Interdisciplinary Evaluation of Phytotherapy Resource Calendula Officinalis L. in Patients with Tuberculosis and Combined Pathologies

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Abstract. The article presents a comprehensive analysis of the pharmacotherapeutic potential and marketing aspects of the use of medicinal products based on Calendula officinalis L. in patients with tuberculosis complicated by comorbid conditions. Particular attention is paid to the clinical feasibility of using calendula herbal preparations as part of palliative and supportive therapy, taking into account frequent lesions of the gastrointestinal tract, hepatobiliary system, mucous membranes, skin, respiratory tract and genitourinary system. Based on the results of the content analysis of registration information and the assortment of the Ukrainian market, the current calendula preparations were systematized by release forms, ATC classification and manufacturers. A SWOT marketing analysis was conducted to determine the strengths and weaknesses, opportunities and threats regarding the presence of this group of herbal remedies on the domestic pharmaceutical market. Regulatory challenges were considered and proposals for their inclusion in state support programs and clinical protocols of supportive treatment were substantiated. The authors emphasize the feasibility of wider use of Calendula officinalis L. in the pharmacotherapy of tuberculosis in order to improve the quality of life of patients and increase the effectiveness of the main treatment.

Keywords: Calendula officinalis L., tuberculosis, comorbidity, phytotherapy, SWOT analysis, herbal medicines, anti-inflammatory effect, ATC classification.

Introduction. Tuberculosis remains one of the most pressing medico-social problems of our time, despite modern strategies to combat this infection. According to the World Health Organization, more than 10 million new cases are recorded annually worldwide, and a significant share of patients have concomitant diseases that aggravate the course of the main pathology, complicate treatment and worsen quality of life [1].

In Ukraine, tuberculosis remains a serious challenge for the health-care system, given the high incidence, the spread of multidrug-resistant forms of the pathogen, unequal access to effective therapy, and the socio-economic vulnerability of patients [2–4].

One of the key problems of modern phthisiology is the high level of comorbidity among patients with tuberculosis. Lesions of the hepatobiliary system, the gastrointestinal tract, and extra-pulmonary respiratory organs, as well as secondary immune disorders, form a complex clinical profile requiring a multidisciplinary approach. Hepatotoxicity of anti-tuberculosis medicines, the development of dysbiosis and dyspeptic disorders, allergic reactions, depressive states and chronic fatigue necessitate concomitant therapy capable of reducing adverse effects of the main treatment, stabilizing functional systems and helping the body adapt to long-term medicinal exposure [5].

Against this background, interest is growing among researchers and practicing physicians in phytotherapeutic agents as part of supportive care. Herbal medicines – especially those with multicomponent plant extracts – have the potential for gentle, physiological correction of impaired functions, a reduction of toxic load on detoxification organs, and enhanced resistance. One of the most promising plants in this regard is Calendula officinalis L. (pot marigold) – well studied in pharmacognostic and clinical terms and traditionally used in folk and evidence-based medicine owing to its anti-inflammatory, antiseptic, choleretic, wound-healing and immunostimulating properties [6–11]. Use of calendula preparations can be justified at both outpatient and inpatient stages of tuberculosis treatment – to prevent complications, mitigate adverse effects of antibiotic therapy, and support the functions of the liver, digestive system, skin and mucous membranes. Combined herbal products in which calendula potentiates the action of other medicinal components are of particular value. At the same time, amid growing demand for phytotherapy, a systematic analysis is needed of

the Ukrainian market for Calendula officinalis L. preparations, their registration status, dosage forms, availability and reasonableness of inclusion in supportive-treatment schemes.

Thus, studying the current state of calendula use in the pharmacotherapy of tuberculosis with comorbid conditions – its market presence, regulatory status and clinical potential – is both relevant and necessary. Special attention in this study is devoted to a SWOT-marketing approach that makes it possible to assess the strengths and weaknesses of calendula-based phytomedicines and to identify opportunities for their further integration into modern clinical practice.

The purpose of the study was to conduct a comprehensive study of the pharmacotherapeutic potential of medicinal products based on Calendula officinalis L. (marigold), used in the maintenance therapy of patients with tuberculosis in combination with comorbid pathologies.

Special emphasis is placed on those clinical situations when patients have concomitant disorders of the gastrointestinal tract, hepatobiliary system, genitourinary system, respiratory organs, as well as manifestations of secondary immunodeficiency. The assessment of the feasibility of using herbal medicines based on marigolds in such cases is due to their pharmacological activity, in particular antiseptic, choleretic, reparative, immunomodulatory and anti-inflammatory properties.

An additional goal of the study is to identify and analyze factors that affect the effectiveness of implementing phytotherapy using Calendula officinalis L. preparations in clinical practice, which is accompanied by a study of the structure of their market offer, the availability of various forms of release, the dynamics of registration status and accessibility for the end consumer.

The application of marketing analysis methodology, in particular the structured analysis of strengths, weaknesses, opportunities, threats, allows not only to characterize the current state of the market of herbal preparations with marigolds in Ukraine, but also to formulate practical conclusions regarding their positioning in the schemes of concomitant therapy of patients with tuberculosis and comorbid conditions.

Thus, the study is aimed at an interdisciplinary assessment of the phytotherapeutic resource of Calendula officinalis in a complex clinical context, as well as at identifying ways to optimize the pharmaceutical provision of patients with tuberculosis with herbal remedies.

