

ORIGINAL ARTICLE

ENLIGHTENMENT ACTIVITIES IN THE FIELD OF HEALTH AND MEDICINES IN THE CONTEXT OF GOOD PHARMACY PRACTICE

DOI: 10.36740/WLek202107120

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ABSTRACT

The aim: To study and substantiate normative, organizational and methodical approaches to the conducting of enlightenment activities in the field of health preservation and proper use of medicines in the context of the prospect of implementation of Good Pharmacy Practice (GPP) in Ukraine.

Materials and methods: The research methods are: questionnaire survey, bibliographic, systemic review, systemic analysis, generalization, graphical modeling. The questionnaire survey was conducted by filling out questionnaires by pharmacists on paper or electronic media.

Results: It is found that 51,5% of the pharmacies surveyed are involved in sanitary enlightenment activities on health preservation and proper use of medicines. The need for introducing mechanisms to encourage pharmacy institutions to participate more actively in sanitary enlightenment among the population is substantiated. The expediency of combination of active and passive forms of sanitary enlightenment in pharmacies is shown. The enlightenment program «Health and Medicines» for the population has been developed. Methodical approaches to conducting enlightenment classes have been worked out. The algorithm infographic, describing the content of main consumer (patient) measures towards quality control of medicines purchased in the pharmacies, has been developed.

Conclusions: The implementation of the results of the study into the professional activities of pharmacists will significantly increase the erudition of citizens on preserving health and proper use of medicines and is the important element in the implementation of international GPP standard in domestic pharmacies.

KEY WORDS: enlightenment activities, health, medicines, pharmacies, quality, Good Pharmacy Practice

Wiad Lek. 2021;74(7):1666-1673

INTRODUCTION

One of the important tasks of the health care system according to the Law of Ukraine «On Medicines» is to provide the population with good quality medicines. In the last 20 years, a great deal of work has been done in the domestic pharmaceutical sector to successfully accomplish this task. At the same time, as of today many painful problems have accumulated in the system of medicines supply of population, which require immediate solution, in particular, uncontrolled self-medication of citizens with over-the-counter and prescription medicines, cases of malpractice and unprofessionalism among healthcare specialists, distribution of falsified and unregistered medicines on the pharmaceutical market, etc. This situation is further complicated by the socio-economic crisis and aggressive marketing policies of pharmaceutical companies and the uncontrolled advertising of medicines in the media [1].

An important way of solving the above problems is to promote comprehensively the erudition, awareness and personal responsibility of citizens for their health, as outlined in the WHO European Health 2020 Strategy [2]. The pharmaceutical professional community, as an integral part of the multidisciplinary team of healthcare professionals, plays an important role in this area.

THE AIM

The aim of this work is to study and substantiate normative, organizational and methodical approaches to the conducting of enlightenment activities in the field of health preservation and proper use of medicines in the context of the prospect of implementation of Good Pharmacy Practice (GPP) in Ukraine.

MATERIALS AND METHODS

As research materials used: information obtained during the questionnaire survey, scientific publications; regulations, normative and methodical documents in the field of health care and pharmacy; information posted on professional specialized websites and official websites of executive authorities.

The questionnaire survey was conducted by filling out questionnaires by pharmacists on paper or electronic media. The indicators determined during the statistical processing of the data of questionnaire survey of pharmacists are shown in the Table I.

The research methods are: questionnaire survey, bibliographic, systemic review, systemic analysis, general-

Table I. The indicators determined during the statistical processing of the data of questionnaire survey of pharmacists working in pharmacies of Ukraine

Indicator	Formula for calculation	Explanation of the formula
The minimum sample size	$n = \frac{N}{1 + 0,015 \times N}$	n – the number of pharmacies whose specialists are to be interviewed in the sample; N – the number of pharmacies in the general population (total number of pharmacies in Ukraine)
The relative share of answers by options	$w_i = \frac{n_i \times 100}{n}$	w _i – the relative share of answers by option; n _i – the number of answers by option
The average error of representativeness of the sample	$\mu_i = \sqrt{\frac{w_i \times (1 - w_i)}{n} \times \left(1 - \frac{n}{N}\right)}$	μ _i – the average error of the representativeness of the sample for the share of answers by option
The margin error of representativeness of the sample	$\Delta_i = t \times \mu_i$	Δ _i – the margin error of sample representativeness for the share of answers by option; t – confidence coefficient (equal to 2 for a probability of 0,954, which is the most commonly used in practice)
The dispersion	$\sigma_i^2 = w_i \times (1 - w_i)$	σ ² – the dispersion for the share of answers by option
The standard deviation	$\sigma_i = \sqrt{\sigma_i^2}$	σ _i – the standard deviation the share of answers by option

