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**RISK FACTORS MANAGEMENT IN THE PROVISION  
OF PHARMACEUTICAL SERVICES**

**316.01 PHARMACY**

**Summary of the doctoral thesis in pharmaceutical sciences**

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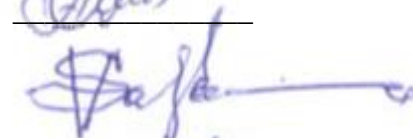
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## INTRODUCTION

Patient safety and the quality of pharmaceutical services are increasingly influenced by the growing risks in the pharmaceutical field. In the Republic of Moldova, these risks are also amplified by the shortage of pharmacists, staff overwork, prescription errors, similar trade names of medicines, lack of continuous training in the field of risks and the lack of an effective error reporting system. [4].

At an international level, pharmaceutical risk management is a current topic, with the objective of implementing standardized solutions to reduce medication errors. [23]. In the Republic of Moldova, alignment with these standards is essential for improving the quality of pharmaceutical services and adapting to the requirements of the European healthcare system [1]. The pharmaceutical industry is exposed to various risks, from medication errors and adverse reactions to financial losses and damage to the reputation of pharmacies. In the Republic of Moldova, these risks are exacerbated by the shortage of pharmacists, staff overwork, excessive multitasking and lack of ongoing training. [7].

Prescription errors and similar brand names of drugs are also critical factors that can increase the incidence of medication errors. In addition, the lack of an effective error reporting system prevents the real assessment of the situation and the implementation of necessary corrective measures.

**The purpose of the study** was to analyze and evaluate the risk factors affecting pharmaceutical activity within community pharmacies, develop an integrated risk management methodology to improve the quality of pharmaceutical services, reduce medication errors and promote the training and continuous education of pharmacists in this field.

In accordance with the purpose of the study, the following **objectives** were formulated:

1. Detailed analysis of bibliographic sources regarding existing research in the field of risk identification and assessment, RM and RFM, including in the pharmaceutical field;
2. Identification and assessment of risk factors (risks) in the exercise of the pharmacist's activity and their influence on the process of providing pharmaceutical services within community pharmacies;
3. Identification, classification and analysis of medication prescription errors as a major risk factor in the pharmacist's activity in assisting the population with medications;
4. Identifying and assessing the risks associated with similar drug names and developing strategies to prevent LASA errors;
5. Development and implementation of a risk management methodology in pharmaceutical practice, including solutions for safer medication, recommendations for minimizing risk factors and preventing medication errors;
6. Developing educational programs aimed at training and educating future specialists and practicing pharmacists in effective risk management during the exercise of pharmaceutical activity.

**Research hypothesis:** Implementation of an integrated risk management system, standardization of pharmaceutical processes, training and continuous education of pharmacists in these areas will lead to a significant reduction in medication errors in community pharmacies.

**Scientific research methodology.** The study used pharmacists' questionnaires, highlighting their perceptions of risks specific to pharmaceutical activity. The real-time risk monitoring technique allowed direct observation and documentation of the frequency and dynamics of medication errors in the community pharmacy environment. The Ishikawa diagram was used to

classify and systematically organize risk factors/risks according to the stages of the pharmaceutical process. The risks were assessed by the Expert Analysis Method according to their impact and probability. Also, the analysis of prescription errors in medical prescriptions allowed the investigation of one of the most critical risk factors, highlighting the frequency and typology of errors that can influence the entire drug dispensing process. The analysis of the SNM facilitated the identification of risks associated with similar trade names of drugs, another important factor in the occurrence of medication errors.

**The scientific novelty of the research** consists in the development, for the first time, of an integrated pharmaceutical risk management algorithm, which brings together in a practically applicable form, a complex set of quantitative and qualitative methods. This algorithm represents an innovative scientific synthesis, in which the essential stages of the pharmaceutical process – ordering, receiving, storing, preparing and dispensing drugs – are subjected to a systemic assessment, with the identification and prioritization of risk factors/risks that can generate medication errors.

The application of this algorithm allowed for a detailed analysis of the main vulnerabilities in the pharmaceutical activity and highlighted, in particular, the negative impact of prescription errors, similar trade names of drugs and the lack of standardized procedures. At the same time, the research highlighted the significant discrepancy between the real number of medication errors identified by the applied methods and the lack of official reporting to the authorities, which underlines the urgency of implementing a functional risk monitoring and reporting system.

Ultimately, the proposed algorithm allowed the formulation of clear strategies for reducing medication errors, standardizing pharmaceutical processes, and improving the professional training of pharmacists.