Materials and methods. In the process of preparing the study, an interdisciplinary approach was applied, combining elements of pharmacognostic, clinical and pharmacological, marketing and regulatory analysis in order to comprehensively study herbal medicines based on Calendula officinalis L. used in the treatment of concomitant pathologies in patients with tuberculosis.

1. Sources of information

The materials for the study were:

- open electronic databases of medicines registered in Ukraine (in particular, the State Register of Medicines of Ukraine, the electronic database “Compendium”, resources of the Ministry of Health of Ukraine);
- instructions for the medical use of calendula preparations;
- pharmaceutical market data on the availability, dosage forms and manufacturers of drugs;
- scientific literature covering the pharmacological properties of Calendula officinalis L.;
- statistical sources on the incidence of tuberculosis in Ukraine, official reports of the World Health Organization, the European Center for Disease Control and Prevention.

2. Marketing analysis of Calendula officinalis L. preparations.

A systematization of herbal medicines registered in Ukraine containing Calendula officinalis L. as the main or auxiliary active ingredient was carried out. All preparations were classified by dosage forms, Anatomical Therapeutic Chemical Classification (ATC), composition of active ingredients, presence of combinations with other phytocomponents and manufacturers.

3. SWOT analysis of herbal medicines Calendula officinalis L.

To assess the marketing potential of herbal medicines based on calendula, the SWOT analysis tool was used, which allows characterizing:

- ❖ strengths (properties and advantages of herbal medicines from calendula as part of concomitant therapy for tuberculosis);

- ❖ weaknesses (limited evidence base, regulatory barriers, insufficient inclusion in standardized treatment regimens);
- ❖ opportunities (expanding demand for herbal medicine, introduction into palliative medicine protocols, pharmacoeconomic advantages);
- ❖ threats (competition with synthetic drugs, reduction in the number of registered positions, risk of unavailability).

4. Visualization and statistics methods

Based on the collected information, analytical tables were formed on:

• quantitative composition of drugs by release forms;
• distribution by ATC groups, ICD-11 [12-13];
• main manufacturers and registration dates.

Also, pie charts were constructed, reflecting the specific weight of individual dosage forms, groups of use and the presence of combinations. Descriptive statistical methods (percentage, ranking) were used to analyze the market.

5. Content analysis method

A qualitative content analysis of pharmacological descriptions of drugs containing Calendula officinalis L. was carried out in order to assess the compliance of their pharmacological profile with the basic needs of patients with tuberculosis and concomitant pathologies (liver damage, gastrointestinal disorders, immune deficiency, dermatological and dental complications).

The research of the article is a fragment of research works of Lviv Medical Institute on the topic of "Improving the system of circulation of drugs during pharmacotherapy on the basis of evidentiary and forensic pharmacy, organization, technology, biopharmacy and pharmaceutical law" (state registration number 0120U105348, implementation period 2021-2026); Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law" on the topics "Multidisciplinary research of post-traumatic stress disorders during war among patients (primarily combatants)" (state registration number 0124U002540, implementation period 2024-2029) and "Interdisciplinary scientific and methodological research in the field of pharmaceuticals and veterinary medicine: innovations, modernization, technologies, regulation" (state registration number 0125U000598, implementation period 2025-2031) [14-19].

Results and discussion.

Pharmacological properties of Calendula officinalis L.

Medicines created on the basis of Calendula officinalis L. flowers (marigolds) are widely used in phytotherapy due to their multicomponent chemical composition, which provides a wide range of pharmacological activity. They exhibit a complex effect on the body, which is especially valuable in the treatment of patients with tuberculosis, who often suffer from combined lesions of various systems and organs.

The pharmacological activity of marigolds is due to the presence of biologically active substances, among which the main role is played by triterpene saponins, flavonoids (especially quercetin and isorhamnetin), essential oils, carotenoids (lutein), organic acids, coumarins, polysaccharides, as well as traces of alkaloids [20-21]:

- o Triterpene saponins have anti-inflammatory and reparative effects, promote tissue healing.
- o Flavonoids provide capillary-strengthening, antioxidant, choleretic and anti-inflammatory effects.
- o Carotenoids are involved in epithelial regeneration, protect mucous membranes.
- o Essential oils have an antiseptic effect, especially in conditions of inflammatory and purulent processes.
- o Polysaccharides have immunostimulant properties, activating macrophages and phagocytosis.

Data on the pharmacokinetics of Calendula officinalis L. in the human body are limited, but some studies indicate that flavonoids and saponins are well absorbed in the gastrointestinal tract, metabolized in the liver and excreted mainly with bile. When calendula ointments or infusions are applied externally, bioactive components accumulate in the epidermis and mucous membranes, exerting a local effect without significant systemic effects [22-26].

