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ANALYSIS OF THE STATUS OF PROVISION OF PHARMACEUTICAL CARE TO PATIENTS WITH MULTIPLE SCLEROSIS IN UKRAINE

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Considering modern approaches to the treatment of chronic non-communicable diseases, as well as the experience of active involvement of pharmacists in multidisciplinary teams of healthcare professionals, it is relevant to determine the professional role of a pharmacist in teams providing medical and social care to patients with multiple sclerosis (MS).
The aim: *to analyze the state of pharmaceutical care (PC) provision to Ukrainian patients with multiple sclerosis (MS).*
Materials and methods. *The study is based on scientific works of domestic and foreign researchers on this problem, regulatory documents on the provision of medical care to patients with MS and the results of a sociological survey of patients diagnosed with MS. The study used methods of scientific information search, narrative approach, generalization, survey, statistical analysis, and others.*
Results. *The pharmaceutical component of the medical care process was determined and a list of drugs used in the complex therapy of MS was determined: H02AB – glucocorticoids, L01BB – structural purine analogues, L01FA – CD 20 inhibitors, L03AB – interferons, L04AA – selective immunosuppressants, L04AG – monoclonal antibodies, L04AX – other immunosuppressants.*
The analysis of the availability of DMT drugs showed that only 75% of the recommended drugs are physically available in Ukraine, with drugs with lower efficacy prevailing. The low availability of highly effective drugs (drugs) of the 3rd category for Ukrainian patients with MS is due to the lack of state funding for their purchase, which makes treatment with such drugs financially burdensome for patients.
The survey found that 64.5% of patients would like to receive additional support from pharmacists. Possible elements of pharmaceutical care that are important for patients with MS were identified, such as counselling, coordination with public organizations, explanation of new treatment options, and symptom monitoring.
When assessing patients' adherence to PC, factors such as age, gender, location, displaced status, work restrictions, or time since diagnosis did not significantly influence patients' positive attitudes. Furthermore, these factors did not influence patients' preferences for preferred pharmacist interaction format (face-to-face, mixed, or telepharmacy).
Conclusions: *There is a need to expand the availability and update the registration of drugs for the treatment of MS. Patients with MS have a positive attitude towards pharmaceutical care, but need more awareness of its possibilities. Social status affects the perception of the need for pharmaceutical care and the choice of the format of its provision*
Keywords: multiple sclerosis, pharmaceutical care, drugs, pharmacist

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1. Introduction

Currently, approximately 2.9 million people worldwide suffer from multiple sclerosis (MS) [1]. MS is a chronic inflammatory, demyelinating and neurodegenerative disease of the central nervous system, which usually begins in the third or fourth decade of life. The disease has a complex etiology, and its causes are not yet fully understood. However, it is known that it is one of the main causes of non-traumatic neurological disability in young people, leading to significant socio-economic consequences and the need for lifelong support and treatment [2, 3]. The development of MS can be caused by a combination of different factors: immunological, environmental, geographical, genetic, vitamin D levels, smoking, obesity, infectious factors, etc. [3]. There is also a connection between MS, its course and the person's stress state [4, 5].

MS therapy is always complex, as the disease can cause a variety of symptoms, including changes in sensation, vision problems, muscle weakness, depression, coordination and speech difficulties, severe fatigue, cognitive impairment, and balance problems. In addition, MS causes mobility impairment and disability in more severe cases. Treatment begins from the moment of final diagnosis and continues throughout life - since MS is one of those diseases that cannot be completely cured. Modern therapy only allows you to successfully control the symptoms of MS, improve the functional and emotional state of the patient [6, 7].

Given the above, the scientific community is actively searching for effective treatments for this disease, because all currently available treatments are aimed only at slowing the progression of MS, reducing the frequency of exacerbations, and alleviating symptoms [7, 8].

Before the full-scale war in Ukraine, according to unofficial statistics, there were about 21 thousand patients with MS. MS has certain geographical features [9]. Howev-

er, it is worth noting that as of today, there is no official registry of patients with MS in Ukraine, and therefore, there are no official statistics on the prevalence and incidence. According to the International MS Federation, the relevant figures for Ukraine are 3.7 per 100 thousand population [1].

Therefore, following modern approaches to the treatment of chronic non-communicable diseases [10, 11], as well as the experience [12, 13] of the active involvement of pharmacists in the work of a multidisciplinary team (MDT) of health care professionals (HP), it is relevant to determine the functional content of the pharmacist's role in multidisciplinary teams that provide medical and social care to patients with MS. The relevance of the above-mentioned studies is added by the Resolution CM/Res (2020)3 of the European Commission [14] on measures within the framework of the planned activities of pharmacy institutions in European countries to provide FD in the structure of medical care (MD) in HC institutions and pharmacies, which will contribute to improving adherence to treatment, timely diagnosis of diseases at earlier stages, referral of patients to a doctor and improving the quality of drug provision.

The aim – analysis of the state of pharmaceutical care for Ukrainian patients with multiple sclerosis.

2. Research planning (methodology)

The study was conducted in several stages, which are presented in Table 1.

In the first stage, a narrative review was conducted to form a comprehensive description and interpretation of previously published work on a selected topic, which provides a flexible and precise approach to the analysis and interpretation of the literature [15]. Despite the lack of agreed-upon guidelines for reporting a narrative review [15], we followed a standard chronological order for conducting the review and included four common elements: justification for the narrative review; clarity of the review boundaries (time) and definitions (keywords); justification of inclusion and exclusion criteria; details of the analysis and interpretation.