**Scientific issues addressed in the thesis.** The research identified and classified risk factors in community pharmacies, providing solutions for preventing medication errors and improving patient safety. The analysis of medical prescriptions highlighted the frequency and typology of prescription errors, underlining the need for a correction and prevention system. The study assessed the risks associated with similar trade names of medicines, applying measures to reduce this error factor. An integrated risk management methodology was developed and implemented, including operational procedures, continuing education of pharmacists and optimization of pharmaceutical processes. The research contributed to the development of an educational program aimed at training future pharmacists in the prevention and management of pharmaceutical risks. Through this integrated approach, the work supports the development of an effective risk management system, applicable in pharmaceutical practice in the Republic of Moldova.

**Theoretical significance of the work.** By integrating the results into the educational process, the work formed the basis for introducing the discipline "Pharmaceutical Risk Management" into the curriculum of the Pharmacy study program, and the thematic improvement course "Specialized Pharmaceutical Care for High-Risk Patients", contributing to the training of future pharmacists and practicing pharmacists. For future pharmacists, the Course Support and Methodological Recommendations for the Pharmaceutical Risk Management discipline were developed, and for pharmacists in community pharmacies - the Guide to Implementing Risk Management in Community Pharmacies. At the same time, the study provided theoretical support for the development of legislative amendments regarding similar names of medicines.

**The applicative value of the thesis.** The research results represent application tools regarding the management of risk factors/risks in the **drug authorization** process (proposals for amending

the Order No. 739/2012 of the MoH RM on regulating the authorization of medicinal products for human use and introducing post-authorization amendments, approved by Order No. 1041 of the MoH RM dated 15.11.2021, Implementation Act No. Rg02-001689 of 07.04.2022), **provision of pharmaceutical services** by pharmacists in community pharmacies (Guideline on the Implementation of Risk Management in Community Pharmacies examined and recommended at the meetings of the Department of Social Pharmacy "Vasile Procopișin", minutes no. 09 of 17.03.2023, the Scientific and Methodological Commission in the Pharmacy field, minutes no. 02 of 24.03.2023, the Quality Management Council, "Nicolae Testemițanu" SUMPh, minutes no. 06 of 25.04.2023, Council of Experts of the MoH RM, minutes no. 01 of 24.04.2024, approved by Order of the MoH RM no. 686 of 19.08.2024), **training and improvement of pharmacist specialists** in the teaching process (development of the course Pharmaceutical Risk Management (optional subject) for 4th year students in the Curriculum for the study program 0916.1 Pharmacy implemented in the academic year 2021-2022, Implementation Act no. 03-158 of 21.01.2022), (development of the Course Support and methodological recommendations for the discipline Pharmaceutical Risk Management. (examined and approved in the meetings of the Department of Social Pharmacy "Vasile Procopișin", minutes no. 06 of 13.01.2023, the Scientific and Methodological Commission for Pharmacy, minutes no. 01 of 18.01.2023, the Quality Management Council, "Nicolae Testemițanu" SUMPh, minutes no. 04 of 02.02.2023), (development of the thematic improvement course "Specialized pharmaceutical care for high-risk patients", Implementation Act no. 03-1453 of 02.05.2024). Thus, the study goes beyond the academic sphere, having a direct and tangible impact on the pharmaceutical system, contributing to increasing the quality of services and reducing pharmaceutical risks.

**Approval of results.** The research results were presented in the form of oral communications within the following national and international activities: XXVIII National Meeting on the History of Pharmacy (2019, Sibiu, Romania); Annual Scientific Conference of Scientific and Didactic Staff, PhD Students, Master Students, Residents and Students (2019, Chisinau, Moldova); Scientific conference with international participation "Obtaining and pharmaceutical research of molecules and pharmaceutical products with therapeutic potential" within the framework of the Moldova-Belarus International Bilateral Project (2020, Chisinau, Moldova); Scientific and practical conference dedicated to the memory of university professor "Vasile Procopișin" - "The pharmacist and his role in the healthcare system" (2020, Chisinau, Moldova); Congress dedicated to the 75th anniversary of the founding of the "Nicolae Testemițanu" SUMPh (2020, Chișinău, Moldova); XXVII International Scientific and Practical Conference of Young Scientists and Students "Topical Issues of New Medicines Development", Dedicated to the 150th Anniversary of the Birth of M.O. Valyashka (2021, Haricov, Ukraine); Scientific and practical conference with international participation "Medicine quality assurance system - problems and solutions" (2021, Chisinau, Moldova); Annual scientific conference: "Research in biomedicine and health: quality, excellence and performance" (2021, 2022, 2023, Chisinau, Moldova); Scientific and practical conference with international participation "Medicine quality assurance system - problems and solutions" (2021, Chisinau, Moldova); National scientific and practical conference with international participation "Current events and perspectives in the pharmaceutical study of medicinal plants" (2021, Chisinau, Moldova); Scientific and practical conference "Systemic approach - methodology in pharmaceutical research" (2021, Chisinau, Moldova); Scientific and practical conference "Doctor-pharmacist relations in the promotion of advanced pharmaceutical services", "Nicolae Testemițanu" SUMPh (2021, Chișinău, Moldova); The 9th International

medical congress for students and young doctors. Medespera (2022, Chişinău, Moldova); The 4th Edition of the International Exhibition of Innovation and Technology Transfer Excellent Idea - 2025 (2025, Chişinău, Republica Moldova).