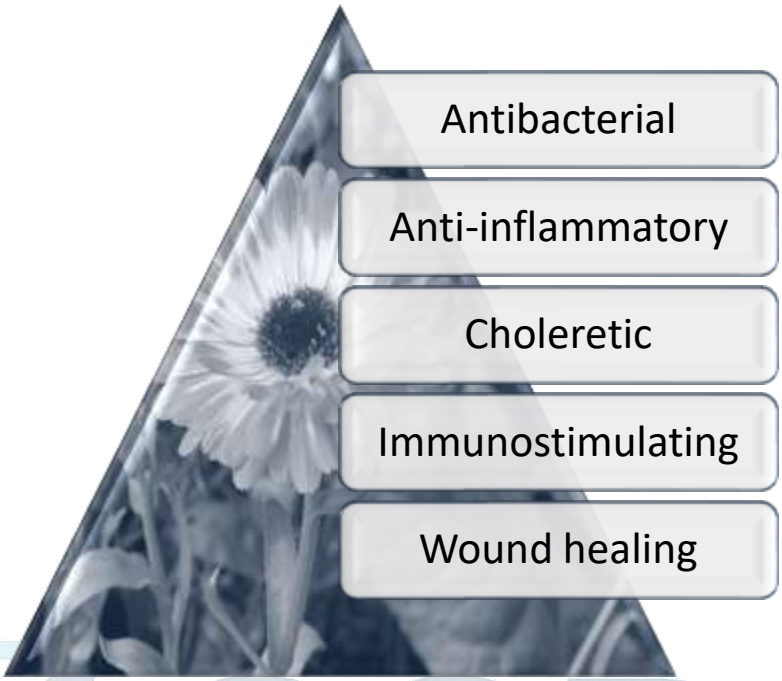

Fig. 1. Pharmacological effects of Calendula officinalis L. in the human body.

Calendula has a direct bactericidal and bacteriostatic effect on gram-positive and gram-negative microorganisms, in particular on Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli and Proteus vulgaris. This effect is especially important for the treatment of complications associated with bacterial lesions of the skin, mucous membranes of the mouth and throat, as well as for the prevention of secondary infections in patients with tuberculosis [27-28].

Anti-inflammatory activity is due to the inhibition of cyclooxygenase and lipoxygenase enzymes, which leads to a decrease in the synthesis of pro-inflammatory mediators, such as prostaglandins, leukotrienes and thromboxanes. The use of calendula preparations reduces swelling, redness, pain, and also helps to reduce the severity of chronic inflammation in various tissues and organs [29].

Calendula stimulates the formation and secretion of bile, which is important in hepatotoxicity of anti-tuberculosis therapy. Choleretic properties are combined with hepatoprotective action, contributing to the normalization of liver function, reducing stagnation in the biliary tract and improving fat digestion [30].

Herbal preparations Calendula officinalis L.

Herbal preparations from calendula activate nonspecific immune defense factors, in particular phagocytosis, macrophage activity and interleukin synthesis. This is especially important for people with weakened immunity, including those undergoing long-term antibiotic therapy or having concomitant immunodeficiency conditions.

Lesions of the mucous membrane of the oral cavity, pharynx and larynx in patients with tuberculosis are a common manifestation of both the underlying disease and a side effect of drugs. The use of calendula tincture, extracts and sprays with it has shown effectiveness in reducing pain, burning, dryness and inflammation. In such products as Rotokan, Phytodent, Homeovox, calendula plays a key role in healing the mucous membrane.

In patients with bronchopulmonary lesions, calendula as part of combined products (Bronchophyt, Phytobronhol) facilitates expectoration, reduces inflammation of the respiratory tract mucosa, and improves bronchial secretion.

From the digestive system, calendula exhibits gastroprotective and antispasmodic effects, which justifies its use in cases of dyspepsia, gastritis, enterocolitis – typical concomitant conditions

of tuberculosis. Products based on it (for example, Gastrophyte) improve appetite, normalize intestinal motility and promote regeneration of the gastrointestinal mucosa [31].

In dermatological practice, calendula preparations (Traumel C, Clotrex, Ugrin) demonstrate high effectiveness in the treatment of mycoses, eczema, folliculitis, which often occur against the background of antibiotic therapy or immunodeficiency states characteristic of tuberculosis.

Marketing analysis of herbal medicines Calendula officinalis L.

The pharmaceutical market of Ukraine is characterized by a significant variability of drugs containing Calendula officinalis L. (marigold) as the main or auxiliary active ingredient. In order to systematize the available spectrum of herbal medicines from calendula, an analysis of the state registration of the relevant products as of 2024 was carried out. The results obtained are given in the Table 1.

Table 1. Drugs with Calendula officinalis L. registered in Ukraine: form, composition, ATC code.

No.	Name of the drug	Dosage form, dosage	Main active ingredients	ATC-code
1.	Calendula flowers	Dry plant material, filter bags	Calendula officinalis L. flowers	R02AA20
2.	Calendula tincture	Solution for internal and external use	Ethanol extract of calendula flowers	D03AX
3.	Calendula ointment	Ointment for external use	Calendula tincture 0.1 g/g	D03AX
4.	Vagikal	Vaginal suppositories	Calendula officinalis 150 mg	G02CC
5.	Phytodent	Oral tincture	Calendula + chamomile + yarrow + rose hips, etc.	A01AD11
6.	Rotokan	Liquid extract for rinsing	Calendula + chamomile + yarrow	A01AD11
7.	Bronhofit	Herbal collection	Calendula + sweet + linden + sage, etc.	R05CA10
8.	Gastrofit	Herbal collection	Calendula + mint + nettle + chamomile, etc.	A16AX
9.	Phytonephrol	Herbal collection	Calendula + bearberry + eleutherococcus	G04BX
10.	Elekasol	Oral drops	Calendula + chamomile + sage + eucalyptus	A16AX25
11.	Tazalok	Oral tincture	Calendula + parsley + celery	G02CX10
12.	Prostalad	Ointment	Calendula + St. John's wort + echinacea + arnica, etc.	G04CX10
13.	Klotrex	Tincture	Calendula + gentamicin + clotrimazole + yarrow	D01AC
14.	Ugrin	Ointment / gel / solution	Calendula + lavender + chamomile + tansy	D11AX
15.	Traumeel S	Homeopathic tablets	Calendula + arnica + echinacea + belladonna, etc.	M02AX10 / M09AX19
16.	Sedative PC	Homeopathic tablets	Calendula + belladonna + viburnum + aconite, etc.	N05CM50
17.	Homeovox	Dosage form, dosage	Calendula + belladonna + ferrum phosphoricum, etc.	R07AX10