Table II. The results of statistical processing of the data of questionnaire survey of pharmacists of pharmacies of Ukraine on the conducting of sanitary enlightenment activities

The answer option	The relative share of answers by option (w _i), %	The average error of representativeness of the sample (μ _i)	The margin error of representativeness of the sample (Δ _i)	The dispersion (σ ²)	The standard deviation (σ _i)
Option A: «Participate constantly»	51,5	0,04	0,09	0,25	0,50
Option B: «Do not participate at all»	14,4	0,03	0,06	0,12	0,35
Option C: «Participate very rarely»	34,1	0,04	0,08	0,22	0,47

ization, graphical modeling. Mathematical and statistical processing and analysis of the questionnaire survey results was performed using the software product Microsoft Excel 12.0 (Office 2008).

RESULTS

We have analyzed the requirements of the current regulations and legal base for carrying out sanitary enlightenment work in the framework of pharmaceutical activity. The Ethical Code of Ukrainian Pharmacists plays an important role in this regard. This document declares that the prevention of diseases, preservation and strengthening of human health, including the participation in sanitary enlightenment work, is the main task of the professional activities of pharmacists. The Ethical Code obliges pharmacy professionals to counteract quackery, participate in the fight against pharmacomania, medicament addiction, drug addiction (narcotism) and alcoholism [3]. The necessity of intensification of sanitary enlightenment work is emphasized in the Concept of development of the pharmaceutical sector in the field of health care of Ukraine

for 2011-2020. One of the priority tasks of this concept is the development of the program of measures for raising erudition and awareness of the consumers of medicines with the aim to introduce responsible self-medication and increase the safety of the use of medicines [4].

The importance of sanitary enlightenment work as one of the main areas of pharmaceutical practice is emphasized in the joint guidance of WHO and the International Pharmaceutical Federation (FIP) on GPP [5]. According to the provisions of this document, the range of services provided in the framework of pharmaceutical assistance combined with the dispensing of medicines also includes informing, counseling and enlightenment in the field of health care. Pharmacists should be actively involved in informing the patients about the correct use of medicines, vaccines and other medications. To do this, the pharmacy must have appropriate information materials, stands, leaflets, booklets to provide the citizens with them. Pharmacists can provide enlightenment lectures for the population and participate in preventive activities on healthy lifestyles, disease prevention and responsible self-medication.

As part of the study of the readiness of domestic

Table III. The themes of the enlightenment program «Health and Medicines» for the population

No.	The names of modules and themes
Module 1. Fundamentals of healthy lifestyle	
1.1	Fundamentals of healthcare organization.
1.2	Principles of patient ethics.
1.3	Regulations for the prevention of tuberculosis, HIV/AIDS, hepatitis and sexually transmitted infections.
1.4	Regulations for the prevention of acute respiratory viral infections.
1.5	Principles of prevention of bad habits and addictions.
1.6	Principles of non-communicable disease prevention and health promotion.
1.7	Principles of diagnosing the diseases.
1.8	Basic rules of home care for patients.
1.9	Basic rules of providing first medical aid.
1.10	First medical aid kits.
Module 2. Fundamentals of pharmacy	
2.1	History of pharmacy: brief overview.
2.2	Pharmacy: the social role and foundations of the organization.
2.3	Pharmacy institutions: tasks, functions and basic requirements for the activity.
2.4	Pharmacy goods: general overview.
2.5	Medicines: basic notions and classification.
2.6	Dietary supplements: basic notions and classification.
2.7	Medicinal plant raw materials: procurement rules.
2.8	Sources of information about medicines. Advertising of medicines.
2.9	Regulations for handling prescription medicines.
2.10	Rights of medicines consumer (patient).
Module 3. Fundamentals of responsible self-medication	
3.1	Principles of responsible self-medication.
3.2	Principles of relationship: patient – doctor – pharmacist.
3.3	Quality of medicines. How to identify substandard and counterfeited medicines.
3.4	Regulations for storage and use of medicines at home. Regulations for destruction of substandard medicines.
3.5	Requirements to instructions for medical use of medicines.
3.6	Rules for preparation of pharmaceutical forms from medicinal plant raw materials at home.
3.7	Contraindications to use, side effects and ineffectiveness of medicines.
3.8	The problem of polypharmacy, pharmacomania and medicament addiction.
3.9	Pharmaceutical incompatibilities. Drug-food interaction.
3.10	Poisoning with medicines: prevention and first aid.