**Main scientific results.** As part of the research, an integrated pharmaceutical risk management algorithm was developed and scientifically validated, which allowed the identification, evaluation and classification of 56 risk factors distributed across the stages of pharmaceutical activity, grouped into four priority levels – very high, high (13), medium (40) and low (3).

The analysis of a sample of 1,500 medical prescriptions revealed that the number of prescription errors detected ranged from a minimum of one to a maximum of 12, with the predominance of omission errors, followed by commission errors.

Following the analysis of the risks associated with similar names of medicines, 36 combinations of similar names were identified, with a high risk of confusion in the process of dispensing medicines. The findings of the study highlighted the legislative gaps in the management of this type of risk, which led to the development and promotion of legislative recommendations included in Order 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments, these amendments being approved by Order of the Ministry of Health of the Republic of Moldova no. 1041/2021.

Questioning pharmacists and real-time risk monitoring confirmed the absence of standardized risk management procedures in community pharmacies. This necessitated the development of a Guide on the implementation of risk management in community pharmacies, which includes a coherent set of six standardized operational procedures, covering all stages of pharmaceutical activity – from ordering and receiving medicines to storage, preparation and dispensing. The Guide provides pharmaceutical staff with practical and easy-to-apply tools for identifying, assessing and reducing risks and was approved by Order MS RM no. 686/2024. The relevance and applicability of the Guide were confirmed by the mention with the Silver Medal at the 4th Edition of the International Exhibition of Innovation and Technology Transfer - Excellent Idea - 2025.

In terms of education, the results of the thesis contributed to the development of the university curriculum and continuing professional training. Thus, in the Curriculum of the Study Program 0916.1 Pharmacy, the optional discipline "Pharmaceutical Risk Management" was introduced for 4th year students, and the Course Support and Methodological Recommendations for this discipline were also developed. At the same time, essential elements regarding risk management were included in the continuing professional training program "Specialized pharmaceutical care for high-risk patients", thus strengthening the training of pharmacists and supporting the development of their skills.

## **THESIS CONTENT**

### **1. MANAGEMENT OF PHARMACEUTICAL RISK FACTORS - GUARANTEEING PATIENT SAFETY**

Risk factors and risks analyzed in the literature from different countries, which may affect the activity of pharmacists in community pharmacies, include insufficient or unqualified staff, lack of standardized procedures, inadequate working conditions [2, 19], time pressure and excessive workload [3,14], lack of communication and collaboration, inadequate or insufficiently equipped workspaces, frequent interruptions, similar names and packaging of medicines [21].

In pharmaceutical practice, it is essential to recognize that risk factors and risks are often

interconnected, and that effective risk management involves not only identifying risks, but also the risk factors that contribute to their occurrence [11]. In pharmaceutical practice, it is essential to recognize that risk factors and risks are often interconnected, and that effective risk management involves not only identifying risks, but also the risk factors that contribute to their occurrence.

In the Republic of Moldova, there is a deficiency in information and awareness of risks, risk factors and medication errors in community pharmacies. This lack of reporting leads to the absence of a mechanism for implementing measures to prevent and manage risk situations. The solutions and strategies implemented must fit the needs and unique characteristics of the pharmaceutical market in order to be effective and relevant in preventing risks. The pharmaceutical market in the Republic of Moldova faces various challenges such as lack of qualified personnel, high workload, lack of standardized procedures, etc. [6, 13].

It is essential that pharmaceutical services are not affected by risks or risk factors, as they are responsible for the safety and effectiveness of medicines used by patients, the consequences of which are medication errors, which can lead to adverse reactions, ineffective treatments or even the death of patients [12, 18]. According to studies, every year, in the United States alone, between 7,000 and 9,000 people die as a result of a medication error [15]. In addition, hundreds of thousands of other patients have been affected by medication errors, but often do not report the error.

One of the critical issues facing the pharmaceutical industry is the similar packaging and names of drugs, which represent a real risk for medication errors. In the specialized literature they can also be found under the abbreviation LASA (look-alike, sound-alike). Of the total medication errors, the percentage of LASA errors varies from 6.23 to 14.7%, representing a significant threat [16, 17].