Table 1

Stages of the study and their description

Stage	Description of the activities
Narrative review of scientific literature and regulatory documents regulating the provision of MD to MS patients for a general understanding of the relevance of conducting research on the outlined topic	Formation of a detailed description and interpretation of previously published works on the selected topic and analysis of regulatory and legal documents (RLD) that regulate the provision of medical care for MS. To analyze the RLD of Ukraine regarding the provision of MC to patients with MS and its pharmaceutical component, a search for documents was conducted on the websites of the Verkhovna Rada of Ukraine in the section «Legislation», subsection «Regulatory and legal framework of Ukraine» (35 sources – Laws of Ukraine, Resolutions of the Cabinet of Ministers of Ukraine, Orders of the Ministry of Health of Ukraine) and the State Expert Center of the Ministry of Health of Ukraine in the section «Standardization in the field of health care», subsection «Standardization of medical care» (10 sources) using the keywords «medical guarantee programs», «multiple sclerosis», «medicines» for the last 10 years. In total, 15 documents were selected for processing that had the last update date and were valid at the time of writing the article
Structuring information on the organization of providing comprehensive MC for MS and analysis of pharmaceutical provision of DMT	By analyzing the selected at the previous stage of the RLD, the pharmaceutical component was structured as part of the provision of comprehensive MD to Ukrainian MS patients with further analysis of the state of pharmaceutical provision of disease-modifying therapy (DMT). The presence of registration in the State Register of Medicines of Ukraine, which are presented in the specified component, was checked and data on the possibility of their procurement for budget funds of drugs of various levels of effectiveness from the specified list were checked
Study of the availability of DMT drugs based on a patient survey	To establish the actual state of pharmaceutical provision of DMT patients with MS, a questionnaire was developed, containing 4 blocks of questions. The first block of questions was aimed at determining the socio-demographic characteristics of the respondents – gender, age, social status, place of residence, form of MS at the time of the survey. The questions of the second block of the questionnaire concerned the problems of providing MD and corresponding pharmaceutical provision to patients with MS during the war. The third block of questions was aimed at clarifying the structure and assessment of the level of access to PC, the fourth block was necessary for the preferences of patients' opinions regarding the possible expansion of pharmaceutical services (possible functionality of a pharmacist in MDT). Members of the Charitable Organization "Fund for Assistance to People Suffering from Multiple Sclerosis "99 PROBLEMS" were involved in the testing of the questionnaire. The survey was conducted using Google Forms from May 2024 to January 2025. 121 respondents who had been diagnosed with MS within the last 5 years participated
Processing survey results and designing PC by expanding the functionality of pharmacists	The results were accumulated and systematized in Microsoft Office Excel spreadsheets. To process the results, descriptive statistics methods and the nonparametric chi-square (χ^2) test were used to test the statistical significance of the relationships between the features. Since some categorical variables had small subgroups, an additional χ^2 with a likelihood ratio chi-square was calculated. The level of statistical significance was determined at $p < 0.05$. Degrees of freedom (*df*) were calculated according to the number of response options in the categories. Calculation of χ^2 and p-values was performed using the STATISTICA program.13. The design of the PC model for MS patients was carried out based on the results of the previous stages and the preferences of the patients obtained as a result of their survey
Final stage	Drawing conclusions, identifying limitations and research prospects

Rationale for a narrative review.

This method was chosen due to its flexibility in analyzing a wide range of literature sources, including legislative documents, scientific publications, international treatment protocols, and statistical data [15]. The presented results of the review aim to summarize the current state of pharmaceutical care for patients with MS.

Defining the boundaries of the review.

Time frame: The study covers the last 10 years (2014–2024), as this period is characterized by active development of the legislative framework regarding medical guarantees, changes in procurement policy, introduction of new medicines and adaptation of European standards for MS treatment in Ukraine.

Definition of keywords: Keywords for searching and analyzing documents: multiple sclerosis, MS therapy, pharmaceutical care, medicines, medical guarantee programs for MS patients, State Register of Medicines.

Justification of inclusion and exclusion criteria.

Inclusion criteria: publications in Ukrainian and English; scientific publications and reviews (Scopus, PubMed, Web of Science) analyzing MS therapy and its pharmaceutical provision; official regulatory documents regulating treatment and provision of medicines in Ukraine; clinical recommendations and protocols for MS treatment (Ukrainian and international, for example, recommendations of the German Society of Neurology); statistical reports of the Ministry of Health of Ukraine on the prevalence of MS and state procurement of medicines.

Exclusion criteria: duplication of regulatory acts (only the latest valid editions remain); articles containing clear signs of affiliation with pharmaceutical companies, unless supported by independent sources; publications that do not contain clear methodological approaches to analyzing the effectiveness of treatment; documents that have lost their validity or contain outdated information about medicines and procurement.

3. Materials and methods

The research material was scientific works of Ukrainian and foreign scientists on the researched issue, regarding MC in MS, as well as the results of a survey of patients diagnosed with MS.

Before conducting the survey, all participants gave their informed consent to data processing and use for scientific purposes. The research was conducted in accordance with the Declaration of Helsinki of the World Health Organization "Ethical Principles of Medical Research Involving Human Subjects" in compliance with its main provisions [16]. The questionnaire was approved by the Bioethics Commission of the Zaporizhzhia State Medical and Pharmaceutical University (protocol No. 8 dated 18.10.2023).

A homogeneous convenience sampling was formed for the survey with additional involvement of respondents using the snowball sampling method [17]. Sampling restrictions were applied only to the presence of a diagnosis of MS. The requirements for homogeneity in socio-demographic characteristics (gender, age, education, etc.) were not considered, since their variability may reflect the real population of patients with MS, and the population itself is not large. This allows us to generalize the results to the population of patients with MS and at the same time provides an opportunity to study the potential influence of socio-demographic factors within subgroups [18].

In Table 2, the characteristics of 121 survey participants are provided.

Table 2

Characteristics of respondents

Sign	Share, %	Characteristic	Share, %
Age		Sex	
Up to 20 years old	3.3	Women	79.3
From 21 to 25 years old	16.5	Men	20.7
From 26 to 30 years old	28.9	Social status	
From 31 to 35 years old	7.4	Student	6.6
From 36 to 45 years old	23.1	Working	58.7
From 46 to 50 years old	13.21	Housewife	16.5
From 51 to 55 years old	5.8	Unemployed	14.9
From 56 to 60 years old	1.7	Service in the ranks of the AFU	3.3
MS form at the time of the survey		Place of residence	
Remitting	61.2	Ukraine, frontline	19
Secondary progressive	26.4	Ukraine, rear	62
Primary progressive	5.8	Territory of another state	19
Clinically isolated syndrome (CIS)	6.6	–	

To determine the presence of a statistically significant influence of a number of socio-demographic factors on the respondents' answers to the questions ("Do you think people with MS need additional support from pharmaceutical specialists?" and "In what format would it be convenient for you to receive help from a pharmacist?"), the Pearson χ^2 criterion was used, and in case the assumption of a sufficient sample size in the cells of the conjugation table was not met, its modified version was applied – χ^2 with a likelihood adjustment (a statistical method used to test a hypothesis in the context of maximum likelihood estimation (MLE)) (Likelihood Ratio Chi-Square), which allows adjusting the results for small samples [19]. The results are presented in Table 3.

