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THREATS TO THE SECURITY OF THE PHARMACEUTICAL SERVICES PROVIDED TO THE POPULATION

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Abstract

The article presents an analysis of the problems of ensuring the security of pharmaceutical services provided by medical and pharmaceutical organizations to consumers of medicines in the retail segment of the pharmaceutical market. The data on counteraction to the penetration of substandard, counterfeit and counterfeit medicines into the Russian pharmaceutical market are presented. The potential danger of medical therapy from information errors of medical and pharmaceutical workers, as well as from information errors and lack of training of medicine consumers are analyzed. The role of health professionals in maintaining the socially necessary level of pharmaceutical safety in the prescription, selection and implementation of medical therapy. The authors note that the leading role in providing pharmaceutical safety belongs to medical and pharmaceutical workers engaged in this provision for the population. Their professionalism and responsibility are the main factors in maintaining the medicine supply to the citizens of their country at the socially necessary quality level.

Keywords: Medical and pharmaceutical workers, medicine consumers, pharmaceutical services, pharmaceutical workers.

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1. Introduction

The range of original and generic medicinal preparations (MP), constantly growing in the pharmaceutical market, significantly increases the amount of professional information about the properties of pharmaceutical products, the possession of which for medical and pharmaceutical specialists, as well as patients affects the quality and security of pharmaceutical services (PS) provided to the population on prescription, selection and implementation of medical therapy.

2. Problem Statement

Since the population receives PS directly in medical and pharmacy organisations on prescription, dispense and use of medicine, we have considered the role of medical and pharmaceutical workers in providing PhS. in the retail sector of the pharmaceutical market.

The empirical base of the research consists of scientific works of leading scientists in the field of organization of pharmaceutical business, statistical and other materials on the safety of the pharmaceutical market.

3. Research Questions

The subject area of this study was the analysis of the problem of pharmaceutical safety (PhS) of the population at the levels of "doctor – patient", "pharmacist – consumer of MP". At the present time, pharmaceutical science and practice treat PhS. as a state of protection of citizens, medical and pharmaceutical organisations from threats arising in the sphere of production, distribution and consumption of pharmaceutical goods and services (Kuznetsov & Korzhavykh, 2013).

4. Purpose of the Study

The purpose of the work was to analyse the current threats to pharmaceutical security of the population in the retail sector of the pharmaceutical market in the provision of pharmaceutical services to consumers.

5. Research Methods

The system approach, content analysis, methods of documentary and direct observation were used for the analysis.

6. Findings

To ensure uniform approaches to the characterisation and content of the concept of PS, leading Russian scientists have proposed a definition according to which PS is a form of pharmaceutical activity that meets the specific needs of the patient or medical organisation.

Depending on the content, PS conventionally are divided into basic and advanced. The list of basic services provided to the population by pharmacies include: retail trade of pharmaceutical products

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according to the prescriptions of doctors and the requirements of medical organisations; retail trade of pharmaceutical products without prescription; pharmacy manufacture of medicine; storage and transportation of pharmaceutical products. Additional PS include: reference, information, Advisory services to the population and health workers; ordering, including pre-order of pharmaceutical goods; delivery of pharmaceutical goods to the house; rental of care items; services of phyto-bar; self-service and others (Moshkova, Korzhavykh, & Kuznetsov, 2013).One of the permanent threats in the sphere of PS security is the penetration into the pharmaceutical market of substandard (not meeting the requirements of regulatory documents), falsified (accompanied by false information about the composition and (or) the manufacturer) and counterfeit (in circulation in violation of civil legislation) drugs. In this area of activity, a key role in the field of PhS. is assigned to wholesale trade organisations of MP, pharmacy organisations, as well as state bodies exercising supervision in the field of health care. Thanks to the system of control over the treatment of MP deployed in the Russian Federation, significant volumes of MP representing a threat to public health are withdrawn from the retail sector of the pharmaceutical market annually (Murashko, 2017). Data on withdrawal from civil circulation of substandard, falsified and counterfeit MP for 2015-2016 are given in the Table 01.