Similar drug names can cause medication errors in several circumstances. Pharmacists may confuse drugs when presented with multiple products with similar names. This can be exacerbated by time pressure or a busy work environment where pharmacists must respond quickly to patient requests. Doctors with illegible handwriting may prescribe a drug that can easily be confused with the name of another drug, or patients at home may administer the wrong drug.

Pharmacists should be well informed about similar drug names and be trained in prescription verification and confirmation techniques.

Prescription errors in medical prescriptions are a problem with a major impact on the healthcare system and patient health. They can lead to treatment delays, incorrect drug doses, or incompatible drugs, which can negatively affect patient health.

Studies conducted in some European countries and the USA on the accuracy of medical prescriptions have highlighted the following: over a third of the prescriptions analyzed presented inaccuracies or errors that could compromise patient safety or even endanger their life [22].

The analysis of techniques and methods for identifying risk factors and risks proposed by various researchers and existing strategies and practices of RM and RFM in other countries identified gaps in this area in the Republic of Moldova.

The implementation of risk management and risk factor management in community pharmacies in the Republic of Moldova is imperative to ensure the quality and safety of pharmaceutical services. A systemic approach is needed [8], which includes the analysis and assessment of the country's pharmaceutical market [5], the development of a guide for pharmacists, and the amendment of the legislation on similar names of medicines. These measures will contribute to the prevention and improvement of medication errors and ensure better protection of patients.



## 2. RESEARCH MATERIALS AND METHODOLOGY

### 2.1. Overview of the study

The study conducted is an observational, descriptive, cross-sectional study to identify and analyze risk factors and pharmaceutical risk in community pharmacies in the Republic of Moldova. After an analysis of the methods, techniques and tools used by other researchers, an integrated pharmaceutical risk management algorithm was developed to obtain a detailed assessment of risk factors and risks in community pharmacies in the Republic of Moldova.

The algorithm was designed as a logical model, structured on four functional levels, each level integrating qualitative and quantitative methods for a complex approach to risk identification, analysis, evaluation and treatment.

**I. Identification** – at this stage, two complementary methods were applied: surveying pharmacists and real-time monitoring of pharmaceutical activity.

**II. Analysis** – for this stage, two distinct techniques were applied: analysis of the State Nomenclature of Medicines (SNM) and analysis of medical prescriptions

The results of the application of the 4 methods of identification and analysis of risk factors/risks were presented using the Ishikawa Diagram, which provided a clear picture of the causes of risk in each step of the pharmaceutical process.

**III. Evaluation** – the assessment of the risks and risk factors identified in the pharmaceutical activity was carried out by applying the Expert Analytical Method (EAM), allowing the quantification of the level of risk by involving 30 independent experts. Subsequently, the results obtained were integrated into the Risk Matrix which facilitated the classification of risks into four levels of severity: low, medium, high and very high.

**IV. Treatment** – the final stage involves the application of corrective and preventive measures depending on the level of risk identified.

### 2.2. Methodology applied in the research

Research methods were chosen strategically, taking into account the aims, objectives and specificities of the pharmaceutical field. By combining the following methods, techniques and tools, a comprehensive picture of risk factors and risks has been obtained, including both quantifiable data and qualitative insights reflecting the realities of everyday practice.

**1. The method of questioning pharmacists.** The proposed questionnaire aimed to collect information on occupational risk factors related to the work environment of pharmacists and to identify the main risks in the pharmacies where they work.

#### **Determining the sample of pharmacists.**

According to the statistical biennial of the Agency for Medicines and Medical Devices in 2016, the number of pharmacists in the Republic of Moldova amounted to 3080 pharmacists in urban and rural localities (per 10 thousand inhabitants).

The representative sample was calculated in the program EpiInfo 7.2.2.6, compartment “StatCalc-Sample Size and Power” for the cross-sectional study based on the following parameters:

- Population – no. of pharmacists, RM (2016) – 3080
- Error frequency up to 7.0%
- Permissible error – ES=5.0%
- Design effect=1.5

Result: for 99.0% CI n=246, with 10.0% non-response n= 271

### **Eligibility criteria:**

- ◆ **Subject selection criteria** – randomly, pharmaceutical staff (branch head pharmacist, pharmacist manager, pharmacist, pharmacist assistant);
- ◆ **Exclusion criteria**- students practicing in pharmacy, consultants, persons lacking information about their professional status and in case of unwillingness to give time and information requested, lack of seriousness.

By completing the questionnaire, participants helped to identify common causes of errors in pharmacy and to develop recommendations to avoid and minimize them.

**2. Real-time pharmaceutical risk monitoring technique.** The systemic observation method involved a 4-hour visiting program in 11 community pharmacies to record and monitor the activities and processes carried out, according to a well-defined protocol. The selection method applied for the pharmacies was a non-randomized, convenience method, based on the pharmacies' agreement to cooperate. At the end, detailed reports were produced using Microsoft Excel and SPSS (Statistical Package for Social Sciences), including the results of the observations.