The following is an analysis of the distribution by dosage form (Fig. 2). The market for calendula medicines in Ukraine is represented by a wide range of forms, including:

• Tinctures and liquid extracts – the most common form (30% of the total).

- Herbal preparations (phytopreparations) – 26%.
- Ointments and gels – 17%.
- Suppositories – 4%.
- Tablets (including homeopathic) – 13%.
- Injection solutions and drops for internal use – 10%.

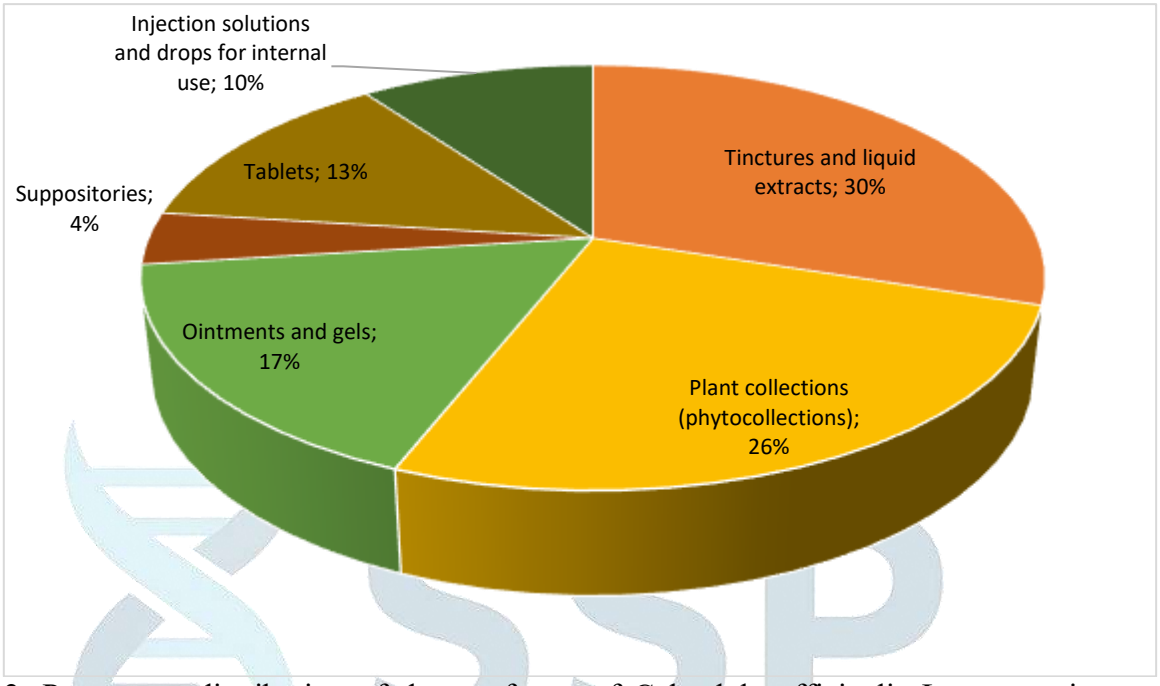

Fig. 2. Percentage distribution of dosage forms of Calendula officinalis L. preparations on the pharmaceutical market of Ukraine

Below are combinations with other active ingredients (Fig. 3).

Most preparations with Calendula officinalis L. are multicomponent. Most often, calendula is combined with the following phytocomponents:

Chamomile (Matricaria recutita) – in anti-inflammatory and antiseptic preparations (Rotokan, Elekasol, Ugrin)	
Peppermint (Mentha piperita) – in soothing and gastroprotective agents (Gastrofit, Bronchofit)	
Yarrow (Achillea millefolium) – in antimicrobial and reparative preparations (Phytodent, Clotrex)	

Licorice (Glycyrrhiza glabra) – in mucolytic and anti-inflammatory combinations (Phytobronhol, Bronchofit)	
Echinacea, arnica, belladonna – in anti-inflammatory homeopathic preparations (Traumeel S, Sedative PC)	

Fig. 3. Combinations of Calendula officinalis L. with other phytocomponents.

The presence of such combinations allows to enhance the clinical effect of calendula and adapt the preparations to a wide range of symptoms [32-36].

The following is a classification according to the ATC.

