomilla* L.), eucalyptus (*Eucalyptus viminalis* Labill.), sage (*Salvia officinalis* L.) and calendula (*Calendula officinalis* L.).

Analysis of available studies on the structure of the range of drugs used for the treatment of diseases of the oral cavity and oropharynx in the countries of the Commonwealth of Independent States (CIS) showed significant differences both in the predominant dosage forms and in the names of producing countries.

The study of the Kazakh market of drugs of the considered pharmacotherapeutic group demonstrated both general trends and differences in the structure of prevailing drugs and geography

of manufacturing countries represented in the local market. Thus, the most widespread drug similar to the Russian market are liquid dosage forms, namely sprays and aerosols. The study of drugs of the above group by origin of substance is absolutely different from the situation in our country. In the market of Kazakhstan 64% of drugs for prevention and treatment of diseases of oral cavity and oropharynx are represented by substances of botanical origin. Among the countries-manufacturers of drugs, drugs of Kazakh origin occupy only 14% of the total amount. This picture may be due to the fact that local manufacturers and importers such as Ukraine and Russia provide the market with botanical substances (based on liquid dosage forms); solid dosage forms are 97% imported goods (the main importers are India, supplying relatively inexpensive drugs with botanical substances, and Russia, supplying modern drugs with high price). At the same time, the state program Kazakhstan-2050 is being implemented in the territory of the Republic of Kazakhstan, in which the priority is given to import substitution of pharmaceutical products. The trend of development of the Kazakhstan market in the field of development of drugs of the considered action with a high probability will be the creation of drugs with substances of botanical origin [20, 21].

In the Republic of Belarus, the assortment structuring by dosage forms is similar to the Russian market, i.e. the largest number of TNs is registered in two types of dosage forms: solid (39 TNs) and liquid (34 TNs). The share of drugs with substances of botanical origin in solid dosage forms is 28.2%, in liquid dosage forms – 40%, which is similar to the Russian market. Significant differences between the