**3. Ishikawa diagram.** The application of the Ishikawa diagram has proven to be effective in pinpointing the causes of medication errors and has contributed to the development of concrete solutions aimed at preventing medication errors in community pharmacies.

**4. Expert Analyzed Method (EAM) in risk assessment.** The survey involved 30 independent experts who assessed the risks according to their likelihood and impact.

#### **Selection of experts.**

The main criterion for the selection of experts was the "broadest possible professional view" on the issues related to the risks of pharmaceutical activity. Face-to-face and telephone interviews were used to assess the competence of future experts. Concrete criteria were established as a basis for the scoring and selection of experts.

To facilitate the calculation of the survey results and their subsequent analysis, the competence coefficient for each selected expert ( $K_e$ ) was calculated depending on the number of points accumulated according to the expression:

$$K_e = \frac{1}{10} \sum_{P=6}^{P=12} P_a \quad (1)$$

where:

$P_a$  – the number of points accumulated according to the concrete criteria.

Following the application of the formula, all 30 experts exceeded the minimum scoring threshold.

In order to ensure a high degree of veracity of the results obtained in the survey, only experts with a competency level of 0.6 and higher participated.

Questioning the selected experts included estimating the probability of occurrence of the indicated risks and their impact on the objectives or the result of the activities.

The next step was to determine the risk exposure, defined as a combination of the probability of occurrence and the potential impact of the risk, representing a two-dimensional indicator with a matrix structure [9]. This exposure was illustrated using the Risk Matrix. Based on the calculated risk factor, the risks were prioritized. Risk ranking is used to set priorities for planning preventive actions [20].

**5. Analysis of prescription errors.** The research sample included 1500 prescriptions collected from 32 community pharmacies in mun. Chisinau. The pharmacies were selected by

stratified sampling method, each administrative sector of the municipality (Center, Botanica, Riscani, Buiucani, Ciocana) being considered as a distinct stratum. Within each stratum, pharmacies were randomly selected in proportion to their density per sector to ensure a balanced geographical distribution. Prescriptions were retrospectively collected from the participating pharmacies' records using simple random sampling from a time interval of 5 consecutive working days. The number of prescriptions sampled from each pharmacy was approximately 45-50.

The parameters of prescribing error were developed by studying the Good prescribing guidelines proposed by the WHO [24] and the Order of the MS of the RM on the manner of prescribing and dispensing of medicines No. 960 of 01.10.2012 [27].

Subsequently, the weight of each type of error, the correlation between the number of drugs prescribed on a single prescription and the number of prescribing errors present in a prescription, the frequency of the number of errors per prescription, the mean of each type of error, the percentage distribution of the values of the variables for each criterion for analyzing the prescriptions (in %) and the separation of errors of commission from errors of omission were identified.

## **6. Analysis of the State Nomenclature of medicines**

In order to identify pairs of similar drug names that may lead to medication errors, we went through the SNM [25] and compared the names of each drug with the others in the list, using Microsoft Excel, with the aim of identifying cases where the names of two or more drugs were similar or visually or auditory confusing. As a result, a list of all pairs of similar names identified was created and relevant information about each of them was recorded.

## **2.3. Mathematical and statistical methods**

The repeated measures **ANOVA technique** was used to test for significant differences between the mean prescription errors of each type (2, 3, 4 and 5).

A requirement for applying the ANOVA technique is the sphericity condition, which assumes homogeneity of variances within all experimental moments and within the differences between these moments. This condition is verified in SPSS by the **Mauchly test of sphericity W**, which shows significant results for the situation investigated ( $W=0.351$  for  $p$  (sig.)= $0.000<0.05$ ). Therefore the sphericity condition is not fulfilled and since the Epsilon coefficients are less than 0.75, the **Greenhouse-Geisser correction** was used for the main F results of the ANOVA technique in the **Tests of Within-Subjects Effects table**. In order to identify the significance of the differences between the means for each of the two types of prescribing errors, the results from the table of **contrast tests** were analyzed.

The **Greenhouse-Geisser correlation** was used to adjust the ANOVA test's degree of freedom when the sphericity assumption is not met.

The **Bonferroni post hoc test** was applied after the ANOVA test to perform multiple comparisons between groups. It adjusts the p-value to control for the Type I error rate, reducing the risk of drawing false conclusions when making multiple comparisons between groups. Pairwise comparisons, using **Bonferroni post hoc tests**, actually confirmed the results obtained in the contrast tests.

Testing for differences was performed using the **Paired Paired Samples t-test**.