Table 01. Information about the withdrawal of MP from circulation for 2015-2016

Criterion for withdrawal of MP	**Number of series, units**		**Dynamics, % (–) – reduction (+) – growth**
	2015	**2016**	
Substandard	701	533	– 24
Falsified	27	11	– 59
Counterfeit	33	29	– 12
Recalled by manufacturer	952	1365	+ 43
The entire series	1713	1938	+ 13

The total number of MP withdrawn from circulation in Russia in 2015 amounted to 2,186 million, and in 2016 – 2,619 million conventional packages. The increase in the volume of seized MP was about 20%. In 2017 the authorities of Novosibirsk have completed 282 of the examination on 23 brand names of MP. As a result, 15 batches of substandard pharmaceuticals in the number 140,096 thousand conditional containers were withdrawn from circulation. The total number of cases of detection of substandard, counterfeit and counterfeit drugs has decreased significantly (Murashko, 2018). On the one hand, these data indicate the reliability of the state system of supervision over the quality of medicine, and on the other – the ongoing attempts of unscrupulous and criminal entities to obtain a guaranteed profit in the pharmaceutical market by harming the health of the population.

In order to protect the population from substandard, counterfeit and counterfeit drugs and to provide an unlimited number of consumers with the opportunity to check the legality of registered medicine, a pilot project on the labeling of medicine in civil circulation was launched in Russia on January 1, 2018. By the end of the year, the individual marking, in the form of QR-code, will be applied to all MP produced in civil circulation. The QR-code will contain information about the authenticity, date of manufacture, manufacturer and batch number, the unique number of the goods, as well as the movement of the package through the distribution network. You can read this information using a special

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application for your smartphone, distributed free of charge. With the full coverage of MP, the system will track more than 6.5 billion packages annually, up to one thousand manufacturing organisations, up to 2.5 thousand wholesale organisations and up to 350 thousand medical and pharmacy organisations.

In the analysis of available literature, it was found that most often consumers of drugs have problems with PhS. due to errors in the prescription, selection and use of drug therapy. According to the Research Institute of Ambulance named after N. V. Sklifosovsky (Moscow), 160 thousand people in Russia suffer from MP poisoning annually, of which about 15% of cases end in deaths, and it is more than 24 thousand people (Lagutkina, 2013).

According to the World Health Organisation (Medicines: rational use of medicines, 2010), published in 2010, more than 54% of all medicines are prescribed, dispensed or sold to consumers improperly and about 50% of patients take them wrongly (Medicines: rational use of medicines, 2010). At the same time, WHO experts reasonably believe that the leading role in the prevention of drug poisoning belongs to pharmaceutical specialists, as they have direct contact with the consumer, possess all professional information about MP.

The Ministry of Health and Social Services of the United States proposed a classification of factors affecting the emergence of threats of MP poisoning:

1 group of factors – *Unavoidable poisoning factors (uncontrollable risks).* These include: MP poisoning due to gaps in modern science associated with the entry into the market of new drugs, lack of knowledge about their interaction with other drugs, food and the environment, as well as the use of drugs not for registered indications; MP poisoning due to unforeseen adverse reactions of the human body, the occurrence of which in nature and severity of the consequences does not correspond to the information on MP contained in the instructions for its use.

2 group of factors – *Preventable factors of poisoning (managed risks)*. They include: errors in the use of drugs; accidental poisoning of drugs; abuse of drugs; self-treatment (Lagutkina, 2013).

From the presented classification of poisoning factors, the main attention should be paid to preventable factors that depend on doctors, pharmacists and consumers of drugs.

Studies have shown that errors in the use of drugs associated with *information errors of doctors*, most often occur due to the lack of complete information about drugs (for example, instructions in a foreign language), or the doctor does not use all the information about drugs (ignores contraindications), or does not pay attention to the individual characteristics and health of the patient (age, allergic reactions, the presence of concomitant diseases). Doctors often prescribe drugs: having a teratogenic effect on women of reproductive age (without a pregnancy test); not recommended for prescribing to persons older than 65 years (Birsa list), as well as persons with professional contraindications (drivers, pilots and others); interacting with the MP, which the patient is already taking; without taking into account the individual characteristics of the patient (allergy to MP); in high doses (for insurance); with errors in spelling of the names of drugs specified in the recipe (omission or replacement of letters, suffixes in the name of drugs, etc.).

The most common causes of *information errors of pharmaceutical workers* that occur when the ML is dispensed to consumers are: a doctor's illegible handwriting in the recipe, errors in reading of the names of the ML specified in the recipe, and dispense of non-prescribed drugs that are similar in spelling

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(for example: such trade names of MP as Tamiflu – Teraflu, Tireotom – Tireokomb; Linex – Linkas; Prostamol – Paracetamol; Ranitidine – Rimantadine); the similarity of appearance of packaging of the same MP in different dosages or even different ML; ambiguities in the instructions for use of ML.

