THE MARKETING SUBSTANTIATION OF THE RELEVANCE OF NEW DOMESTIC PRODUCTS DEVELOPMENT FOR TOPICAL APPLICATION IN DENTISTRY

Over the last few years, the market of dental services in our country is rapidly developing. Modern world technologies of dental disease treatment have influenced on the structure of the domestic pharmaceutical market – new drugs, new dosage forms have appeared, they are used not only in therapeutic dentistry, but also in periodontics, diseases of surgical profile, orthopaedic, aesthetic dentistry and orthodontics. Domestic manufacturers are always in an active innovative search, searching for new marketing opportunities.

**Aim.** To analyze the range of dental preparations for topical application at the pharmaceutical market of Ukraine in order to substantiate the relevance for creating new drugs in this field.

**Materials and methods.** The methods of content and marketing analysis were used; the studies were performed using the Compendium database and the State Register of Medicinal Products of Ukraine.

**Results.** The assortment of preparations for topical application in dentistry by dosage forms and composition has been analyzed. Dental gels with components of synthetic origin have been found to be in the lead. The comparative analysis of dental gels with other oral dosage forms has been conducted; the leading consumer benefits of this dosage form have been determined – good adhesion and high bioavailability. The structure of suppliers has been studied, and a high degree of import dependency has been found (73.3 %).

**Conclusions.** The relevance of development and production of new domestic combined preparations for topical application in dentistry, in particular gels for the treatment and prevention of caries, inflammatory diseases of the periodontium, oral mucosa, as well as pathologies similar in aetiology arising from the use of dental prostheses of various designs.

**Key words:** dental diseases; medicines of topical application; pharmaceutical market; dental gels.
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Маркетинговое обоснование целесообразности разработки новых оральных препаратов для местного применения в стоматологии

В последнее время рынок стоматологических услуг в нашей стране интенсивно развивается. Современные технологии лечения стоматологических заболеваний и в мире повлияли и на структуру орального рынка фармацевтического рынка: появились новые лекарства, новые лекарственные формы, применяемые не только в терапевтической стоматологии, но и в парodontологии, при заболеваниях хирургического профиля, в ортопедической, эстетической стоматологии и ортодонтии. Оральные препараты в основном находятся в активном инновационном поиске, поиске новых маркетинговых возможностей.

Цель: анализ ассортимента стоматологических препаратов для местного применения на фармацевтическом рынке Украины для обоснования целесообразности создания новых лекарственных средств в этой сфере.

Материалы и методы: контент- и маркетингового анализа; исследования проводили с использованием базы данных Компендиума и Государственного реестра лекарственных средств Украины.

Результаты. Проанализирован ассортимент препаратов для местного применения в стоматологии по лекарственным формам и составам. Установлено, что лидирующие позиции занимают стоматологические гели с компонентами синтетического происхождения. Проведен сравнительный анализ стоматологических гелей с другими оральными лекарственными формами, определены главные потребительские преимущества данной лекарственной формы – хорошая адгезионная способность и высокая биодоступность. Изучена структура поставщиков и установлена высокая степень импортозависимости рынка (73,3 %).

Выводы. Показана актуальность разработки и производства новых оральных препаратов для местного применения в стоматологии, в частности гелей для лечения и профилактики кареса, воспалительных заболеваний пародонта, слизистой оболочки полости рта, а также похожих по этиологии патологий, возникающих при пользовании зубных протезов различных конструкций.

Ключевые слова: стоматологические заболевания; лекарственные средства местного действия; фармацевтический рынок; стоматологические гели.

Statement of the problem. Dental diseases remain one of the most widespread problems worldwide due to their steady growth and progressive courses among different age groups of patients [1].

It is known that dental diseases have a negative impact on the human body and lead to various complications not only local, but also systemic in nature [2]. To date, caries has the leading place among diseases of the hard tissues of teeth, while among the pathologies of the soft tissues of the oral cavity there are infectious-inflammatory diseases of the periodontium (gingivitis, periodontitis) and the mucous membrane ( stomatitis). Thus, according to medical statistics, caries occurs in more than 80 % of adolescents and more than 90 % of adults; only 8-12 % of the population have a healthy periodontium, 53 % have the initial inflammatory phenomena, 23 % have the initial destructive changes, and 12 % have moderate and severe lesions [1, 3-5]. In addition, professionals note that the level of dental morbidity among children, especially at an early age, has recently significantly increased. Most often, children seek for specialized medical aid in connection with lesions of the hard tissues of teeth (50-80 %), the periodontial tissues and the mucous membrane of the oral cavity (40-60 %) [3, 6].