Analyzing the data in Table 2, we can state a statistically significant influence (p-value ≤ 0.05) of such a parameter as "social status". There is a statistically significant relationship between the social status of patients with MS and their opinion on the need for additional support from pharmacists ($\chi^2 = 28.993$, $p < 0.001$; $\chi^2_{plausibly.} = 26.882$, $p = 0.001$), which indicates different perceptions of the need for such support among different social groups. A statistically significant relationship was also found between social status and the convenient format of receiving help from a pharmacist ($\chi^2 = 40.635$, $p = 0.001$; $\chi^2_{plausibly.} = 27.257$, $p = 0.039$) – different social groups may prefer different ways of communicating and receiving information from pharmacists.

Table 3

Results of mathematical processing of survey data in accordance with the parameters of the cohort of surveyed patients

Parameters	Questions	χ^2	P value, significance level	χ^2 with a plausibility adjustment	P value, significance level	df, degrees of freedom
Age	Do people with MS need additional support from pharmaceutical professionals	12.372	0.576	13.066	0.521	14
	In what format would you be comfortable receiving help from a pharmacist?	29.987	0.364	31.520	0.294	28
Sex	Do people with MS need additional support from pharmaceutical professionals	2.902	0.234	2.556	0.279	2
	In what format would you be comfortable receiving help from a pharmacist?	4.054	0.399	3.551	0.470	4
Social status	Do people with MS need additional support from pharmaceutical professionals	**28.993**	**0**	**26.882**	**0.001**	**8**
	In what format would you be comfortable receiving help from a pharmacist?	**40.635**	**0.001**	**27.257**	**0.039**	**16**
Place of residence	Do people with MS need additional support from pharmaceutical professionals	10.909	0.091	7.236	0.3	6
	In what format would you be comfortable receiving help from a pharmacist?	21.621	0.042	16.170	0.184	12
Presence of TPO	Do people with MS need additional support from pharmaceutical professionals	3.909	0.419	6.13	0.19	2
	In what format would you be comfortable receiving help from a pharmacist?	12.775	0.120	11.163	0.193	8
The presence of limitations of working capacity	Do people with MS need additional support from pharmaceutical professionals	9.434[a]	0.491	10.384	0.407	8
	In what format would you be comfortable receiving help from a pharmacist?	23.764	0.253	25.871	0.170	20
How long ago was the diagnosis made?	Do people with MS need additional support from pharmaceutical professionals	5.243	0.263	5.736	0.22	4
	In what format would you be comfortable receiving help from a pharmacist?	4.357	0.824	4.375	0.822	8

Statistically insignificant effect (p-value > 0.05): for the remaining cohort parameters (age, gender, place of residence, presence of TPO, presence of work limitations, how long ago the diagnosis was made) no statistically significant relationship was found with the patients' answers to both questions (regarding the need for support and the convenient format for receiving it). This means that patients' opinions and preferences regarding these aspects do not show significant differences between the respective groups.

The results of mathematical processing of survey data are subsequently used to form a complete picture and directions for improving the provision of PC to patients with MS in Ukraine. It should be noted that a small sample size in individual subgroups may affect the power of the statistical test and increase the likelihood of type II errors.

The work uses the methods of scientific information search, narrative method, content analysis, generalization, survey, design, statistical.

3. Results

In accordance with the current legislation of Ukraine, MC (including PC) is provided to MS patients within the framework of the Law of Ukraine "Fundamentals of the Legislation of Ukraine on Healthcare" [20], the Law of Ukraine "On State Financial Guarantees of Medical Services for the Population" [21], the Law of Ukraine "On Medicinal Products" [22], the Resolution of the Cabinet of Ministers of Ukraine dated 07.03.2022 No. 216 "Some Issues of Procurement of Medicinal Products, Medical Devices and Auxiliary Means for Them" [23], the Order of the Ministry of Health of Ukraine dated 01.07.2024 No. 1142 "New Clinical Protocol for Medical Care for Multiple Sclerosis in Adults" [24]. It should be noted that the "New Clinical Protocol" was created based on the clinical guideline of the German Society of Neurology "Diagnose und Therapie der Multiplen Sklerose, Neuromyelitis-opticaSpektrum-Erkrankungen und MOG-IgG-assoziierten Erkrankungen". In addition, for the treatment of concomitant symptoms in MS (e.g. pain and spasticity), healthcare professionals additionally use European clinical guidelines [25].

To solve the problem, we set from the MD process (according to [24]), the pharmaceutical component was isolated and a list of drugs used in the complex therapy of MS was determined:

1) high-dose intravenous methylprednisolone;

2) according to the effect on reducing the recurrence rate, immunotherapeutic drugs [24, 26]:

– efficacy category 1 (beta interferons, fumarates, glatimeroids, teriflunomide);

– efficacy category 2 (cladribine, S1P receptor modulators);

– efficacy category 3 (alemtuzumab, anti-CD20 antibodies: ocrelizumab, rituximab, ofatumumab, natalizumab);

3) vitamin D;

4) drugs for symptomatic therapy:

– spasticity reduction – baclofen, tizanidine, nabiximols (1:1 tetrahydrocannabinol (THC) and cannabidiol);

– gait disorder therapy – fampridine,

– tremor therapy – propranolol, primidone, topiramate, levetiracetam;

– neurogenic intestinal dysfunction: for constipation – lactulose, macrogol, glycerin suppositories; for incontinence – loperamide;

– eye movement disorders – gabapentin, memantine, baclofen;

– dysarthria/dysarthrophonia - fampridine;

– trigeminal neuralgia – carbamazepine, carbamazepine, levetiracetam, lamotrigine, levetiracetam.

At the next stage of the study, an analysis of the pharmaceutical supply of drugs used in DMT MS was conducted, considering their availability in the State Register of Medicines of Ukraine and their availability to patients within the framework of current regulatory and legal regulations. As of December 2024, the availability of registration in the State Register of Medicines, which provides permission for use in Ukraine, was checked, and their availability in the RLDs regulating the procurement of drugs for state funds was analyzed. The analysis information is presented in Table 4.