**Pearson correlation** was used in this research to analyze the relationship between two quantitative variables: the number of medications prescribed on a single prescription and the number of medication errors associated with that prescription.

The **Chi-square ( $\chi^2$ ) test** was used in the research to examine whether there is a significant

association between pharmacists' demographic characteristics and perceived pharmacy risks.

The **Within-Subjects Effects Test** is applied to analyze the effects of variables on the same groups of subjects in a repeated measures experiment. This method allows the assessment of changes in a group of participants under different conditions or at different points in time, which has been useful for analyzing how risk perceptions change over the course of the study or following the implementation of interventions.

The **independent samples t-test** was used to compare the means of two distinct groups and assess significant differences between them.

These mathematical and statistical methods were essential to ensure correct data processing, to validate the research hypotheses and to identify significant relationships between the variables studied.

### 3. PHARMACEUTICAL RISK MANAGEMENT IN COMMUNITY PHARMACIES

#### 3.1. Pharmaceutical risk analysis in community pharmacies

The first method applied to analyze the risk factors and risks affecting the entire chain of pharmaceutical activity, from the ordering of medicines to their dispensing to patients, was to survey pharmacists. The results revealed that among the most common errors reported by pharmacists were dispensing of medicinal products on prescriptions containing prescribing errors (16.4%, 95% CI: 13,93 – 18,93), misinterpretation of prescriptions (15.2%, 95% CI: 12,83 – 17,67) and dispensing of Rx products without prescription (13.1%, 95% CI: 10,85 – 15,40). Pharmacists also mentioned factors such as high workload (16.5%, 95% CI: 14,27 – 18,81), large number of patients (15.3%, 95% CI: 13,07 – 17,47) and similar drug names (14.1%, 95% CI: 11,98 – 16,23) as the main risk factors, table 1.

Table 1. **Major factors that can increase the incidence of medication errors at the dispensing stage in the pharmacy**

		Answers		Confidence interval 95%	
		n	Percent	Lower limit	Upper limit
<b>Major factors that can cause errors</b>	Large amount of patients	157	15,3%	13,07	17,47
	Overwork	113	11,0%	9,08	12,90
	Frequent interruptions	79	7,7%	6,06	9,31
	High volume of work	170	16,5%	14,27	18,81
	Similar drug names (e.g. Aferin-Afrin; Dedal-Defal; Lenuxin- Lenixin)	145	14,1%	11,98	16,23
	Patient taking multiple treatments	121	11,8%	9,80	11,98
	Irrational placement of medicines in terms of frequency of use	35	3,4%	2,30	4,51
	Many hours worked per day	101	9,8%	8,01	11,64
	Working conditions and environment	62	6,0%	4,58	7,49
	Conflict/competitive relationships in the work team	45	4,4%	3,13	5,63
Total		1028	100,0%		

Subsequently, the technique of real-time monitoring of pharmaceutical risks was applied, which allowed a practical and direct approach to the risks. Through observation of the pharmaceutical activity and discussions with pharmacists, risks and risk factors specific to each

stage of the pharmaceutical process were identified. For the dispensing stage, the main risk was found to be the similar names of medicines, which can lead to confusion and therefore medication errors. At the pharmacy supply stage, one of the major risks was identified as the ordering of inappropriate quantities of medicines, either in excess or insufficient. In terms of storage of medicines, major risks were observed to include inadequate room conditions, lack of appropriate facilities and failure to arrange products correctly. At the goods receiving stage, the major risk was not checking for apparent defects in the medicines. For the preparation stage, the most important risks were related to incorrect weighing of medicinal substances and the use of substances of inadequate quality.

The third method used was the Ishikawa diagram, which allowed the graphical representation of all the risk factors and risks collected through the questionnaire method and the real-time risk monitoring technique, separated into five essential stages of the pharmaceutical activity: ordering medicines, receiving medicines, storage, preparation and dispensing of medicines. In total, 56 risk factors/risks that can cause medication errors were identified, of which 8- factors for the ordering stage, 8- for the receiving stage, 6- for the storage stage, 17- for the preparation stage and 17- for the dispensing stage.

### **3.2. Expert analysis in pharmaceutical risk assessment**

The risk factor/risk assessment was conducted through the EAM, an approach involving 30 independent pharmaceutical experts. They assessed the risk factors/risks based on their professional experience, using two rating scales: one for the likelihood of risk occurrence and one for the severity of the potential impact of the risk. The aim was to quantify the risk factors/risks and prioritize them according to the likelihood and impact of each risk factor/risk, providing an objective assessment of risk exposure. Based on the obtained average of probability and impact values, and using the Risk Matrix, the risks were categorized into the following:

- low level risks: average between 1 and 5
- medium level risks: average between 6 and 10
- high level risks: average between 11 and 15
- very high risks: average between 16 and 25

A total of 56 risk factors/potential risks that can cause medication errors have been calculated, categorized in 5 stages, of which 8 for the activity of ordering medicines, 8 potential risks for the activity of receiving products, 6 risks for the activity of storing products in the pharmacy, 17 causes of errors for the activity of preparing medicines and 17 causes of errors for the activity of dispensing medicines.