These pathologies are common causes of the tooth loss, resulting in the need for partial or complete prosthetics [7]. According to the scientific literature, the use of dentures is one of the most common causes of inflammatory reactions, leading to the appearance of hypersensitivity and bleeding gums, and in the long course to the development of serious chronic diseases. In this case, inflammatory processes can manifest themselves as gingivitis, periodontitis, stomatitis, pressure ulcers and chronic trauma [8-10].

However, in modern dental practice one of the main places is occupied by the local treatment of oral cavity diseases [1, 5, 11, 12].

In view of the above, providing the population with effective dental drugs for topical application requires sufficient information on their range and development opportunities for the pharmaceutical market. In this regard, there is a need for marketing research of the domestic market of drugs of this group.

Analysis of recent research and publications. The domestic pharmaceutical market
of dental drugs in different periods was studied in the works of L. L. Davtyan, O. F. Piminov, T. G. Yarnyh, L. I. Shulga, N. V. Khokhlenkova, T. P. Zarichna, G. R. Kozyr, Y. M. Kobets et al. [13-15].

Identification of aspects of the problem unsolved previously. However, despite the attention of the scientific community to the problem, publications on the feasibility of creating dental products for topical application are fragmentary. In particular, there is no detailed analysis of compositions (the structure of API) of dental drugs for topical application and their pharmacological action, as well as a limited number of studies of dental drugs to eliminate pathologies that arise during adaptation to prostheses.

Objective statement of the article. The aim of the work was to analyze the range of dental preparations for topical application at the pharmaceutical market of Ukraine in order to substantiate the relevance for creating new drugs in this field.

Materials and methods. The methods of content and marketing analysis were used in the work. The studies were conducted using the Compendium database [16] and the State Register of Medicinal Products of Ukraine [17].

Presentation of the main material of the research. According to the ATC-classification, there is group A01A – “Stomatological preparations”, which, in turn, is divided into subgroups: A01A B – “Anti-infectives and antiseptics for local oral treatment” and A01AD – “Other agents for local oral treatment” [16]. The study of the range of dental drugs at the domestic market has shown that as of early 2019, the study group has about 60 drugs for all dosage forms, among them gels, solutions and sprays are the most common (Fig.).

According to the prescribing information, dental preparations contain chemical, biogenic, herbal components and combinations thereof [16, 17]. The list of possible combinations is rather wide. The characteristics of active pharmaceutical ingredients (API) in the composition of the drugs under research (the number of references to these substances in the composition of drugs and their pharmacological action) are given in Tab. 1.

According to the results of the analysis of the dental drug composition (Tab. 1), chlorhexidine gluconate, metronidazole benzoate and benzidamine hydrochloride with the antibacterial, anti-inflammatory, antiseptic and analgesic action take the leading positions among substances of synthetic origin; among products of natural origin there are API based on chamomile and sage with the astringent, anti-inflammatory, antimicrobial, antiseptic, disinfectant, hemostatic and analgesic activity. It has been found that among drugs containing components of natural origin the combined drugs prevail, their pharmacological action is provided not by one species, but by a complex of the plant raw material (PRM) (“Phytodent”,

Fig. Distribution of dental drugs for topical application by dosage forms
### Table 1