pharmacies to implement the requirements of GPP, we conducted the questionnaire survey of pharmacists who studied at the Department of Quality Control and Standardization of Medicines of the Shupyk National Medical Academy of Postgraduate Education in 2018–2019 in different cycles of postgraduate advanced training in «General Pharmacy» and «Analytical and Control Pharmacy» specialties. The contingent of respondents included pharmacists, pharmacists-analysts and pharmacists-interns working in pharmacies in Kyiv, Zhytomyr, Vinnytsia, Khmelnytsky, Cherkasy regions. The questionnaire survey was conducted during the introductory conference of the relevant cycle. The number of respondents also included pharmacists working in pharmacies in Dnipropetrovsk, Zaporizhia, Ternopil, and Chernihiv regions, with whom scientific cooperation agreements have been concluded. Given that the ISO 9001 standard and the guideline on GDP require the involvement of all staff in matters of quality assurance of medicines, the ranking of respondents by the level of their position in the pharmacy was not carried out. The main requirements for

the respondents were as follows: complete higher pharmaceutical education; work as a pharmacist in a pharmacy; pharmacists must work in different pharmacies and must represent different settlements of Ukraine.

In total, we received and processed 132 questionnaires, which is twice the minimum sample size for pharmacies, the total number of which, according to statistical data of Ukraine at the time of the study was 16,200. The calculation of the minimum sample size for pharmacies was carried out according to the formula proposed by Z. M. Mnushko and N. N. Kareva. 85 % of the studied pharmacies are privately owned pharmacies that retail sales of medicines, the rest are manufacturing and hospital pharmacies of state or communal ownership. 20 % of the surveyed respondents (pharmacists) belonged to the management staff (pharmacy directors or heads of pharmacy departments) [6].

The questionnaire contained 41 questions, each of which had three options, from which the respondent chose one answer. Then, using the software product Microsoft Excel 12.0 (Office 2008), for each question the relative share of answers by options and statistical indicators were calculated.