According to the international ATC classification, calendula preparations are divided as follows:

- A01A – dental products (Phytodent, Rotokan)
- A05A/A16A – hepatoprotectors, other metabolic products (Phytohepatol, Elekasol)
- R05C – cough and cold products (Bronchophyt, Phytobronhol)
- D03A/D01A/D11A – dermatological products (Calendula ointment, Clotrex, Ugrin)
- G02C/G04C – gynecological and urological products (Vagikal, Prostalad)
- N05C/R07A/M02A/M09A – homeopathic and anti-inflammatory (Sedative PC, Traumel S)

This classification confirms the multisystem pharmacological profile of Calendula officinalis L. and its widely used in the maintenance therapy of patients with tuberculosis and concomitant diseases.

SWOT analysis of herbal preparations of Calendula officinalis L.

In order to comprehensively assess the market prospects of herbal preparations based on Calendula officinalis L. in the pharmacotherapy of patients with tuberculosis and concomitant disorders, a SWOT analysis was conducted (Fig. 4). This method allows to systematize both the internal characteristics of the drugs (their advantages and disadvantages) and external factors that may contribute to or hinder their effective promotion and inclusion in clinical practice [37-41].

Strengths	Weaknesses
1. Natural origin and environmental safety. Calendula officinalis L. is a well-known medicinal plant with a long history of use in traditional medicine. Its natural origin provides a high level of biocompatibility and a low probability of severe side effects. **2. Multifactorial pharmacological action.** Calendula preparations have a wide range of therapeutic activity: anti-inflammatory, antiseptic, choleretic, reparative,	**1. Limited evidence base for specific nosologies.** Despite the presence of numerous clinical observations, full-fledged randomized controlled trials on the effectiveness of calendula in the treatment of specific conditions (for example, hepatotoxicity in tuberculosis) are rare or absent. **2. Absence in evidence-based medicine protocols.**

immunostimulating, antimicrobial. This allows them to be used in various clinical situations accompanying tuberculosis. **3. Availability of multicomponent preparations.** Most calendula preparations are presented in combination with other medicinal plants (chamomile, mint, yarrow, licorice, sage), which enhances the overall effect, makes therapy more targeted and adaptable to the needs of a particular patient. **4. Variety of dosage forms.** The drugs are available in the form of tinctures, ointments, suppositories, herbal teas, gels, drops, tablets, and homeopathic remedies, which provides flexibility in prescribing and individualization of therapy.	Calendula preparations are practically not included in national or international clinical guidelines and protocols for the treatment of tuberculosis, which limits their official use in state medical institutions. **3. Market instability.** Some preparations have lost registration or have been withdrawn from production, which creates risks for long-term use in treatment regimens. **4. High variability in quality.** The production of herbal remedies is less regulated compared to synthetic drugs, which can lead to different concentrations of active substances in products from different manufacturers.
Opportunities	**Threats**
1. Growing demand for natural remedies. The global trend towards the use of herbal medicine, organic products and "soft" remedies increases the interest of both patients and doctors in herbal medicines, in particular those with a mild, regenerative and anti-inflammatory effect. **2. Potential in palliative and supportive therapy of tuberculosis.** Calendula officinalis L. may be effective in reducing the side effects of antibiotics, alleviating symptoms from the gastrointestinal tract, mucous membranes, skin, as well as in improving the quality of life of patients. **3. Possibility of inclusion in new complex therapy protocols.** Inclusion of herbal medicine in individualized treatment regimens for multidrug-resistant tuberculosis, especially in cases where long-term use of hepatotoxic drugs is not possible. **4. Potential for export expansion.** Ukrainian producers of herbal remedies can promote calendula products to foreign markets, in particular to Europe and Asia, where there is a stable demand for herbal remedies.	**1. Competition from synthetic drugs.** The market is dominated by antibacterial, anti-inflammatory, hepatoprotective agents with clearly proven effectiveness, which reduces the clinical motivation to prescribe herbal remedies without official indications. **2. Regulatory uncertainty.** Lack of unified requirements for herbal remedies, different interpretations of herbal remedies in regulatory documents, difficulties with registering new forms. **3. Risk of loss of registration and shortage.** Some calendula preparations have already been withdrawn from circulation or have lost registration (for example, Flora, Venen Theiss gel, Alorom), which indicates the instability of the market presence of this group of drugs. **4. Skepticism on the part of the medical community.** In some professional circles, there is a prejudice against herbal medicine as an auxiliary or ineffective link in the treatment of serious infectious diseases, such as tuberculosis.

Fig. 4. SWOT matrix analysis of herbal medicines Calendula officinalis L.

Thus, herbal medicines based on Calendula officinalis L. have real potential for expanded use in pharmacotherapy of concomitant disorders in tuberculosis. However, their widespread implementation requires further standardization, expansion of the evidence base, and integration into clinical protocols and national programs of supportive treatment [42-44].

Analysis of the market of herbal medicines based on Calendula officinalis L. in Ukraine demonstrates the stable presence of drugs of this group in pharmaceutical circulation, but also reveals

a number of dynamic changes associated with transformations of the regulatory environment, changes in consumer preferences, and competitive pressure from synthetic drugs.

According to registration data, more than 20 medicinal products containing Calendula officinalis L. flowers in pure form or as part of multi-component herbal preparations, tinctures, ointments, suppositories or tablet forms are available on the domestic market. Table 2 provides examples of the most common preparations, indicating the dosage form and manufacturer.

Table 2. Preparations with Calendula officinalis L. registered in Ukraine: dosage form and manufacturer.