**API IN THE COMPOSITION OF DENTAL DRUGS THAT ARE AVAILABLE AT THE PHARMACEUTICAL MARKET OF UKRAINE**

| The name of the API | Number of references in the composition of drugs | Pharmacotherapeutic action                                                                 |
|---------------------|--------------------------------------------------|---------------------------------------------------------------------------------------------|
|                     | 1                                               |                                              | **API of synthetic origin**                                                                 |
| Chlorhexidine gluconate | 10                                             | Antimicrobial, antiseptic                                                                   |
| Metronidazole benzoate          | 8                                              | Anti/protozoal, antibacterial                                                              |
| Benzidamine hydrochloride       | 8                                              | Anti-inflammatory, analgesic, antiseptic                                                    |
| Lidocaine hydrochloride         | 4                                              | Anesthetic                                                                                  |
| Hexitidine                  | 4                                              | Antifungal, antiseptic, topical hemostatic, analgesic, coating and deodorizing               |
| Choline salicylate           | 3                                              | Anesthetic, anti-inflammatory                                                               |
| Cetalkonium chloride         | 2                                              | Antimicrobial, antifungal                                                                  |
| Polidocanol 600 (macrogol lauryl ether )  | 2                                              | Local anesthetic                                                                            |
| Camphor (racemic)           | 2                                              | Antiseptic, analgesic and anti-inflammatory                                                 |
| Clotrimazole                 | 1                                              | Antibacterial, antifungal, antiprotozoal                                                    |
| Benzocaine                 | 1                                              | Anesthetic                                                                                 |
| Thymol                     | 1                                              | Antiseptic                                                                                 |
| Salicylic acid             | 1                                              | Antimicrobial, antiseptic                                                                   |
| Sodium fluoride            | 1                                              | Remineralizing, bactericidal, caries prophylactic                                             |
| Hydrochloride              | 1                                              | Antiseptic                                                                                 |
| Diclofenac sodium           | 1                                              | Analgesic, antipyretic, anti-inflammatory                                                    |
|                     | 2                                               |                                              | **API of natural origin**                                                                   |
| *Matricaria chamomilla*     | 10                                             | Painkiller, anti-inflammatory, antiseptic, hemostatic, astringent, disinfectant              |
| *Salvia officinalis*        | 7                                              | Astringent, anti-inflammatory, antiseptic, disinfectant, hemostatic, antimicrobial           |
| Propolis                   | 4                                              | Bactericidal, analgesic, antiseptic, anti-inflammatory, reparative                           |
| *Acorus calamus*           | 4                                              | Antiseptic, antibacterial, analgesic, anti-inflammatory, disinfectant                         |
| *Mentha piperita*          | 4                                              | Antiseptic, antibacterial, analgesic, antifungal                                             |
| *Eucalyptus viminalis*      | 3                                              | Antimicrobial, analgesic, antiseptic, disinfectant, immunomodulating                         |
| *Quercus robur*            | 3                                              | Astringent, anti-inflammatory                                                               |
| *Calendula officinalis*     | 3                                              | Anti-inflammatory, bactericidal, wound healing                                               |
| *Thymus serpyllum*         | 3                                              | Anti-inflammatory, antimicrobial                                                            |
| *Achillea millefolium*      | 2                                              | Hemostatic, anti-inflammatory, bactericidal                                                |
| *Arnica montana*           | 2                                              | Hemostatic, astringent, analgesic                                                           |
| *Symphytum officinale*      | 2                                              | Anesthetic, anti-inflammatory, hemostatic, reparative                                         |
| *Capsicum*                 | 1                                              | Antiseptic, refreshing, locally irritating, distracting, moderate antibacterial               |
| *Hypericum perforatum*     | 1                                              | Astringent, anti-inflammatory, antimicrobial, reparative                                     |
| *Urtica dioica*            | 1                                              | Wound healing, hemostatic, anti-inflammatory, analgesic                                     |
| *Styphnolobium japonicum*  | 1                                              | Bactericidal, anti-inflammatory, analgesic                                                  |
As can be seen from the analysis of the market, gels take the predominant position among various dosage forms; it is due to the effectiveness of their action and ease of use in the oral cavity [18-20]. Taking into account the data of scientific publications and the composition of the group of drugs studied [12, 16-23] a comparative characterization of the physicochemical and technological properties of dental gels with other oral dosage forms under research was conducted to determine their advantages and disadvantages (Tab. 2).

As shown by the comparative analysis (Tab 2), gels are characterized by good consumer properties and high bioavailability due to ease of use, localization of action, high adhesive ability and prolonged retention on the surface of oral cavity tissues.

A COMPARATIVE CHARACTERISTIC OF DENTAL GELS AGAINST OTHER ORAL DOSAGE FORMS

| Properties                                                                 | gel | spray, aerosol | solution, tincture, liquid extract | fast dissolving tablet, lozenges | PRM, blends | oromucosal paste | dental inserts |
|---------------------------------------------------------------------------|-----|----------------|------------------------------------|---------------------------------|-------------|----------------|---------------|
| Adhesive ability                                                         | +   | +*            | -                                  | -                               | -           | +*            | +            |
| Prolongation of the effect (prolonged retention on the surface of the oral cavity tissues) | +   | +*           | -                                  | -                               | -           | +*            | +            |
| Localization of the action                                               | +   | +             | -                                  | -                               | -           | +             | +            |
| Possibility of taking medicines on an outpatient basis                   | +   | +             | +                                  | +                               | +           | +             | -            |
| Ready-to-use form                                                        | +   | +             | +                                  | +                               | -           | +             | +            |
| Easy of transporting                                                     | +   | -             | -                                  | +                               | +           | +             | +            |

Note. +* – property is available, but weaker than in gels.