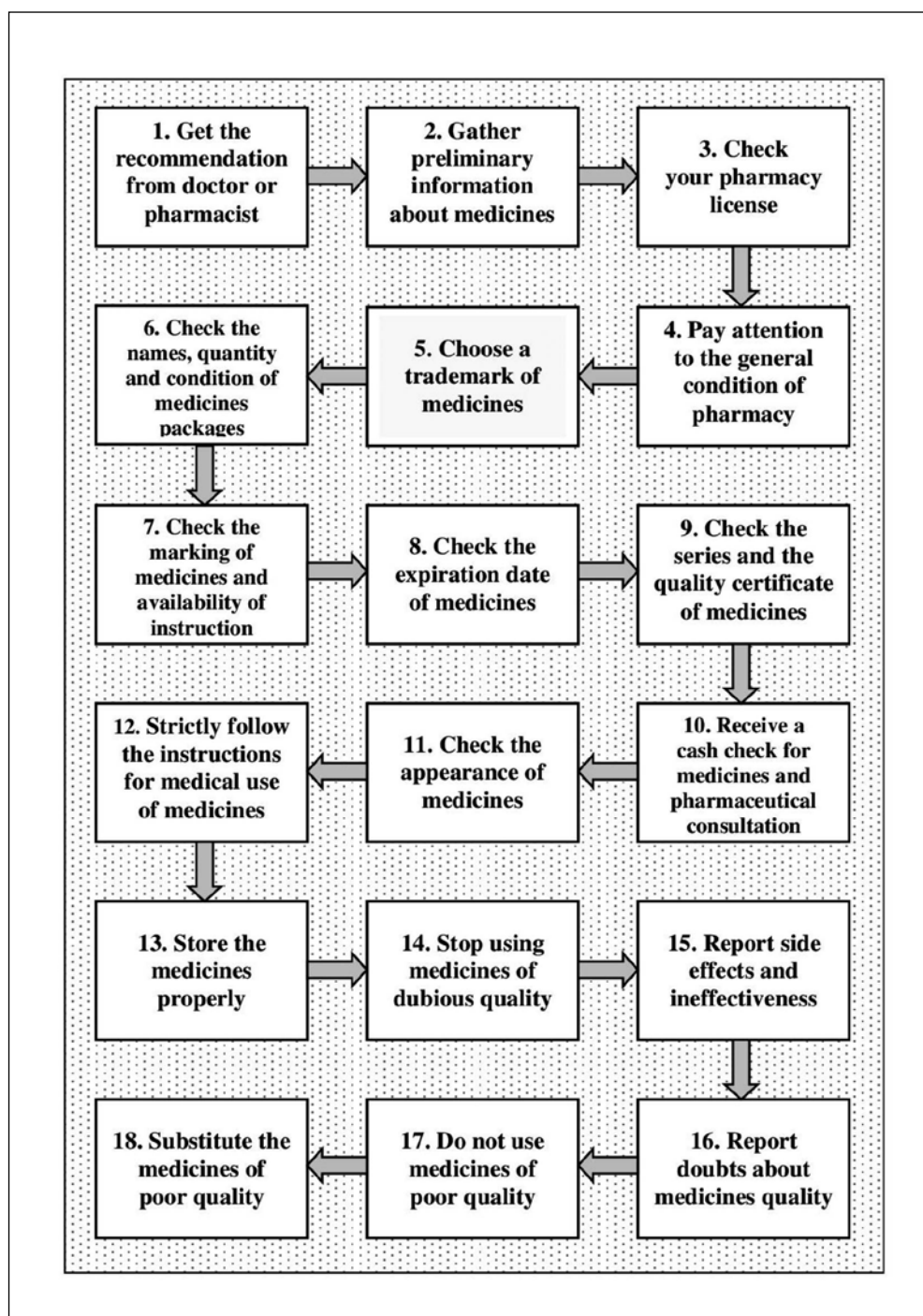


Fig. 1. The blocks of information in the structure of the algorithm infographic «How to prevent the purchase and use of medicines of poor quality»

ed. One of the questions was: «Does your pharmacy conduct sanitary enlightenment activities on the rational use of medicines, healthy lifestyles and disease prevention?» The study showed that 51,5 % of the surveyed pharmacies are participate constantly in sanitary enlightenment (Option A); do not participate at all – 14,4 % (Option B); participate very rarely – 34,1 % (Option C). The results of statistical processing of the data of questionnaire survey are given in Table II.

Statistical processing of the data of questionnaire survey of pharmacists of pharmacies showed that the statistical indicators of the sample with a probability of 0,954 are within

acceptable limits of their limit values, which confirms the representativeness of the sample [6].

In order to find optimal forms and methods of sanitary enlightenment work, we analyzed the experience of the national health care system, which showed the feasibility of combining active (involving direct interaction of professionals with the population) and passive forms of sanitary enlightenment work conducted in pharmacies [1].

In the framework of the above, as well as in order to popularize and enhance the prestige of the pharmaceutical profession in the society, we have proposed and developed the enlightenment program «Health and Medicines» for the

Table IV. The textual content of the algorithm infographic «How to prevent the purchase and use of poor quality medicines»