No.	Name of the drug	Dosage form	Manufacturer
1.	Calendula flowers	Dry herbal flowers	PJSC "Liktravy"
2.	Calendula tincture	Tincture	PJSC "Pharmaceutical Factory "Viola""
3.	Calendula ointment	Ointment	PJSC "Halychpharm"
4.	Vagikal	Vaginal suppositories	Farmina Ltd (Poland)
5.	Rotokan	Liquid extract	PJSC "Halychpharm"
6.	Phytodent	Tincture	PLC "Phytobiotechnologies"
7.	Bronhofit	Herbal collection	PLC "Pharmaceutical Company Zdorovya"
8.	Gastrofit	Phytocollection	PJSC "Liktravy"
9.	Tazalok	Oral drops	PLC "EKOPHARM"
10.	Ugrin	Tincture	PLC "SVC" "Biosphere"
11.	Klotrex	Ointment	PLC "Kusum Pharm"
12.	Prostalad	Tincture	PLC "Biolik"
13.	Elekasol	Phytocollection	PJSC "Liktravy"
14.	Phytonephrol	Phytocollection	PJSC "Liktravy"
15.	Traumeel S	Ointment / gel / injection form	Biologische Heilmittel Heel GmbH

The following pharmaceutical companies are most actively represented on the market of calendula herbal medicines:

- PJSC "Galychpharm" (part of the "Arterium" corporation) – specializes in the production of plant-based extracts and tinctures, in particular Rotokan, calendula tinctures, ointments.
- PrJSC "Liktravy" - a leading manufacturer of herbal preparations (Gastrofit, Phytonephrol, Elekasol) containing Calendula officinalis L. in combination with other medicinal plants.
- LLC "Pharmaceutical Company Zdorovya" – produces preparations (Bronhofit) with the inclusion of calendula for the treatment of respiratory diseases.
- LLC "SVC" Biosphere" – produces tinctures of combined action for external and internal use.
- LLC "EKOPHARM", LLC "Biolik", LLC "Phytobiotechnologies" – specialize in complex multicomponent preparations based on calendula.

There are also imported manufacturers on the Ukrainian market, for example, Farmina Ltd (Poland) – manufacturer of Vagical suppositories, and Heel GmbH (Germany) – manufacturer of homeopathic remedies of the Traumeel C series.

Market trends

1. Reduction in the number of monopreparations. Compared to previous years, there is a decrease in the number of preparations where Calendula officinalis L. is the only active ingredient. Some of these preparations have lost registration or are not represented in pharmacies, for example, Alorom ointment, Flora tincture, Venen Theiss gel.

2. Growth in the number of combined preparations. Current market dynamics demonstrate a tendency to expand the range of herbal preparations with combined action. Calendula is most often used as part of a multicomponent formula that provides a synergistic effect – these include Tazalok, Prostalad, Ugrin, Bronchofit, Gastrofit.

3. Active re-registration and updating of dossiers. Some manufacturers are actively re-registering their products, taking into account the updated legislative requirements for the quality, safety and evidence of herbal remedies. This creates both temporary difficulties (loss of registration of old forms) and prospects for the emergence of new drugs adapted to modern standards.

4. Demand for topical forms. Among patients undergoing anti-tuberculosis therapy, topical agents are in high demand: ointments, tinctures, rinse solutions, suppositories. This is explained by the high frequency of stomatitis, gingivitis, dermatitis on the background of antibiotic therapy.

Thus, the Ukrainian pharmaceutical market offers a significant number of drugs based on Calendula officinalis L., which are actively used in the practice of supportive herbal therapy. The growing interest in natural remedies, the development of local production and export potential create a positive environment for the further integration of calendula into clinical practice.

Studying the regulatory status of Calendula officinalis L.-based drugs in Ukraine is an important component of the overall analysis of their market stability and prospects for inclusion in clinical practice [45-46]. The availability of phytotherapeutic agents is determined not only by their availability on the market, but also by the validity of registration certificates, compliance with modern requirements for quality, safety and efficacy, as well as the ability of manufacturers to maintain the continuity of the registration process in the face of changes in legislation (Table 3).

Table 3. Registration status of herbal medicines with Calendula officinalis L. in Ukraine.

No.	Name of the drug	Registration certificate number	Validity period (from / to)	Status
1.	Calendula tincture	UA/3565/01/01	22.12.2020 – valid	Active registration
2.	Calendula ointment	UA/3546/01/01	23.04.2020 – valid	Active registration
3.	Rotokan	UA/4607/01/01	23.03.2021 – valid	Active registration
4.	Phytodent	UA/3681/01/01	27.02.2020 – valid	Active registration
5.	Bronhofit	UA/3546/01/01	23.04.2020 – valid	Active registration
6.	Vagikal	UA/5821/01/01	15.03.2022 – valid	Active registration
7.	Prostalad	UA/1194/01/01	13.06.2019 – valid	Active registration
8.	Tazalok	UA/8499/01/01	26.04.2018 – valid	Active registration
9.	Elekasol	UA/5757/01/01	21.06.2016 – valid	Active registration
10.	Ugrin	UA/8220/01/01	20.11.2018 – valid	Active registration
11.	Homeovox	UA/9316/01/01	26.04.2019 – valid	Active registration
12.	Traumeel S	UA/5934/01/01 – 04/01	19.05.2017 – valid	Active registration
13.	Alorom	—	—	Re-registration
14.	Venen Theiss gel	—	—	Re-registration
15.	Flora	—	—	Re-registration
16.	Heliskan	—	—	Re-registration
17.	Gynecofit	—	—	Re-registration

Analysis of the registration status of calendula preparations in Ukraine

In general, the vast majority of preparations containing Calendula officinalis L. retain valid registration in Ukraine and are present on the pharmaceutical market. These include both monopreparations (tincture, ointment) and combined herbal remedies (collections, tinctures, suppositories, homeopathic remedies). This indicates a stable demand and pharmacotherapeutic feasibility of using this medicinal plant in medical practice.