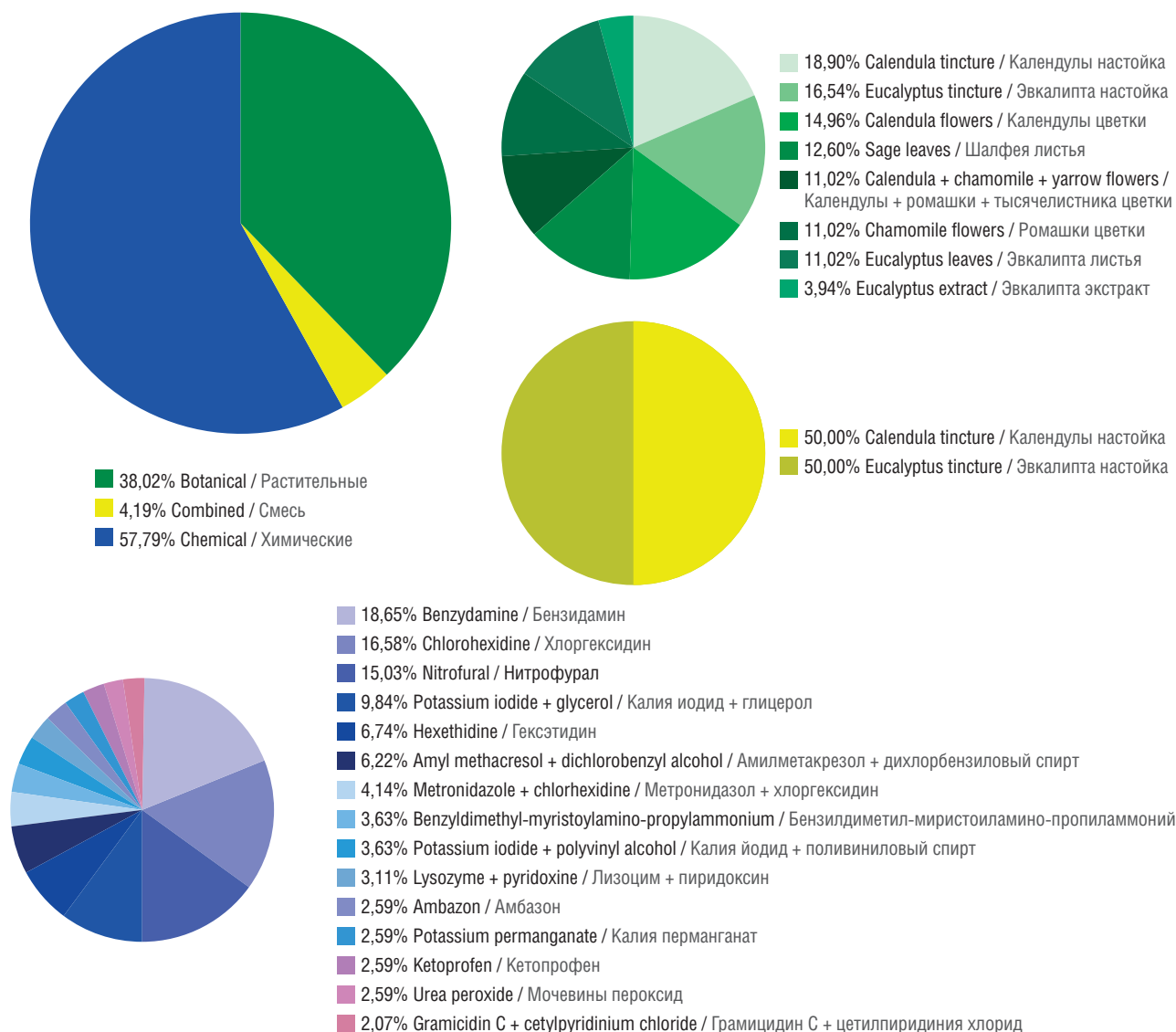


Figure 4. Structure of the range of finished dosage forms used for local treatment of infectious and inflammatory diseases of oral cavity and oropharynx by origin of pharmacologically active substance (top 25 international nonproprietary names, trade names of which account for 80% of all valid registration certificates)

Рисунок 4. Структура ассортимента готовых лекарственных форм, применяемых для местного лечения инфекционно-воспалительных заболеваний полости рта и ротоглотки, по происхождению фармакологически активного вещества (топ-25 международных непатентованных наименований, торговые наименования которых составляют 80% от всех действующих регистрационных удостоверений)

markets of drugs of the group under consideration by the countries-manufacturers of medicinal products were revealed. In Belarus, the share of goods of local origin in the case of liquid dosage forms is only 8.8%, in the case of solid dosage forms – 7.7% [22, 23]. The tendency of the local market of drugs in the Republic of Belarus is also an aspiration to import substitution. The State Program for the Development of the Pharmaceutical Industry of the Republic of Belarus for 2016–2020 was implemented, however, it included localization of production of high-cost drugs. There is no significant increase in the number of local manufacturers of drugs for the treatment of diseases of the oral cavity and oropharynx, but there is a general trend towards the creation of drugs with a substance of botanical origin [24].

In the Republic of Uzbekistan, the largest share among the dosage forms is occupied by solid (50%), followed by liquid (34%) forms; the largest share among the drugs of the considered action are drugs with a substance of botanical origin; the share of local manufacturers

is 60.5%. According to the researchers, the development and import substitution of drugs with botanical substances of local origin is a promising direction for the development of the drug market of the above-mentioned action [25–28].

The study of available market research of the Ukraine local market of drugs for the treatment of diseases of the oral cavity and oropharynx showed that the share of local manufacturers by the number of TNs is 82.7%; among the countries-manufacturers of drugs imported to Ukraine: India, USA and UK. Structurization of the range of drugs of the group under consideration by dosage forms showed that the largest number of TNs was registered in liquid dosage form and as medicinal herbal raw materials (30.7% each) [29]. It is difficult to speak about the trends of further development of this market of drugs for the prevention and treatment of diseases, but the production of drugs with substances of botanical origin is likely to be successful in terms of the local raw material base and the cost of drugs produced.

Marketing study of assortment structure / Маркетинговое изучение структуры ассортимента

Assortment breadth and completeness

The share of the considered drugs was analyzed by determining the specific weight of each INN in the structure of the whole assortment of this pharmacotherapeutic group.