Continuation of Table 1

| 1                          | 2                                      | 3                                      |
|---------------------------|----------------------------------------|----------------------------------------|
| Chelidonium majus         | 1 Anti-inflammatory, analgesic         |
| Rosa canina               | 1 Anti-inflammatory, immunostimulating |
| Piper nigrum              | 1 Antimicrobial, locally irritating     |
| Artemisia absinthium      | 1 Antimicrobial                        |
| Satureja hortensis        | 1 Astringent, bactericidal, antispasmodic |
| Dianthus deltoides        | 1 Antiseptic, analgesic                |
| Zingiber officinale       | 1 Anti-inflammatory                    |
| Althaea officinalis       | 1 Anti-inflammatory, enveloping, reparative |
| Melilotus officinalis     | 1 Anti-inflammatory, analgesic, antibacterial |
| Rheum rhaponticum        | 1 Anti-inflammatory, astringent, prevents tartar formation |
| Sanguisorba officinalis   | 1 Anti-inflammatory, hemostatic, analgesic, astringent, antiseptic |
| Sambucus nigra            | 1 Anti-inflammatory, analgesic         |
| Deproteinized hemoderivate of calf blood                               | 1 Protects tissues in hypoxia and nutritional deficiency, promotes tissue regeneration, accelerates and improves wound healing |
| Salt of Pomorie Lake      | 1 Anti-inflammatory, reparative, weak analgesic |

“Rotokan”, “Stomatophyt”, “Stomatophyt A”, “Phyto-kan-GNCLS”, “Stomat-phyto”, “Maraslavin”, “An-ginophyt”).
the oral cavity tissues [12, 18-23], which are the leading factors for application in dental practice. In addition, in inflammatory periodontal diseases, the oral mucosa is inflamed and sensitive to coarse food and drugs; therefore, the use of a semisolid dosage form is optimal in the treatment of such pathologies. Thus, despite the sufficiently wide range of topical dental preparations, all drugs should be prescribed only in the rational dosage forms, in which they maximize their therapeutic effect and minimize the possible side effects [24].

In Tab. 3 the structure of API and indications for use in dental gel formulations available at the pharmaceutical market and permitted for sale in Ukraine are summarized.

According to the results obtained (Tab. 3), there are 15 dental gels at the pharmaceutical market of Ukraine, of them only one is monopreparation, the rest are combined drugs.

### Table 3

THE STUDY OF THE COMPOSITION AND INDICATIONS FOR USE OF DENTAL GELS PRESENT AT THE PHARMACEUTICAL MARKET OF UKRAINE

| API                        | The name of the drug | Manufacturer                          | Pharmacotherapeutic group | Indications                                                                 |
|----------------------------|----------------------|---------------------------------------|---------------------------|-----------------------------------------------------------------------------|
| Metronidazole benzoate,   | Metroviol denta      | PJSC PF “Viola”, Ukraine              | Antiseptic drugs          | Infectious-inflammatory diseases of the periodontium and the oral mucosa; toothache of infectious origin |
| chlorhexidine gluconate    |                      |                                       |                           |                                                                             |
| Stomato-gel Zdorovia       |                      | PC Zdorovia LLC, Ukraine              | Antimicrobial and anti-     |                                                                             |
| Metronidazole denta        |                      | Arpimed Ltd., Republic of Armenia     | septic agents for topical  |                                                                             |
| Metrohex                   |                      | Group Pharmaceuticals Ltd., India      | application in dentistry   |                                                                             |
| Metrogel                   |                      |                                       |                           |                                                                             |
| Metrogyl Denta'            | Unique Pharmaceutical Laboratories, India | Preparations for the               |                           |                                                                             |
|                            |                      | treatment of protozoal infections     |                           |                                                                             |
| Dentagel'                  |                      | PJSC “Fitofarm”, Ukraine              |                           |                                                                             |
| Metrodent'                 |                      | Encube Ethicals Private Limited, India |                           |                                                                             |
| Metronidazole benzoate     | Metrozole denta      | Genom Biotech PVT. Ltd., India        | Antimicrobial and anti-     |                                                                             |
| Diclofenac sodium,         | Dicloran denta       | Unique Pharmaceutical Laboratories, India | septic agents for topical  |                                                                             |
| chlorhexidine gluconate    |                      |                                       | application in dentistry   |                                                                             |
| Choline salicylate,        | Cholisal             | Jelfa AT Pharm Factory, Poland        | Antiseptic drugs           | Inflammatory, ulcerative-necrotic, infectious and trophic lesions of the oral mucosa; use of dentures; minor surgery |
| cetalkonium chloride       |                      |                                       |                           |                                                                             |
| Chamomile flowers tincture | Kamistad             | Stada Artznimmittel AG, Germany       | Topical anesthetics       | Treatment of lesions of gums and the mucous membrane of the oral cavity; use of dentures; prevention of pain and discomfort caused by teething and orthodontic procedures |
| lidocaine hydrochloride,   | Camident-Zdorovia    | PC Zdorovia LLC, Ukraine              |                           |                                                                             |
| thymol                     |                      |                                       |                           |                                                                             |
Chamomile is used as a component of natural origin in dental gels in the form of tincture and extract, and as a local anesthetic, lidocaine hydrochloride. In addition, only 4 gels (including 1 domestic drug Kamident-Zdorovie, “PC Zdorovie” LLC) in indications for use have a recommendation for the treatment of pathologies or injuries of the mucous membrane caused by the use of a denture, which is very relevant today, taking into the prevalence of this procedure among patients of different age groups [7-10].