At the same time, it should be noted that some of the products were removed from the register or did not receive re-registration after the expiration of the previous validity period. In particular, the registration certificates of such products as Alorom, Flora, Venen Theiss gel, Gynecofit, Heliscan, Phytokan-GNTSLS, which were previously actively used as local antiseptic or gynecological products, have lost their validity.

The reasons for losing registration can be different: unprofitability of production, decrease in demand, change of production lines, increase in requirements for the quality of documentary support or non-compliance with modern criteria of evidence.

Regulatory challenges

1. Restrictions on dosage forms

Some traditional forms (ointments, alcohol tinctures, homeopathic drops) face complications during re-registration due to changes in requirements for toxicological and clinical documentation. This limits the expansion of the range of herbal medicines or leads to their temporary disappearance from the pharmacy chain.

2. Changes in requirements for evidence

Updated regulatory approaches, in particular the requirements of the State Expert Center of the Ministry of Health of Ukraine, require a higher quality of the evidence base regarding the effectiveness and safety of medicines, even of herbal origin. This increases the burden on manufacturers, who must adapt documentation and pharmacovigilance to international standards.

3. Lack of preferences for herbal remedies in public procurement

Herbal remedies are usually not included in the lists of medicines required for procurement within the framework of public programs, which significantly limits their availability for patients receiving treatment in municipal or specialized anti-tuberculosis institutions.

Thus, although most preparations with Calendula officinalis L. in Ukraine remain available and registered, their regulatory environment is complex and dynamic. The need for standardization, increased transparency of requirements and support for domestic manufacturers of herbal remedies is an important condition for preserving the phytotherapeutic potential of calendula in medical practice, in particular in the supportive treatment of tuberculosis and related disorders.

Tuberculosis remains a severe and long-term infectious disease, which is often accompanied by the development of comorbid pathologies associated with both direct damage to organs and systems by Mycobacterium tuberculosis and side effects of anti-tuberculosis therapy. Lesions of the gastrointestinal tract, hepatobiliary system, mucous membranes of the oral cavity, skin, genitourinary system, and respiratory organs are especially common. In this regard, there is a growing need for a comprehensive approach to treatment, which includes not only specific antibacterial therapy, but also concomitant, supportive and palliative care.

Clinical feasibility of inclusion in pharmacotherapy regimens

Phytopreparations based on Calendula officinalis L. have a wide range of pharmacological properties, which allow them to be used as part of palliative and symptomatic therapy regimens. Their use is clinically feasible due to:

- good tolerability and natural origin;
- anti-inflammatory, antiseptic, immunostimulating and reparative effects;
- possibility of local or systemic application depending on the form;
- compatibility with anti-tuberculosis drugs;
- reduction in the frequency of complications from the gastrointestinal tract, liver, mucous membranes.

In patients with tuberculosis, phytotherapy using calendula can play a role in reducing inflammation, accelerating the repair of mucous membranes and skin, normalizing liver function, reducing side effects of antibiotic therapy, as well as improving general well-being.

Examples of the use of calendula forms for concomitant therapy

1. Gastrointestinal tract (gastrointestinal disorders)

- Gastrophyte (herbal collection): contains calendula flowers, mint, nettle, chamomile, St. John's wort. It is used for dyspepsia, gastritis, decreased appetite and liver disorders that often accompany long-term use of antibiotics.
- Calendula tincture: in small doses can help normalize motility, stimulate bile secretion, reduce pain in gastritis and enterocolitis.

2. Respiratory organs, concomitant bronchitis and respiratory infections

- Bronhofit, Phytobronhol: contains calendula, licorice, linden, sage. Used for prolonged cough, bronchitis, pharyngitis and laryngitis. Promote expectoration, soften mucous membranes and reduce inflammation.

3. Gynecological pathology

- Vagical (suppositories): contains standardized calendula extract, used for colpitis, cervicitis, bacterial vaginosis. Topical use in women with pelvic tuberculosis or with reduced immunity.
- Tazalok (drops): a multicomponent herbal remedy from calendula, parsley, celery, which has a mild hormone-regulating effect.

4. Dental practice

- Rotokan: liquid extract of calendula, chamomile and yarrow. Used for rinsing with gingivitis, stomatitis, periodontitis. Quickly reduces inflammation and pain in the oral cavity.
- Phytodent: tincture, effective for chronic stomatitis, inflammation of the gums, cracks in the oral mucosa.

5. Dermatological manifestations

- Traumeel C: ointment/gel based on calendula, arnica, echinacea. It has anti-inflammatory, analgesic and reparative effects, is used for eczema, dermatitis, abscesses.
- Clotrex: a combined ointment of calendula, gentamicin, yarrow, clotrimazole – effective for mycoses, pustular skin lesions, which often occur in patients with secondary immunodeficiency.