To characterize the breadth and completeness of the assortment we used the calculation method, the results of which are presented in Figure 5.

Calculation of the completeness coefficient for all three groups of drugs (comprising substances of botanical, chemical or a mixture of substances of botanical and chemical origin) was performed using the same methodology. For this purpose we compared the data on actual RCs of drugs of the pharmacotherapeutic effect under consideration in the GRLS and data on introduction of at least one TN of each INN into civil turnover for the last 2 years (2022–2023). The study showed that all INNs of the considered pharmacotherapeutic effect under at least one INN were put into civil turnover, therefore, the completeness coefficient of this group of drugs is 100%, which indicates that drugs with all INNs registered in Russia are available on the market. This fact has a positive impact on the ability of a doctor to prescribe the drug necessary for therapy, and on a patient, as he or she will have the opportunity to purchase the prescribed drug.

The study of the assortment completeness coefficient for individual INNs was carried out according to a similar methodology. For example, at the moment, there are 13 active RCs registered among drugs with INN hexetidine (substance of chemical origin) [5], among which

only 8 RCs have been introduced into civil turnover [7]. Thus, the completeness coefficient for this INN will be 61.54%.

It was shown that drugs not under all TNs, having actual RCs, were introduced into the civil turnover during the last 2 years. This may be due to the lack of the necessary substance at a particular manufacturer for the production and release into turnover of a batch of goods, the process of drug development (when the manufacturer has not yet had time to conduct all the necessary quality control studies to put the drug into turnover) or the manufacturer has only registered the RC for the drug and has not yet released any batch of goods into turnover. The calculations showed that the lowest assortment completeness coefficient for individual INNs is minimal for drugs with active substances of botanical origin (e.g., INNs Eucalyptus leaf extract, Eucalyptus leaf tincture, Calendula tincture). The result obtained may indicate that these INNs are the least demanded by doctors and patients (this may be due to inconvenience of administration and storage, presence of alcohol in the composition), from the manufacturer's point of view, production of a batch of drugs with these INNs is resource-intensive. To express the results graphically, we used a list of INNs from the top 25 INNs, the INNs of which account for 80% of all active RCs of the drugs under consideration (see Fig. 5).

Renewal index

Goods renewal index is an indicator of the industry progress – development, improvement of the assortment structure and compliance of the assortment with the needs of specialists and