Table 4

Analysis of the physical availability of DMT MS drugs in Ukraine

INN, ATX Code	Recommended by the MC Clinical Protocol	It is allowed to purchase with budget funds	Trade name, drug form	Country of manufacture
1	2	3	4	5
Methylprednisolone, H02AB04	yes	yes	METYPRED, powder for solution for injection, 1000 mg per vial	Finland/Portugal
	yes	no	METYPRED, powder for solution for injection, 250 mg per vial	
	yes	no	METIROM, powder and solvent for solution for injection, 500 mg; 1 vial with powder (500 mg), 1 ampoule with solvent (7.8 ml)	Romania
	yes	yes	SOLU-MEDROL, powder and solvent for solution for injection, 1000 mg; 1 vial with powder and 1 vial with 15.6 ml solvent in a carton box	Belgium
	yes	no	SOLU-MEDROL, powder and solvent for solution for injection, 125 mg/2 ml; 1 Act-O-Vial with powder and 2 ml solvent	
	yes	no	SOLU-MEDROL, powder and solvent for solution for injection, 40 mg/ml; 1 Act-O-Vial with powder and 1 ml solvent	
	yes	no	SOLU-MEDROL, powder and solvent for solution for injection, 500 mg; 1 vial with powder and 1 vial with 7.8 ml solvent	
Efficiency category 1				
Interferon beta-1b, L03AB08	yes	yes	BETAFERON®, lyophilized powder for solution for injection, 0.3 mg (9.6 million IU); 1 vial with powder + 1.2 ml solvent in pre-filled syringes with needle adapter	Germany
Interferon beta-1a, L03AB07	yes	yes	BETFER 1a PLUS, powder for solution for injection, 6,000,000 IU (30 mcg); 1 vial with powder + 1 ampoule with 1 ml solvent in blister pack	Ukraine
	yes	yes	REBIF®, solution for injection, 22 mcg (6 million IU) / 0.5 ml; 0.5 ml in a pre-filled syringe	Italy/Switzerland
	yes	no	REBIF®, solution for injection, 44 mcg (12 million IU) / 0.5 ml; 0.5 ml in a pre-filled syringe	
Dimethyl fumarate, L04AX07	yes	yes	DIMETHYL FUMARATE, capsules 120 mg, pack of 14	India
	yes	yes	DIMETHYLFUMARATE-VISTA, capsules 120 mg, pack of 10 in blister; 2 blisters per pack	Chile/Spain/Czech Republic/Germany
	yes	yes	DIMETHYLFUMARATE-VISTA, capsules 240 mg, pack of 10 in blister; 6 blisters per pack	
	yes	yes	DIMETHYLFUMARATE-MILI-120, capsules 120 mg, pack of 14	India
	yes	yes	DIMETHYLFUMARATE-MILI-240, capsules 240 mg, pack of 60	
	yes	yes	DIMETHYLFUMARATE-TEVA, gastro-resistant hard capsules, 120 mg, pack of 14	Israel
	yes	yes	DIMETHYLFUMARATE-TEVA, gastro-resistant hard capsules, 240 mg, pack of 60	
	yes	yes	TECAFUM, gastro-resistant hard capsules, 120 mg, pack of 7 × 2	Turkey/Bulgaria
	yes	yes	TECAFUM, gastro-resistant hard capsules, 240 mg, pack of 7 × 8	
	yes	yes	FUMAROX, modified-release capsules, 120 mg, pack of 10 × 3	India
	yes	yes	FUMAROX, modified-release capsules, 240 mg, pack of 10 × 3	

Continuation of Table 4

1	2	3	4	5
Diroximel fumarate	yes	Not registered in Ukraine		
Glatiramer acetate, L03AX13	yes	yes	GLATIRAMER ACETATE-VISTA, solution for injection, 20 mg/ml, 1 ml per syringe; 1 syringe in blister; packs of 28, 30, or 90 (3 × 30) blisters	Netherlands/ Spain/Chile/ Malta
	yes	yes	GLATIRAMER ACETATE-VISTA, solution for injection, 40 mg/ml, 1 ml in a pre-filled syringe	Spain/ Chile/ Malta/ Netherlands
	yes	yes	COPAXONE 40, solution for injection, 40 mg/ml; 1 ml per pre-filled syringe; pack of 12	United Kingdom/ Netherlands/ Israel/ Hungary
	yes	yes	COPAXONE®-TEVA, solution for injection, 20 mg/ml, 1 ml per syringe; pack of 28	United Kingdom/ Netherlands /Hungary/ Israel
Teriflunomide, L04AA31	yes	no	AUBAGIO®, film-coated tablets, 14 mg; pack of 28 (14 × 2) and pack of 84 (14 × 6)	France
	yes	no	AUBAGIO®, film-coated tablets, 7 mg; pack of 28 (14 × 2)	
Efficiency category 2				
Cladribine, L04BB04	yes	no	LITAK, solution for injection, 2 mg/ml, 5 ml per vial; pack of 5 vials in a carton box	Switzerland/ Germany/ France
	yes	no	MAVENCLAD®, tablets, 10 mg; pack of 1, 4, or 6 tablets in blister	Italy
Ozanimod	yes	Not registered in Ukraine		
Ponesimod	yes	Not registered in Ukraine		
Fingolimod, L04A A27	yes	yes	GILENYA, capsules 0.5 mg; packs of 14 (7 × 2) and 28 (14 × 2)	Switzerland
	yes	yes	PMS-FINGOLIMOD, capsules 0.5 mg; pack of 28 (14 × 2)	Canada
	yes	yes	FINGELIA, capsules 0.5 mg; pack of 98 (14 × 7)	Greece
	yes	yes	FINGELIA, capsules 0.5 mg; pack of 28 (14 × 2)	Ukraine
	yes	yes	FINGOLIMOD-VISTA, capsules 0.5 mg; pack of 28 (7 × 4)	Chile/Spain/ Czech Republic
	yes	yes	FINGOLIMOD ACCORD, hard capsules 0.5 mg; 7 capsules per blister, 4 blisters per carton	United Kingdom/Poland/ Hungary/India/ Italy/Spain/ Malta
	yes	yes	FINGOLIMOD MEDEC, capsules 0.5 mg; packs of 28 (14 × 2) and 84 (14 × 6)	India
	yes	yes	FINGOLIMOD MEDEC, capsules 0.5 mg; packs of 28 (7 × 4) and 84 (7 × 12)	
	yes	yes	FINMOD, capsules 0.5 mg; packs of 10 and 30 (10 × 3)	
	yes	yes	FORSADO, capsules 0.5 mg; packs of 28 (7 × 4) and 30 (10 × 3)	
Efficiency category 3				
Alemtuzumab, L04AA34	yes	no	LEMTRADA, concentrate for solution for infusion, 12 mg/1.2 ml; pack of 1 vial	Ireland/Germany
Natalizumabum	yes	Not registered in Ukraine		
Ocrelizumab, L04AG08	yes	no	OCREVUS®, concentrate for solution for infusion, 300 mg/10 ml	Germany/Switzerland
Ofatumumab, L04AA52	yes	no	BONSPRI, solution for injection, 20 mg/0.4 ml; 0.4 ml per pre-filled syringe; 1 syringe in blister tray; packs of 1 or 3 blister trays in a carton box	Switzerland/ Spain/Germany
	yes	no	BONSPRI, solution for injection, 20 mg/0.4 ml; 0.4 ml per syringe	Switzerland