Based on the calculated risk factor value, risks were categorized into:

- low level risks – Intervention priority 4;
- medium level risks – Intervention priority 3;
- high level risks – Intervention priority 2;
- very high risks – Intervention priority 1.

Thus, 8 medium risks (priority 3) were detected for the ordering stage, 1 low risk (priority 4), 5 medium risks (priority 3) and 2 high risks (priority 2) for the receiving stage, 6 medium risks (priority 3) for the storage stage, for the stage of preparation of medicinal products, 1 low risk (priority 4), 12 medium risks (priority 3) and 4 high risks (priority 2) have been calculated and the stage of dispensing of medicinal products contains 1 low risk (priority 4), 9 medium risks (priority 3) and most high risks (priority 2) - 7.

In total, 3 low level risks (priority 4), 40 medium level risks (priority 3), 13 high level risks (priority 2) and no very high-level risks (priority 1) were detected in the 5 steps analyzed, figure 1.

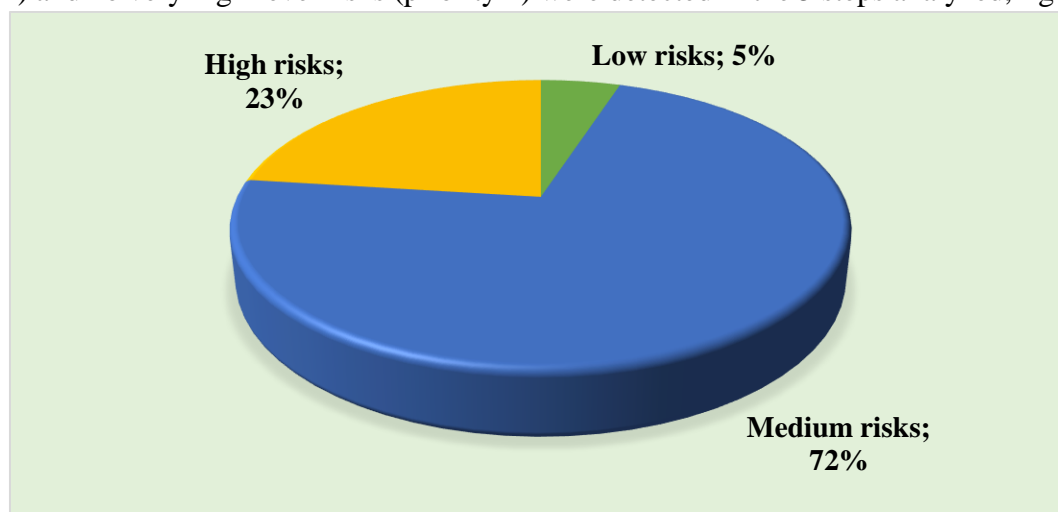


Figure 1. Risk categorization, %

Response strategies were developed for each risk category, such as accepting minor risks, actively monitoring medium risks, avoiding critical risks by modifying procedures and dealing with high risks through corrective and preventive measures.

The following high risk (priority 2) activities were highlighted in the research, for which urgent action is required to minimize the likelihood and impact: inaccurate handwriting of prescriptions (14,55), fatigue of pharmacy staff (11,75), overwork (11,01), prescriptions containing errors (12,00), insufficient staff knowledge (10,44), inattention of staff (10,18), the person receiving the products is involved in several tasks at the same time (11,22), prescriptions with expired expiry date (10,04), incomplete prescriptions (12,96), similar packaging of medicines (10,65) and insufficient staff concentration (9,71).

All medium and high risks can be included in the Risk Register in descending order, with the risks with the highest risk factor value first.

## 4. MEDICATION ERRORS IN THE PROVISION OF PHARMACEUTICAL SERVICES

### 4.1. Evaluating prescriptions to prevent medication errors

Errors can be eliminated when they are documented, reported and evaluated as part of a continuous quality improvement cycle [15]. Barriers to learning from medication errors are the lack of an effective error reporting system, fear of disciplinary or legal repercussions for health professionals, lack of time and resources to analyze each error in detail, and insufficient training on error management and prevention. To prove this, we have addressed a request to the Agency for Medicines and Medical Devices in which we asked for information about the rate of medication errors in the Republic of Moldova in the last 5 years.