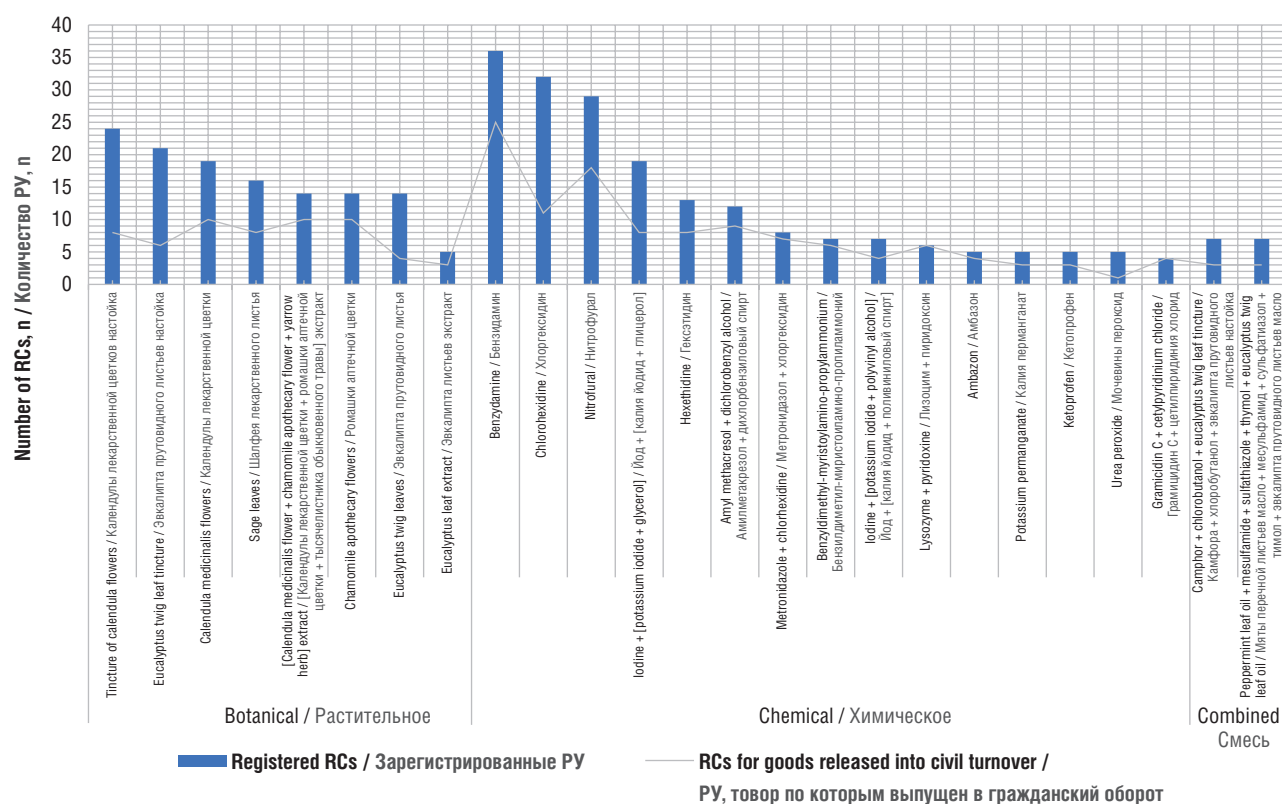


Figure 5. Marketing study of the breadth and completeness of the range of finished dosage forms used for topical treatment of infectious and inflammatory diseases of oral cavity and oropharynx: top 25 international nonproprietary names, trade names of which account for 80% of all valid registration certificates (RCs)

Рисунок 5. Маркетинговое изучение широты и полноты ассортимента готовых лекарственных форм, применяемых для местного лечения инфекционно-воспалительных заболеваний полости рта и ротоглотки, – топ-25 международных непатентованных наименований, торговые наименования которых составляют 80% от всех действующих регистрационных удостоверений (РУ)

patients. The calculation was performed for the period from 2018 to 2022; during this period, RCs for 4 drugs with new INNs were issued.

In 2020, the combination "lidocaine + lysozyme + cetylpyridinium chloride" with complex anesthetic effect due to lidocaine and two antiseptic agents of different chemical structure (lysozyme and cetylpyridinium chloride) was registered for the first time (LP-006147 dated 17.03.2020; TN: Lysobact Complete®; RCH and manufacturer: Bosnalek SA, Bosnia and Herzegovina). This drug is an improved analog of the drug with INN "lysozyme + pyridoxine" (best known TN: Lysobact®; RCH and manufacturer: Bosnalek SA, Bosnia and Herzegovina) and drugs with INN "lidocaine + cetylpyridinium chloride" (best known TN: TheraFlu Lar® Menthol; RCH: GlaxoSmithKlein Healthcare JSC, Russia; manufacturer: Novartis Saglik Gida ve Urunleri San. Ve Tic. A.S., Turkey).

Also in 2020, the combination "flurbiprofen + cetylpyridinium chloride" was registered for the first time, which has a complex antiseptic (cetylpyridinium chloride), analgesic and anti-inflammatory effect (flurbiprofen) (LP-006474 dated 24.09.2020; TN: Maxicold® Lor Tabs double action; RCH: OTCPharm JSC, Russia; manufacturer: Pharmstandard-Leksredstva JSC, Russia). This drug is an improved analog of the drug with INN flurbiprofen (best known TN: Strepsils® Intensive; RCH and manufacturer: Reckitt Benckiser Healthcare Manufacturing Ltd, Thailand).

In 2021, for the first time a drug containing sodium hypochlorite as an active ingredient with antiseptic effect was registered (LP-007484 dated 11.10.2021; TN: Triaseptin®; RCH: Euromed LLC, Russia; manufacturer: Peoples' Friendship University of Russia, Russia).