Continuation of Table 4

1	2	3	4	5
Rituximab, L01FA01	yes	no	MABTERA®, concentrate for solution for infusion, 100 mg/10 ml; 10 ml per vial	Switzerland/ Germany/USA
	yes	no	MABTERA®, solution for injection, 1400 mg/11.7 ml; 11.7 ml per vial	Switzerland
	yes	yes	REDDITUX, concentrate for solution for infusion, 10 mg/ml; in bulk	India
	yes	yes	REDDITUX, concentrate for solution for infusion, 10 mg/ml; 10 ml (100 mg) or 50 ml (500 mg) per vial	
	yes	yes	RIXATON, concentrate for solution for infusion, 10 mg/ml; 10 ml (100 mg) or 50 ml (500 mg) per vial; packs of 2 or 3 vials of 10 ml in a carton box	Austria/Slovenia/Germany/ Switzerland
	yes	no	RUXIENCE®, concentrate for solution for infusion, 10 mg/ml; 10 ml or 50 ml per vial	USA/Ireland/ Belgium
	yes	yes	TRUXIMA, concentrate for solution for infusion, 100 mg/10 ml; 10 ml (100 mg) per vial and 500 mg/50 ml; 50 ml (500 mg) per vial (*registration valid until* 21.03.2025)	Republic of Korea/Hungary/Germany/ France
	yes	yes	TRUXIMA, concentrate for solution for infusion, 100 mg/10 ml; 10 ml (100 mg) per vial and 500 mg/50 ml; 50 ml (500 mg) per vial	

Analyzing the data in Table 3, it was determined that out of 16 INNs recommended by the Clinical Protocol, only 11 INNs are physically available to Ukrainian MS patients, which is 75% of the amount recommended by the Clinical List: 1 for glucocorticosteroid therapy, 5 from the group of efficacy category 1; 2 from the second efficacy group and 4 from the 3rd efficacy category. Diroximel fumarate (1st efficacy group), Ozanimod, Ponesimod (2nd efficacy group), Natalizumabum (3rd efficacy group) are not registered in Ukraine. That is, the list of available DMT drugs for domestic MS patients is dominated by drugs from the lowest efficacy group. In addition, according to the resolution of the Cabinet of Ministers of Ukraine [23], access to 7 INNs is provided at the expense of the state budget: 1 for GCS therapy, 4 from the 1st efficacy group and 1 each from groups 2 and 3 of the efficacy category.

The above indicates the low availability of highly effective drugs (category 3) for Ukrainian patients with MS. After all, the state does not finance the purchase of expensive drugs, such as Ocrevus (114,200 UAH), Bonspri (26,300 UAH), and the cost of DMT with highly effective drugs is a financial burden for the patient.

To determine which drugs are taken by MS patients and which group of effectiveness, we conducted a survey of MS patients and determined the list of drugs (Fig. 1) as of January 2025.

Thus, drugs of the first category of effectiveness are taken by 53.5% of patients diagnosed with MS; drugs of the second category of effectiveness – 13.1% (including 1.6% – drugs not registered in Ukraine), drugs of the third category of effectiveness – 18.9% (including 3.3% – drugs not registered in Ukraine). 4.8% of respondents participate in clinical trials, and 19.6% of those surveyed noted that they do not take any drugs (including 2.4% of those surveyed are waiting for the necessary drugs for several months). Patients temporarily abroad due to the war receive the necessary DMT as part of charitable assistance or medical insurance.

The survey found that 64.5% of patients would like additional support from pharmacists, and 24.8% were hesitant about the possibilities of PC in their diagnosis. This indicates the need to strengthen educational activities among patients and medical professionals about PC and the role of pharmacists in its provision.

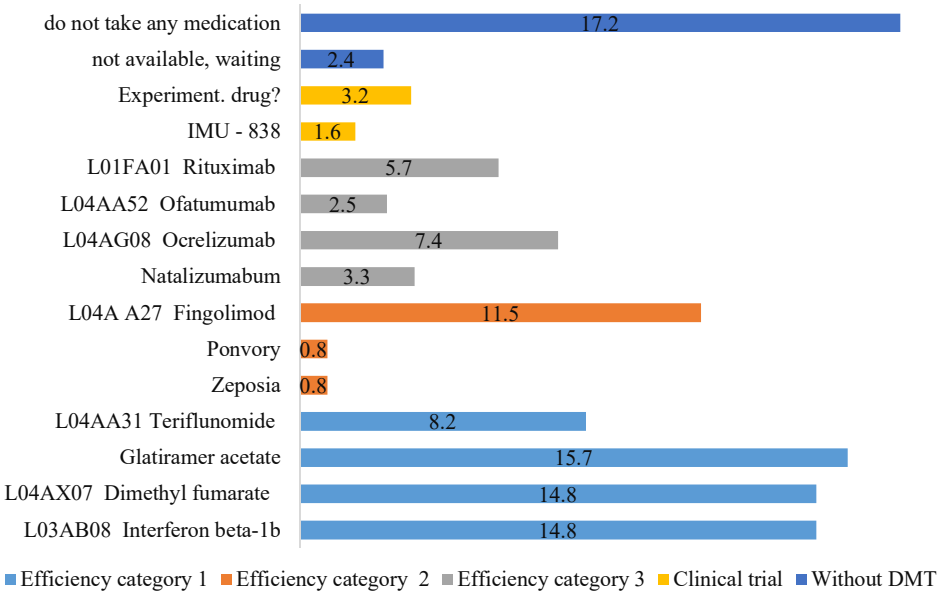

Fig. 1. Diagram of the distribution of respondents by the category of effectiveness of drugs taken by patients diagnosed with MS

Also, based on the systematization of responses from patients with MS, we identified possible elements of PC. As can be seen from Fig. 2, the most significant for patients with a diagnosis of MS are measures that will expand the functional content of pharmacists' professional roles and improve the quality of PC: advising patients on existing state support programs; coordination with volunteer and public organizations dealing with the needs of people with MS; advising and explaining new opportunities (new drugs and medical devices) to support patients with MS, including alternative medicine; coordination with the MS community (patient civil organizations); providing explanations regarding sensations and symptoms that may indicate an exacerbation of the disease and vice versa.