To regularise the appointment of MP and prevent errors when reading recipes in Russia it is forbidden to register the MP with similar names, but different composition and action.

Information errors of medicine consumers are reduced, first of all, to the fact that they are either not informed about all the properties of drugs, or they are not able to understand and use this information correctly. This leads to a spontaneous increase in the dose of MP to increase the effectiveness of treatment or unconscious use of several dosage forms of the same drug at the same time; unreasonable intake of MP due to inaccessible to the consumer labeling and accompanying medicine information.

Accidental poisoning of MP is estimated in tens of thousands of cases in each country where such statistics are kept. It most often affects children resulting from the ingestion of medicines for cough and cold, prescribed to other family members. Mainly, it is liquid MP, which children aged 2 to 5 years are able to open and drink.

In the structure of accidental poisoning in Russia, the leading place is occupied by MP from such pharmacotherapeutic groups as: non-narcotic analgesics (Analgin, Paracetamol); anticonvulsants (Phenobarbital, Diazepam); codeine-containing drugs (Codterpin, Codelac); neuroleptics (Phenozepam, Azaleptin).

Abuse refers to the constant or one-time intentional excessive consumption of drugs, which carries a threat of negative consequences for physical or mental health. This can be used in order to achieve narcotic or toxic intoxication, suicidal use, as well as a special case of self-treatment with erroneous excessive intake of MP.

So, the main groups of MP on prescription, abused by citizens of the United States, Canada and Germany are codeine-containing drugs, neuroleptics, tranquilizers, antidepressants, sedatives, barbiturates and steroids. Citizens of Russia most often abuse anticonvulsants, codeine-containing, neuroleptic agents and antidepressants.

In all countries, the main methods of illegal receipt of prescription drugs for the purpose of abuse are fake prescriptions, sale of recipes, obtaining prescriptions from several doctors, online pharmacies.

Of the over-the-counter drugs, most cases of abuse in all developed countries are reported for non-narcotic analgesics, antitussives, antihistamines, decongestants and laxatives.

Self-treatment is a "reasonable" use of medicines that are on the free market by the patient, for the prevention or treatment of mild health disorders to provide professional medical care. The features of self-treatment, as a rule, are: lack of knowledge about the effective and safe use of drugs; violation of the requirements governing the dispense of prescription and non-prescription MP by the pharmacies; violation of legislation on medicine advertising; lack of effective state system of promotion of healthy lifestyles. As statistics show, the negative result of self-treatment, first of all, is the incompleteness of therapy and transfer of the disease to the latent phase of the course, complications due to the loss of time for effective treatment, the emergence of resistance of infectious agents with the wrong choice and errors in the dosage of antibacterial and viral therapy, and others.

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7. Conclusion

The results of the study of the problems of ensuring the security of PS in the retail segment of the pharmaceutical market indicate a significant potential danger to the modern health care system and consumers of medicines associated with the ever-growing range of supply and volume of professional information in the pharmaceutical market. In our opinion, in such circumstances, the leading role in providing PhS. belongs to medical and pharmaceutical workers engaged in the provision of PhS. to the population. Their professionalism and responsibility are the main factors in maintaining the medicine supply to the citizens of their country at the socially necessary quality level.

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References

Kuznetsov, D. A., & Korzhavykh, E. A. (2013). Cluster analysis of the scientific concept "Pharmaceutical safety". *Life without dangers. Health. Prevention. Longevity, 3*, 68–73.

Lagutkina, T. P. (2013). Increasing the role of pharmacies in ensuring drug safety. *Effective management, 10*, 38–42.

Medicines: rational use of medicines. (2010). Retrieved September 06, 2018, from: http://www.who.int/medicines/areas/rational_use/en/

Moshkova, L. V., Korzhavykh, E. A., & Kuznetsov, D. A. (2013). Modern problems of pharmaceutical safety. *Life without dangers. Health. Prevention. Longevity, 1*, 20–27.

Murashko, M. (2017). About results of work of Federal Service for Supervision in the field of Health Care in 2016 and plans for 2017. *Bulletin Of Roszdravnadzor, 2*, 5–16.

Murashko, M. A. (2018). On the outcome of the Federal Service for Supervision in the phere of Health Care in 2017 and plans for the 2018. *Vestnik Roszdravnadzor, 2*, 5–15