Based on the analysis of dental gel manufacturers it has been found that the market is import-dependent (73.3 %). Thus, by the number of drugs on offer India takes the first place (6), followed by Ukraine (4), Germany (3) and Poland and Armenia (1). However, according to the results of the analysis, domestic dental gels, unfortunately, do not have the original composition, and are often generic drugs of foreign production.

These dental gels according to the ATC-classification belong to the groups A01A B67** “Metroxidazole, combinations” (53.3 %) and A01A D11 “Others” (46.7 %) and are most often used in cases of infectious inflammatory diseases of the periodontium and the mucous membrane of the oral cavity. It should be noted that at the market there are absolutely no preparations in the form of gels for the prevention of caries (A01A A). The insufficient number of domestic products for use in the adaptation period during prosthetics at the pharmaceutical market is also a pressing issue. Considering etiopathogenesis of periodontal diseases and symptoms that occur when patients adapt to prostheses it is necessary to provide a medicinal product with the polyvalent action, namely the antimicrobial, anti-inflammatory, analgesic, hemostatic and reparative action. The main issue in the development of new dental gels is the choice of an antimicrobial agent that would protect against bacteria, without disrupting the normal flora of the oral cavity, contribute to the enhancement of the protective properties of saliva and strengthen the local immunity. However, according to the analysis of drugs in the form of dental gels, in group A01A B “Antimicrobial and antiseptic preparations for topical application in dentistry” only synthetic metronidazole-containing preparations are available.

Therefore, the data analyzed indicate the relevance of creating competitive domestic combined dental preparations for topical application, in particular gels, which would have a multivector effect and increase the effectiveness of pharmacotherapy of caries, infectious-inflammatory diseases of the periodontium and mucous membrane of the oral cavity, as well as prostheses-related pathologies, i.e. had a complex effect on both hard and soft tissues of the oral cavity.

**Conclusions**

1. The assortment of preparations for topical application in dentistry by dosage forms and composition has been analyzed. Dental gels (22.7 %), solutions and sprays (19.7 % each) mainly containing API of synthetic origin were found to be in the lead.

2. The comparative analysis of dental dosage forms for topical application has determined a significant advantage of gels in their consumer characteristics.

3. The composition of the manufacturing companies has been analyzed; the API structure and indications for use in dental gel form have been summarized. There is a high degree of import dependence of the market (73.3 %);
thus, among dental gels of domestic production there are only 4 products having the composition similar with gels of foreign production: Kamident-Zdorovia (Ukraine) – Kamistad (Germany); Metroviol Denta, Stomato-Gel Zdorovia and Dentagel (Ukraine) – Metronidazole Denta (Republic of Armenia), Metrohex, Metrogyl Denta and Metrodent (India).

4. The marketing research conducted has found a limited number of domestic dental gels at the pharmaceutical market of Ukraine. Due to the problem of the early loss of teeth and prosthetics, only 1 gel of the Ukrainian production is recommended for the treatment of pathologies or injuries of the mucous membrane caused by the use of dentures. In addition, there are no gel formulations available to prevent caries, which is a precursor to many oral diseases and one of the common causes of the tooth loss.

5. Therefore, a relevant direction of the pharmaceutical technology today is the search for effective API that would have a complex effect on the hard and soft tissues of the oral cavity, and development of new quality, competitive and affordable domestic drugs in the form of dental gels.

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