The next step in the study was to analyze the factors determining MS patients' adherence to PC and the impact of these factors on patients' preferences for the method of PC provision using Pearson's χ^2 test (between-group analysis).

It was determined that when answering the question "Do you think people with multiple sclerosis need additional support from pharmaceutical specialists?", despite some hesitation, different characteristics of patients and their medical status (gender, place of residence, presence of "TPO" status, disability, duration of illness), a clear trend is observed in the respondents' answers regarding the need for support for patients with MS by pharmaceutical specialists. Similar results were observed when respondents answered the question "In what format would it be convenient for you to receive help from a pharmacist?" – patients, regardless of personal characteristics, choose a mixed format of PC provision (remotely and in person) (Fig. 3–6).

Fig. 2. Diagram of the distribution of opinions of patients with MS on the question "what problems can a pharmacist help solve?"

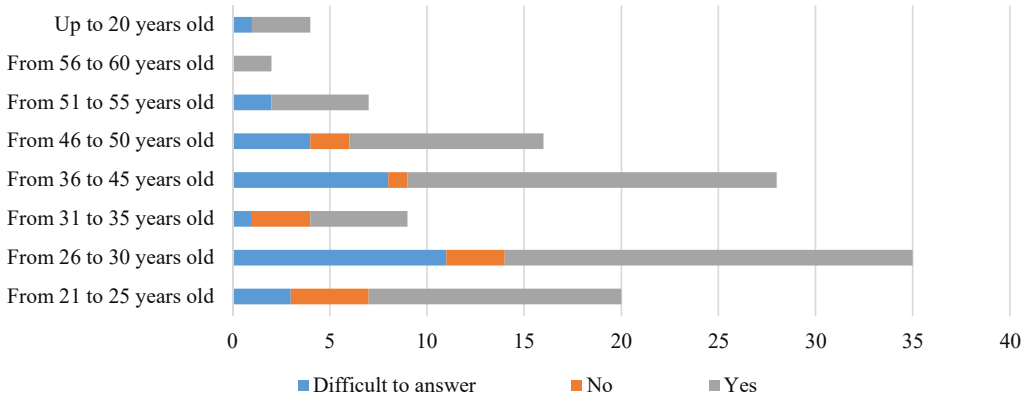

Fig. 3. Diagram of the distribution of respondents' answers depending on age to the question "Do you think people with MS need additional support from pharmaceutical specialists?"

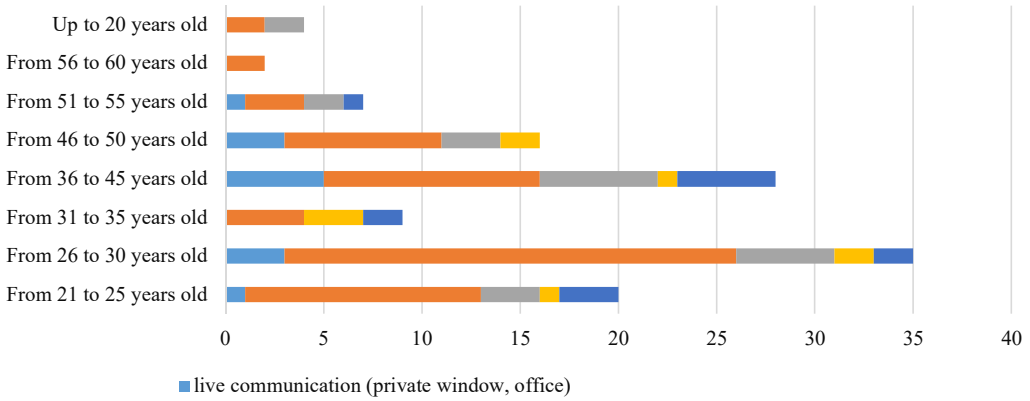

Fig. 4. Diagram of the distribution of respondents' answers depending on age to the question "In what format would it be convenient for you to receive help from a pharmacist?"

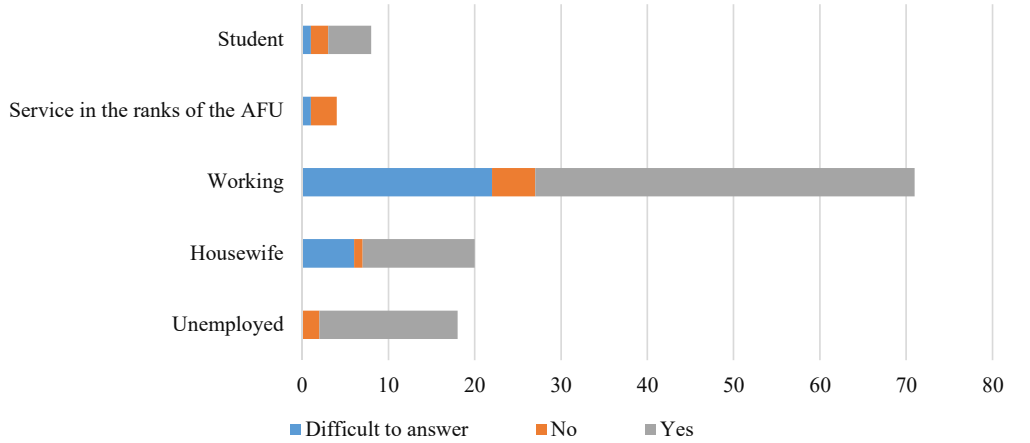

Fig. 5. Diagram of the distribution of respondents' answers depending on social status to the question "Do you think people with MS need additional support from pharmaceutical specialists?"