Argumentation of the importance of the availability of such products in public procurement

Phytopreparations based on Calendula officinalis L. are an important part of palliative and supportive pharmacotherapy in the treatment of tuberculosis. Their wide clinical use and positive impact on the quality of life of patients justify the need to include individual items in the lists recommended for procurement from the state or local budget.

Among the advantages of this approach:

- ✓ Pharmacoeconomic feasibility – most phytopreparations have a low cost compared to synthetic analogues.
- ✓ Improving adherence to treatment – reducing side effects helps reduce the risk of interruption of the main anti-tuberculosis therapy.
- ✓ Comprehensive support of the body – the effect on various systems (liver, immunity, skin, mucous membranes) improves the general condition of patients.
- ✓ Domestic production – the vast majority of drugs are produced in Ukraine, which reduces logistical and currency risks.

Thus, the inclusion of herbal remedies from Calendula officinalis L. in state health care programs could significantly improve the effectiveness of treatment of patients with tuberculosis, especially in conditions of high comorbidity and polypharmacy, characteristic of this category of patients.

Content analysis of herbal medicines with Calendula officinalis L.

As part of the study, a qualitative content analysis of instructions for medical use of herbal medicines containing Calendula officinalis L. registered in Ukraine was conducted. The aim of the

analysis was to compare the declared pharmacological properties of the drugs with the needs of patients with tuberculosis with concomitant comorbid conditions [47-51].

The results of the analysis showed that the vast majority of drugs contain in their descriptions such pharmacological effects as: anti-inflammatory effect (100% of drugs), antiseptic activity (85%), choleretic effect (52%), reparative/wound healing (78%), immunostimulating (41%), and antispasmodic (33%). Most of them are recommended for use in stomatitis, gingivitis, gastritis, cholecystitis, bronchitis, skin inflammations, which correlates with typical complications and background conditions in patients with tuberculosis.

Multicomponent preparations, where calendula is combined with chamomile, yarrow, mint, St. John's wort and licorice, are particularly illustrative. Such combinations enhance the anti-inflammatory and antimicrobial effect, while contributing to the normalization of gastrointestinal tract function, reducing side effects of antibiotic therapy and improving the general condition of patients.

Thus, the content analysis confirmed that the pharmacological profile of preparations based on Calendula officinalis L. meets the needs for supportive and palliative therapy of patients with tuberculosis, in particular in the presence of liver lesions, gastrointestinal disorders, immune deficiency, dermatological and dental complications.

Conclusions. The results of the analysis confirm the feasibility and prospects of using herbal medicines based on Calendula officinalis L. as a component of palliative, supportive and symptomatic therapy in patients with tuberculosis with comorbid pathologies. Due to its multicomponent composition and multivector pharmacological activity, calendula shows significant therapeutic potential in the fields of gastroenterology, dermatology, pulmonology, gynecology, dentistry and hepatology, which is extremely relevant for patients with tuberculosis who require an individualized approach to treatment and support of functional body systems.

Calendula medicines available on the Ukrainian market cover a wide range of release forms and combinations with other phytocomponents. This allows for flexible adaptation of therapy to the specific clinical needs of patients. At the same time, there is a decrease in the number of monopreparations, partial losses of registrations, as well as an uneven presence of herbal remedies in treatment protocols. At the same time, the market maintains active dynamics and orientation towards combined forms, which corresponds to the global trend towards enhancing the effect by combining several medicinal plants.

The conducted SWOT analysis demonstrated that herbal medicines with Calendula officinalis L. have a number of significant advantages - natural origin, good tolerability, multifactorial action, affordable cost, but face barriers related to the limited evidence base and regulatory instability. In the context of the growing demand for natural remedies and the relevance of palliative care, Calendula officinalis L. may well take a more significant position in the schemes of concomitant pharmacotherapy of tuberculosis.

Prospects for further research:

- Conducting randomized controlled trials of the effectiveness of calendula preparations in patients with tuberculosis and concomitant conditions (dyspepsia, gingivitis, dermatitis, hepatotoxicity).
- Assessment of the clinical and economic effectiveness of including herbal remedies in palliative care protocols for tuberculosis.
- Creation of new combined forms with standardized composition, focused on the needs of patients with chronic co-infectious pathology.

Proposals for regulatory authorities:

1. Promote the registration of domestic herbal remedies based on calendula, simplifying the procedures for confirming the effectiveness of remedies with proven long-term clinical practice.

2. Consider the possibility of including certain herbal remedies in national palliative care protocols, in particular in the field of anti-tuberculosis care.

3. Provide for the participation of herbal remedies in state and local procurement programs in cases of registered indications and positive pharmacoeconomic assessment.

4. Integrate phytotherapeutic components into the concept of pharmaceutical care, in particular by developing local recommendations for family doctors and phthisiologists on the use of calendula preparations as part of maintenance treatment.

Thus, Calendula officinalis L. has a reasonable potential to be included in the comprehensive support of tuberculosis pharmacotherapy, contributing not only to the relief of symptoms, but also to the improvement of the quality of life of patients, providing a more humanistic, biopsychosocial approach to the treatment of a complex infectious pathology.

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