In 2023, the combination "benzildimethyl-myristoylamino-propylammonium + flurbiprofen" was registered for the first time, which has antiseptic (benzildimethyl-myristoylamino-propylammonium), analgesic and anti-inflammatory (flurbiprofen) effects (LP-008095 dated 25.04.2022; TN: Mitrasetin®-Prolor; RCH and manufacturer: Pharmstandard-Leksredstva OJSC, Russia). This drug is a modified analogue of a drug with INN flurbiprofen (best known TN: Strepsils® Intensive; RCH and manufacturer: Reckitt Benckiser Healthcare Manufacturing Ltd, Thailand) in combination with INN benzildimethyl-myristoylamino-propylammonium (best known TN: Miramistin®; RCH: Infamed LLC, Russia; manufacturer: Infamed K LLC, Russia).

The update index was calculated as follows: the number of unique INNs brought to the market for the first time in the period from 2018 to 2022 (4 INNs) was divided by the total number of INNs with current RCs (80 INNs), the resulting value was expressed as a percentage. Thus, the update index of drugs of the considered pharmacotherapeutic group is 5.00%, which is quite low, and the largest number of RCs with unique INNs was registered in 2022, while in 2018 and 2019 there were no registrations. The obtained value of the update index can be explained by the complexity and duration of development of drugs with new INNs. At the same time, it should be noted that the new INNs of drugs of the considered action registered in Russia are analogues of drugs of foreign origin, the pharmacological effect of which was extended by the introduction of a second active substance (the exception is the drug with the TN: Triaseptin®).

The study of the update index shows that despite being labor-intensive, time-consuming and costly, the development of drugs with unique INNs is relevant in terms of complex treatment and treatment with drugs that have unique mechanisms of action or affect specific receptors. In addition, the introduction of new drugs into the assortment may be considered appropriate due to the mismatch between the rate of expansion of patients' needs and the introduction of new assortment items.

Vital importance index

It was found that it included only 4 INNs of MPs of the considered action:

- iodine + (potassium iodide + glycerol) (best known TN: Lugol®);
- potassium permanganate (best known TN: Potassium permanganate®);
- povidone iodine (best known TN: Povidone iodine®);
- chlorhexidine (best known TN: Chlorhexidine®).

The vital importance index of INN drugs of this pharmacological action is 5.00%, which is low.

SWOT analysis / SWOT-анализ

The results of SWOT-analysis (**Table 1**) show that, despite the presence of possible market threats from side effects of drugs, risk of lack of substances or equipment for production, the development of new drugs is supported by such factors as limited assortment, low activity of pharmaceutical companies in terms of launching new products, their high commercial potential, support for import substitution initiatives, opportunities to optimize drug supply and better meet the needs of patients and doctors. The development of proprietary products addresses an important challenge in strengthening the production and technological sovereignty of national pharmaceutical companies.

CONCLUSION / ЗАКЛЮЧЕНИЕ

Evaluation of the characteristics of drugs included in the database by country-manufacturers of finished dosage forms shows that the vast majority of drugs of the considered pharmacotherapeutic effect are produced in the territory of the RF, which may be due to the availability of substances and equipment for production, the existence of programs of the Government of the RF aimed at import substitution and development of the domestic pharmaceutical industry. The study of drugs included in the database by dosage forms and INNs demonstrates that the largest number of drugs is represented by liquid dosage forms (solution for topical and external use, spray for topical use, tincture, etc.). The second place by the number of TNs is occupied by solid dosage forms (orally dissolving tablets, tablets for preparation of solution for topical and external use, etc.).

The prevalence of liquid and solid dosage forms is explained by their physiological convenience, ease of use and storage. If we consider drugs of the considered pharmacotherapeutic action from the point of view of substance origin, the largest share in the developed base is occupied by drugs having chemical origin of substance, followed by drugs containing medicinal plant raw materials or their derivatives. Such a share distribution is relevant from the point of view of narrowly targeted action and relative simplicity of development of new drugs.

As for the analysis of the dynamics of registration of the studied drugs, in recent years, the number of newly registered drugs has been increasing and the ratio of registered drugs of domestic and foreign origin has been changing towards domestic ones. In addition, there is a clear tendency to increase the share of drugs with substances of chemical origin, which once again confirms the assumption about the narrow focus of action and relative ease of development of such drugs.