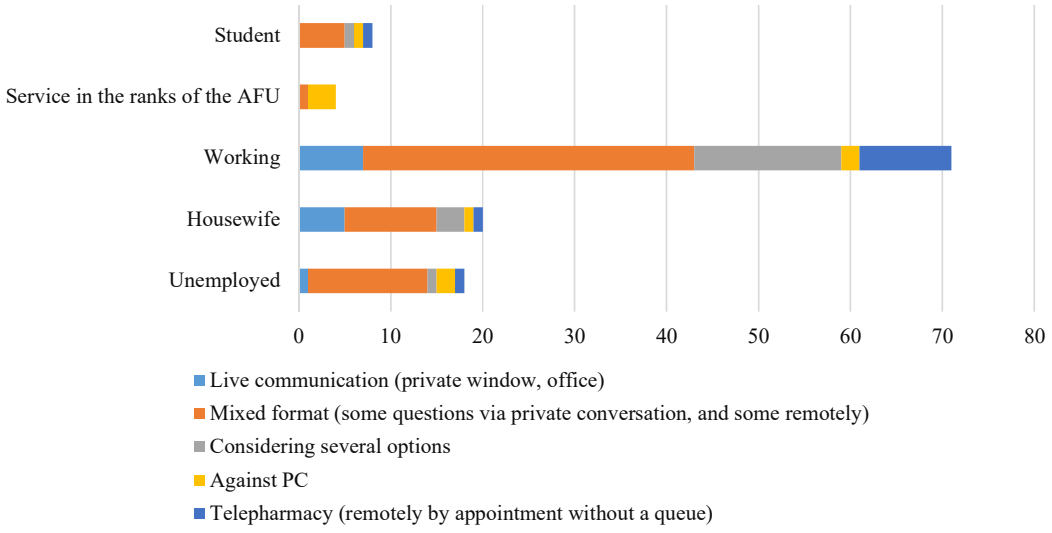

Fig. 6. Diagram of the distribution of respondents' answers depending on social status to the question "In what format would it be convenient for you to receive help from a pharmacist?"

However, the results regarding the dependence of views on social status showed that, unlike other groups of respondents (students, housewives and the unemployed), working patients are more hesitant about the need for support from a pharmacist (the relationship between the factor and beliefs is moderate (Phi = 0.49; Cramer's V = 0.346, $p < 0.05$) and, in the case of the availability of such an option as pharmacist assistance, they consider all possibilities for providing PC (live communication, mixed format, telepharmacy) (the relationship is moderate Phi = 0.58; Cramer's V = 0.29, $p < 0.05$).

At the same time, the unemployed have a strong belief that additional support from pharmacists is necessary (the answer "difficult to answer" was absent in sta-

tistical calculations). Students, the youngest group of respondents and patients serving in the ranks of the Armed Forces of Ukraine do not consider the option of "live communication with a pharmacist in a pharmacy" at all.

4. Discussion

Based on the analysis of the pharmaceutical component of MC for patients with MS, we have identified the pharmacological groups of drugs used in DMT MS: H02AB – glucocorticoids, L01BB – structural purine analogues, L01FA – CD 20 inhibitors, L03AB – interferons, L04AA – selective immunosuppressants, L04AG – monoclonal antibodies, L04AX – other immunosuppressants.

A retrospective analysis of the provision of DMT drugs to patients allowed us to identify positive changes in the regulation of the provision of medical and pharmaceutical care to these patients regarding the organizational and legal aspects of this process. Thus, in 2024, the Clinical Protocol for MC MS in Adults was adopted, which is based on a multidisciplinary approach to providing MC, on evidence-based medicine data regarding the effectiveness and safety of diagnostic and therapeutic interventions, pharmacotherapy, and organizational principles of its provision, which replaced the Clinical Protocol for Providing MC in the specialty "Neurology" for MS patients, which had not been updated since 2007. Over the past 5 years, the list of drugs approved for use in Ukraine for DMT has been expanded (Cladribine (L01BB04), Alemtuzumab (L04AA34), Ocrelizumab (L04AG08), Ofatumumab (L04AA52)) [27]. Also, an assessment of medical technologies for the use of such drugs in the treatment of MS patients as Cladribine, Ocrelizumab (both drugs received a positive conclusion and a recommendation for inclusion in the procurement through the DQD tool, as they have a high cost) and Alemtuzumab (unfortunately, received a negative conclusion from the authorized body due to the high cost and significant risks of use) [28–30].

As mentioned above, understanding the patient and their MS treatment needs is crucial for optimizing therapeutic strategies, including optimizing PC delivery, improving adherence and outcomes. Recent studies have highlighted the importance of patient convenience with less frequent dosing schedules and home treatment options [31], efficacy, safety and dosing regimens [32], the impact of low income, disability and high patient out-of-pocket costs for DMT on treatment adherence [33], and even pharmacists' preferences for DMT in MS patients have been investigated [34], but studies on patient attitudes towards PC and factors influencing patient perceptions of PC, which are the focus of these studies, are scarce.

The lack of influence of most of the respondents' socio-economic characteristics on the perception of the need for additional support from pharmacists or on the format of receiving this help may indicate that the selected factors do not demonstrate a significant interaction in the context of the questions posed. However, the results obtained may also reflect a specific picture, where the need and preferences for the format of receiving PC are relatively universal for patients in the study sample, regardless of their socio-economic status, which differs from the correlations often observed in other aspects of MC in multiple sclerosis [35, 36].

Given global trends in the pharmaceutical sector of HC [14, 37], and the expanding roles of pharmaceutical professionals [38], we emphasize that pharmacists can work in a variety of MDTs across different HC sectors: in secondary MC, pharmacists are part of clinical MDTs at ward level, which may include working within the MDT during ward or board rounds, resolving pharmaceutical service issues and working together to achieve optimal outcomes; in specialist MDTs, a pharmacist working in a specific specialty is included as a pharmacy specialist and provides advice using their specialist pharmaceutical knowledge. In addition to clinical MDTs, pharmacists can also contribute to issues related to e-prescribing/digital services, governance, patient safety. Pharmacists also play an important role in primary MC: they bring a range of skills to these sectors to improve the optimization of medicines for both acute and chronic conditions [39].