No.	The name of information block	The textual content of the information block
1	2	3
1.	Get the recommendation from doctor or pharmacist	Only a doctor or doctor's assistant in the case of his absence in rural areas can prescribe medicines for medical use. The pharmacist is also entitled to recommend over-the-counter (OTC) medicines for the prevention and symptomatic treatment of diseases, the formation of a first aid kit of pre-medical assistance.
2.	Gather preliminary information about medicines	Having been prescribed medicines, the patient can collect preliminary information about their characteristics, analogues, efficacy and side effects, availability in the pharmacy network, prices, entry into the National List of Medicines and the «Available Medicines» program. Medicines directories, websites of pharmaceutical manufacturers, authorities, international organizations in the field of medicines quality regulation, specialized medical and pharmaceutical sites, etc. can afford the information needed.
3.	Check your pharmacy license	The medicines are only bought in pharmacies and pharmacy points, and in the countryside – in the premises of rural health posts, hospitals, out-patient clinics. The pharmacy must be licensed for the retail sales of the medicines, and the pharmacy manufacturing the medicines should have producer's license, to be found at the consumer's corner and on the State Service of Ukraine on Medicines and Drugs Control website. The pharmacy address listed in the license must correspond to the actual address
4.	Pay attention to the general condition of pharmacy	The pharmacy premises should be clean, dry, well lit and ventilated, maintaining room temperature. The outward appearance of pharmacy staff must comply with the rules of sanitation and hygiene. The medicines should be stored in the pharmacy in accordance with the conditions stated on the package and specified in the instructions for medical use
5.	Choose a trademark of medicines	The consumer should present to the pharmacist a doctor's prescription specifying the international non-proprietary name (INN) of the medicines, and in the case of responsible self-treatment of symptoms, clearly describe his/her problem and answer the pharmacist's questions, on the basis of which the latter recommends the appropriate OTC medicines. From the trademarks available at the pharmacy, the consumer (alone or on the advice of a doctor and/or pharmacist) chooses the medicines that are optimal for him, taking into account their price and experience of medical use. However, if the price of medicines is much lower than usual, it may raise doubts about their quality. In the absence of OTC medicines recommended by the doctor for symptomatic treatment, the pharmacist may suggest an analogue thereof
6.	Check the names, quantity and condition of medicines packages	Check that the trade name, pharmaceutical forms, dosage and quantity of packs of medicines dispensed by the pharmacist correspond to the customer's order. Check that the packaging of the medicines – secondary/outer (most often a cardboard box) and primary/inner (directly in contact with the medicines – blister, ampoule, vial, etc.) is in a proper commodity condition, remains intact, with the first disclosure protection (control) undisturbed. At the same time, poor quality printing and illegible type on the packaging of medicines may raise doubt about their quality
7.	Check the marking of medicines and availability of instruction	The text of the labeling on the packaging of medicines must be in the state language and include the trade name and INN, dosage, serial number, expiry date, registration number of Ukraine and storage conditions. The outer packaging of ready medicines and immunobiological preparations should be in Braille bold easy-palpable type. The instructions for medical use in the state language must be enclosed in the package. The information on the outer and inner packaging must correspond that in the instruction for medical use
8.	Check the expiration date of medicines	Check that the medicines have not expired. The expiry date is stated on the package of medicines. It is forbidden to use medicines after the expiry date! The rest of medicines' shelf life should be sufficient to complete the course of medication
9.	Check the series and the quality certificate of medicines	In case of doubt about the quality of medicines, ask the pharmacist to submit a manufacturer's certificate of quality for a series of medicines, as well as a laboratory conclusion about the quality of imported medicines, a conclusion about compliance with the requirements of national and international standards for immunobiological preparations. The serial number on the package must correspond to the serial number indicated on the certificate of quality and laboratory conclusion. Check the series of medicines banned for circulation in Ukraine on the State Service of Ukraine on Medicines and Drugs Control website
10.	Receive a cash check for medicines and pharmaceutical consultation	The pharmacist must issue a cash check to the consumer for the amount of medicines dispensed and emphasize the need to strictly follow the medical prescription and the requirements of the instructions for medical use regarding the peculiarities of use and storage of medicines. If necessary, the consumer can ask the pharmacist clarifying questions