The analysis of the formed base of drugs using marketing research methods (determination of breadth and completeness of the assortment, renewal index, vital importance index) shows that drugs with all INNs used for local treatment of infectious and inflammatory diseases of the oral cavity and oropharynx are represented on the

Table 1. SWOT analysis on the relevance of development and market launch of a drug with a new unique international nonproprietary name (INN) for the topical treatment of infectious and inflammatory diseases of oral cavity and oropharynx

Таблица 1. SWOT-анализ актуальности разработки и вывода на рынок лекарственного препарата (ЛП) с новым уникальным международным непатентованным наименованием (МНН) для местного лечения инфекционно-воспалительных заболеваний полости рта и ротоглотки

Strengths / Сильные стороны	Weaknesses / Слабые стороны
<p>1. The relevance of developing a drug with unique INN / Актуальность разработки ЛП с уникальным МНН</p> <p>2. In the case of the development of a drug in which medicinal plant raw materials or their derivatives will be used as a pharmacologically active substance: complex pharmacotherapeutic effect on the organism, physiology, fewer side effects / В случае разработки ЛП, в котором в качестве фармакологически активного вещества будут использованы лекарственное растительное сырье или его производные: комплексное фармакотерапевтическое действие на организм, физиологичность, меньшее количество побочных эффектов</p> <p>3. High competitiveness with existing drugs due to the support of the Government of the Russian Federation for domestic drug production / Высокая конкурентоспособность с существующими ЛП вследствие поддержки Правительством Российской Федерации ЛП отечественного производства</p>	<p>1. The cost of resources for the search, development and market launch of a drug with new INN / Затраты ресурсов на поиск, разработку и вывод на рынок ЛП с новым МНН</p> <p>2. The presence of contraindications and side effects of a developed drug / Наличие противопоказаний и побочных эффектов разработанного ЛП</p> <p>3. The cost and constant availability of the substance for a drug production / Стоимость и постоянное наличие субстанции для производства ЛП</p>
Opportunities / Рыночные возможности	Threats / Рыночные угрозы
<p>1. The use of modern, effective drug for the treatment of oral cavity and oropharynx / Использование современного, эффективного ЛП для лечения полости рта и ротоглотки</p> <p>2. Optimization of patients' costs for the treatment of this group of diseases / Оптимизация затрат пациентов на лечение данной группы заболеваний</p> <p>3. In the case of the development of a drug in which medicinal plant raw materials or their derivatives will be used as a pharmacologically active substance: replacement of a drug containing chemically synthesized active substances with one containing herbal components / В случае разработки ЛП, в котором в качестве фармакологически активного вещества будут использованы лекарственное растительное сырье или его производные: замена ЛП с химически синтезированными действующими веществами на ЛП с растительными компонентами</p> <p>4. Development of the Russian pharmaceutical industry / Развитие отечественной фармацевтической промышленности</p>	<p>1. The introduction of a drug with the same INN to the market by a competitor before the release of a drug under development / Выведение на рынок конкурентом ЛП с таким же МНН до выхода разрабатываемого ЛП</p> <p>2. Pressure from manufacturers of products with a similar active ingredient registered as a dietary supplement / Давление со стороны производителей средств с аналогичным действующим веществом, зарегистрированных как биологически активная добавка</p> <p>3. Absence of substance or equipment for the production of a drug / Отсутствие субстанции или оборудования для производства ЛП / Lack of substance or equipment for the production of a drug</p>

market under at least one TN. Very low indices of renewal (5.00%) and vital importance (about 5.00%) were established for drugs of the considered pharmacological action. This may be due to high risks and costs of development of drugs with new INNs, lack of necessary raw materials and equipment. The value of the vital importance index may indicate that this group of drugs is underestimated by the state.

The SWOT-analysis of the relevance of drug development for local treatment of diseases of the oral cavity and oropharynx shows the importance of developing drugs with a unique INN on two criteria at once: optimization of drug supply to the patients and improvement of initiatives aimed at import substitution and development of the domestic pharmaceutical industry.

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