Analysis of the current state of pharmaceutical provision for MS patients in Ukraine indicates several problems that significantly affect the effectiveness of DMT. Of those recommended by the Clinical Protocol of the Ministry of Health of Ukraine, only a part is physically available in the country (only 75% of the list recommended by the protocol), while the list is dominated by drugs from the lowest level of effectiveness (category 1). Highly effective drugs (category 3), which have proven potential to change the course of the disease, are often absent from state procurement or are not registered in Ukraine, which makes them financially inaccessible to most patients.

In addition, modern pharmacotherapy of MS involves the complex use of drugs, which creates risks of polypharmacy, drug interactions, adverse reactions, difficulties with the regimen of administration, storage, disposal of residues (especially in war conditions), etc. Given the complexity of therapy, the physical inaccessibility of a number of drugs in rural areas and in front-line regions, there is an objective need to integrate pharmacists into the MDT providing medical care to patients with MS.

Expanding the professional role of pharmacists in the MDT will improve the effectiveness and safety of pharmacotherapy; strengthen pharmaceutical support for patients with MS; increase adherence to treatment; provide appropriate educational and communicative support for patients and doctors regarding the choice of drugs, interactions, regimens of use and logistical challenges. Thus, the formation of a new PC model with the active participation of the pharmacist in a multidisciplinary approach is a necessary response to modern challenges in providing MS treatment in Ukraine and corresponds to international trends in the integration of pharmacists into the clinical decision-making system.

In addition, all of the above requires implementation in curricula both at the undergraduate level and in the process of continuous professional development of special competencies in clinical pharmacology of drugs, safety of drug use and improvement of professional communication skills for coordinated work in MDT.

Practical significance. The study has significant applied significance for improving PC for MS patients in Ukraine in the context of the transformation of the modern healthcare system and military challenges. Analysis of the provision of DMT drugs, as well as the identified barriers to access to drugs of the second and third categories of effectiveness indicate a critical need to review registration, procurement for state funds and rational distribution of drugs. The results can be used in the process of developing state and regional programs to improve drug availability, expand the role of pharmacists in team clinical decision-making, and also create the basis for developing new organizational solutions involving pharmacists in consulting, logistics, and monitoring of PC as part of MDT in conditions of limited resources and the need to adapt to international standards.

In addition, the identified lack of awareness of patients about the possibilities of PC indicates the need to implement targeted educational campaigns and awareness programs for both patients and healthcare professionals. This will increase the effectiveness of communication in the treatment process and strengthen the role of pharmacists as information and educational agents of HC.

The need to adapt PC formats has been established: from traditional personal consultation to mixed and remote models (telepharmacy). The data obtained can be used when planning new pharmaceutical services in pharmacies, focused on the needs of target patient groups.

The study emphasizes the need to include modules related to clinical pharmacology, multidisciplinary interaction, digital transformation of PC and consultation of patients with chronic diseases, in particular MS, in undergraduate and postgraduate training programs for pharmacists.

Study limitations. The authors acknowledge the methodological limitations of a narrative review of scientific literature and did not intend to conduct a systematic review in this area. The study is based on secondary data and does not contain clinical or empirical data that will be considered in our further studies.

The sample size in this study was relatively small, which may limit the generalizability of the findings. Conducting the study under martial law forced us to use a convenience sampling approach, which was small and could affect the representativeness of the results. An online self-administered questionnaire was used, so a possible bias caused by self-reported data cannot be excluded. Our results are a first step in improving the understanding of patients suffering from MS. However, these results need further expansion and verification to obtain more generalized conclusions.

Prospects for further research. In the future, it is planned to clarify the problematic issues that arise in patients with MS at the stages of diagnosis and rehabilitation, to identify opportunities to expand the role of pharmaceutical professionals in providing PC.

5. Conclusions

1. The pharmaceutical component of MC for patients with MS was studied, considering organizational and legal aspects and access to DMT drugs. The pharmacological groups of drugs used in the organization of DMT MS were determined: H02AB – glucocorticoids, L01BB – structural purine analogues, L01FA – CD20 inhibitors, L03AB – interferons, L04AA – selective immunosuppressants, L04AG – monoclonal antibodies, L04AX – other immunosuppressants. Despite significant progress in the regulatory regulation of the provision of MD and the corresponding pharmaceutical support (in particular, the implementation of a new clinical protocol), state funding provides access to only a limited number of INNs, which makes the cost of highly effective drugs a significant financial burden for Ukrainian patients with MS. Among the available drugs, drugs with lower efficacy prevail, while some highly effective drugs, such as Diroximel fumarate, Ozanimod, Ponesimod and Natalizumabum, are not registered in Ukraine.

At the same time, more than half of the patients (53%) who participated in the survey receive drugs of the first category of DMT efficacy, while the share of those taking drugs of the second and third categories is significantly smaller. A significant part of the patients (19.6%) does not take any drugs, and some of them wait for the necessary drugs for several months, which indicates problems with the availability of treatment. Patients who are temporarily abroad due to the war have a better level of access to DMT thanks to programs that include drugs of the second and third categories of efficacy. Therefore, there is a need to expand availability and update drug registrations.

2. MS patients recognize the need for PC but are not sufficiently informed about its capabilities. Most patients (64.5%) expressed a desire to receive additional support from pharmacists, but almost 25% are hesitant, not realizing the potential of PC. This indicates the need for increased educational work among patients and the medical community, as well as the relevance of expanding the role of pharmacists in the health care system, particularly in the context of a multidisciplinary approach.

3. A study of MS patients' adherence to PC (only 11% refused it) did not reveal the influence of factors such as age, gender, place of residence, status of a temporarily displaced person, disability, and time of diagnosis on their confidence in the need for PC, as well as on their preferences for the format of interaction with a pharmacist (live communication and consultation, mixed format, telepharmacy). However, working respondents are more reserved in their perception of PC, and students and military personnel do not see the feasibility of "live" communication in a pharmacy. Such results, although not always statistically significant, demonstrate the need to adapt PC formats to target groups.

Conflict of interest

The authors declare that they have no conflict of interest regarding this study, including financial, personal, authorship or other nature, that could influence the study and its results presented in this article.

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Data availability

The manuscript has no linked data.

Use of artificial intelligence tools

The authors confirm that they did not use artificial intelligence technologies when creating the presented work.

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