11.	Check the appearance of medicines	After opening the primary/inner packaging of medicines at home, check their appearance for contamination, the number of units in the package, as well as the description contained in the section «Pharmaceutical form» of the instructions for medical use. Changes in the physical properties of medicines (form, color, odor, aggregate state, uniformity, transparency, etc.) may indicate that it is a medicine of poor quality
12.	Strictly follow the instructions for medical use of medicines	Read attentively the instruction for medical use and strictly follow its requirements regarding the peculiarities of use and storage of medicines. Pay particular attention to the sections «Contraindications», «Possible side effects», «Special warnings for use», «Interaction with other medicines, tobacco, alcohol and food», «Storage regulations»
13.	Store the medicines properly	The medicines should be stored and transported in accordance with the instructions for medical use. Some medicines should only be stored in the refrigerator, others in the dark, protected from direct sunlight damp place (medicine cupboard) at room temperature (usually not higher than +25 °C). Do not leave the medicines on the windowsill or on the table. Upon having your medicines delivered home, make sure they have been transported in the right temperature conditions. The car first medical aid kit must be stored in a dark place and the medicines included in it must be renewed in a timely manner when expired
14.	Stop using medicines of dubious quality	If side effects (foreseen and unforeseen in the instructions for medical use) or lack of efficacy are evident during the medical use of medicines, and in the case of doubts about their quality or suspicion of their falsification, the use of these medicines should be stopped immediately!
15.	Report side effects and ineffectiveness	In case of side effects or lack of efficacy during the medical use of medicines, the doctor and/or pharmacist who sold the medicines, should be informed as soon as possible. Also, the patient (or a pharmacist instead) should fill out a notification message card to provide information on side effects and/or lack of efficacy of medicines and send it to the State Expert Center of the Ministry of Health of Ukraine in any convenient way (by mail or fax, e-mail or online form on the site of this center). The form of the notification message card is posted on the website of this center and the website of the State Register of Medicines of Ukraine
16.	Report doubts about medicines quality	If there are doubts about the quality of medicines or suspicion of their falsification, the consumer can contact the territorial body of the State Service of Ukraine on Medicines and Drugs Control (contacts can be found in the consumer's corner and on the website of this service) and submit the corresponding notification message in any convenient way (by mail or fax, e-mail or online on the site of this service). Based on this information, an appropriate check-up will be carried out
17.	Do not use medicines of poor quality	The medicines of poor quality, including those expired, as well as thermolabile ones that have been out of the refrigerator for several hours (which is the non-compliance with the storage conditions of such medicines), are not subject to further use!
18.	Substitute the medicines of poor quality	In the case of purchase of poor quality medicines, if defects are found within the shelf life, the consumer has the right to demand their substitution for medicines of good quality, or the return the money paid for them. The reason for the return is the cash check received during the purchase of these medicines and the laboratory conclusion on non-compliance with the quality requirements, made by the laboratory of the territorial body of the State Service of Ukraine on Medicines and Drugs Control based on the results of laboratory quality control of this series of medicines

population, consisting of three modules: «Fundamentals of healthy lifestyle», «Fundamentals of pharmacy» and «Fundamentals of responsible self-medication». The aim of the program is to develop a conscientious attitude of the citizens to their health, increase the level of adherence to medicament treatment (compliance), master the basics of proper and rational use of medicines and medicinal plant raw materials, regulate the responsible self-medication, as well as familiarize with the principles and methods of healthy lifestyle, disease prevention, caring for patients and providing first medical aid (Table 3).

The enlightenment program developed includes lectures and seminars. Theoretical material is presented at lectures. Seminars can be held in the form of interactive conversations, discussions, group trainings, excursions, individual testing and more. The content of the lecture and seminar

material should be presented in a volume and form that is accessible to the audience, consisting of individuals without special (medical or pharmaceutical) education. Accordingly, a prerequisite is the appropriate level of theoretical training and lecturing skills of the specialists conducting such classes. Forms of learning for the enlightenment program can be: full-time, part-time (evening classes), weekend group, distance or blended with the use of multimedia and Internet technologies. The schedule of classes can be flexible and adapted to the specific learning conditions and features of the contingent of participants in enlightenment classes.

During 2011–2018, the staff of the Department of Quality Control and Standardization of Medicines of the Shupyk National Medical Academy of Postgraduate Education together with the NGO «Institute of Health and Quality of Life «DobroLik» conducted on voluntary basis cycles

of enlightenment classes for the population in educational institutions, NGOs and health care institutions of several cities of Ukraine (Kyiv, Cherkasy, Kryvyi Rih, Lanivtsi). The themes of these cycles were formed on the basis of the developed program «Health and Medicine». The content of individual themes is posted by us on the Internet. Based on this enlightenment program a draft of a cycle of programs on the radio is proposed.

It should be noted that the modern trend, in particular in the field of enlightenment work on the issues of health preservation and use of medicines, has been the development of infographics and short videos for demonstration on the Internet and television channels. In this context, we jointly with the specialists of the State Service of Ukraine on Medicines and Drugs Control, developed the algorithm infographic «How to prevent the purchase and use of poor quality medicines». This algorithm infographic briefly describes the content of main measures to be taken by medicines consumer (patient) to control the quality of medicines purchased at the pharmacy. The names of the blocks of information and the textual content of the algorithm infographic are shown in Figure and Table IV.

The step-by-step execution by the medicines consumers (patients) of the set of measures listed in Table IV provides a significant reduction in the likelihood of poor quality medicines purchase and use.

DISCUSSION

In the context of the above, it becomes evident that the acquisition of competence by pharmacy professionals in the field of conducting enlightenment work, as well as the formation of their personal interest in the promotion and dissemination of pharmaceutical knowledge, is an important and pressing issue. Therefore, today there is an objective need to create the conditions for improving the skills of pharmacy specialists in organizing enlightenment activities among the population. In particular, we propose the introduction of the «Ethical, enlightenment and advisory aspects of pharmacist's activity» thematic improvement cycle [1].

Our study showed that 51,5 % of the surveyed pharmacies are regularly participate in sanitary enlightenment. At the same time, in the works of other researchers, in particular L. Gala, it is shown that in most domestic pharmacies sanitary enlightenment work is not carried out at all or is performed only formally. In addition, despite declaring the importance of sanitary enlightenment work in the regulatory documents of Ukraine, they lack clear guidelines for pharmacists on volume of work and methods of promoting healthy lifestyles and disease prevention [7]. Therefore, in our view, in the context of the prospect of GPP implementation, the government and professional pharmaceutical associations should seek mechanisms to encourage pharmacy institutions to participate more actively in sanitary enlightenment work, for example, by providing certain tax breaks or benefits in licensing business activities, etc.

Summarizing all of the above, it can be stated that the role

of enlightenment work in quality assurance of medicines and pharmaceutical services cannot be underestimated. This is especially true of the stages of retail sales and medical use of medicines (in a hospital and outpatient setting), which are the closest to patients and the largest in terms of turnover compared to other stages of the life cycle of medicines in the national pharmaceutical market. For this reason, executive authorities in the field of state control of the medicines quality, professional pharmaceutical associations and pharmacies must pay due attention to the enlightenment work among the population regarding the quality of medicines.

CONCLUSIONS

1. The analysis of the GPP recommendations and requirements of the current European and national regulations has been carried out, which showed that enlightenment work on raising erudition and awareness of citizens on preserving health and proper use of medicines is one of the priority areas of professional activities of pharmacists.
2. According to the results of the questionnaire survey of pharmacists working in different regions of Ukraine, it is found that 51,5 % of the pharmacies surveyed are involved in sanitary enlightenment activities. However, in some of these pharmacies enlightenment work is done only formally. In other pharmacies, enlightenment activities are not conducted at all, which indicates the necessity of introducing mechanisms to encourage pharmacy institutions to participate more actively in sanitary enlightenment work among the population.
3. The analysis conducted showed that today in Ukraine there are no clear recommendations for pharmacists to organize the enlightenment work. Based on the study of overall experience of the domestic health care system, it is concluded that it is most appropriate to use a combination of active and passive forms of sanitary enlightenment work in pharmacies.
4. In order to increase the medical and pharmaceutical erudition of citizens, as well as to popularize and enhance the prestige of the pharmacist profession in the society, the enlightenment program «Health and Medicines» for the population has been developed. The program includes three modules: «Fundamentals of healthy lifestyle», «Fundamentals of pharmacy» and «Fundamentals of responsible self-medication». Organizational and methodical approaches to conducting enlightenment classes have been worked out.
5. In the framework of the preparation of enlightenment materials on preserving health and proper use of medicines, the algorithm infographic has been developed, which describes the content of main measures to be taken by medicines consumer (patient) to control the medicines quality purchased in the pharmacy. It is shown that step-by-step execution of these measures provides a significant reduction in the likelihood of purchase and use of poor quality medicines by the consumers (patients).

The implementation of the results of the study into the professional activities of pharmacists will significantly increase the erudition of citizens on preserving health and proper use of medicines and is the important element in the implementation of international GPP standard in domestic pharmacies.

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Author is grateful to the staff of the Faculty of Preventive Medicine and Pharmacy of the Shupyk National Medical Academy of Postgraduate Education who agreed to participate in the study for their cooperation, time and motivation. This work was performed within the framework of the research work of the Department of Quality Control and Standardization of Medicines «Substantiation of methods of increasing solubility of substances, methods of quality control and organizational and methodological aspects of the integrated model of quality assurance medicines at the stages of realization and medical use» (state registration number 0115U002158).

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Conflict of interest:

The Authors declare no conflict of interest.

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Received: 2020-06-02

Accepted: 2021-06-01

A – Work concept and design, **B** – Data collection and analysis, **C** – Responsibility for statistical analysis, **D** – Writing the article, **E** – Critical review, **F** – Final approval of the article