In response to this request, AMMD communicated that during the period 15.06.2018-15.06.2023, no cases of medication errors were reported to AMMD by either healthcare professionals or drug users. This indicates that there is no effective system for reporting medication errors.

Medication errors in medical prescriptions, identified in the 1500 prescriptions, signaled a significant problem in terms of the quality of the drug prescribing process. In total, 6533 errors

were identified in the 1500 medical prescriptions, such as missing doctor's phone number (91,7%, 95% CI: 90,34 – 93,13), missing prescription expiration date (87,5%, 95% CI: 85,79 – 89,14), and mistakes in prescribing dosage (79,2%, 95% CI: 77,15 – 81,25).

The results obtained demonstrated that errors are omnipresent in the analyzed prescriptions, with a significant finding that none of the medical prescriptions was free of errors. Only 13 (0,87%, 95% CI: 0,40 – 1,34) of the total prescriptions contained a single error, while 1 (0,07%, 95% CI: 0,00 – 0,20) had the maximum of 12 errors. Most often, prescriptions contained 3 (20,6%, 95% CI: 18,55 – 22,65), 4 (25%, 95% CI: 22,81–27,19), or 5 (19,07%, 95% CI: 17,08 – 21,05) errors, figure 2.

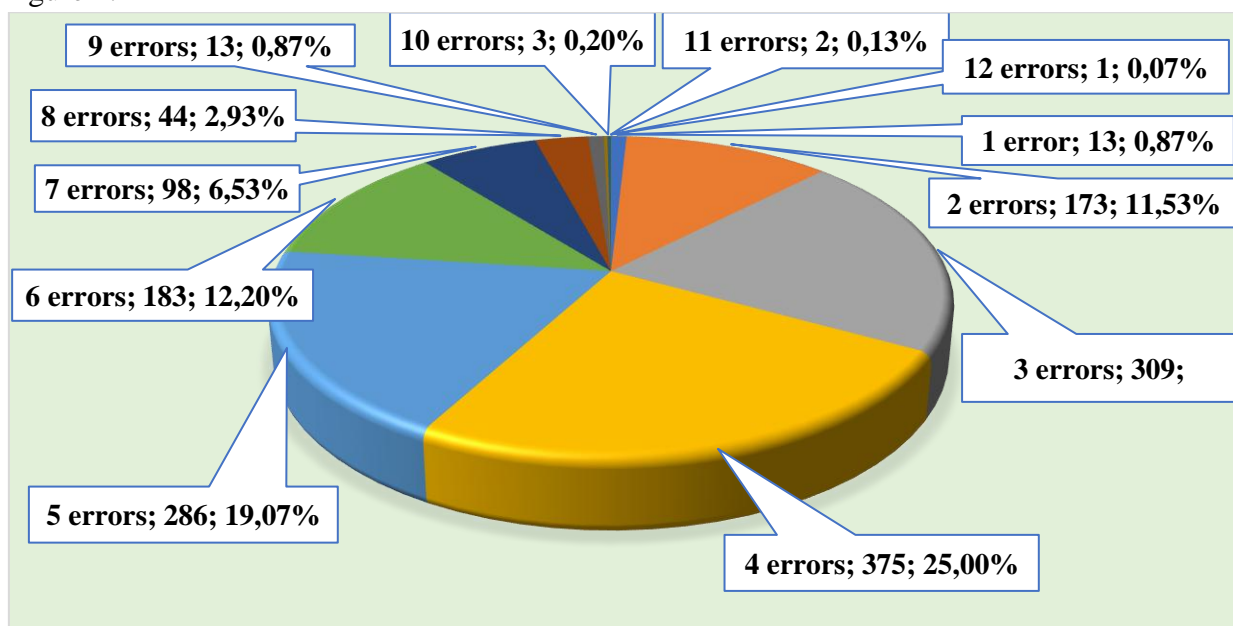


Figure 2. **Frequency chart of the number of errors per recipe, %**

Using the Pearson correlation, a significant correlation was demonstrated between the number of medications prescribed on a single prescription and the number of errors present, this correlation being strong, according to the correlation strength measurement scale in absolute value ( $r > 0.5$ ), indicating that a greater number of medications prescribed is associated with an increased probability of medication errors, table 2. The large number of prescribed medications increases the risk of polypharmacy which can cause drug interactions, adverse effects and complicate treatment management [22].

Table 2. **Correlation between the number of drugs prescribed on a prescription and the number of medication errors**

		Number of drugs per prescription / Rx	Number of errors
Number of drugs per prescription / Rx	Pearson correlation (r)	1	,510**
	Sig. (2-tailed)		,000
	N	1500	1500
Number of errors	Pearson correlation (r)	,510**	1
	Sig. (2-tailed)	,000	
	N	1500	1500
**. Correlation is significant at the 0.01 level (2-tailed).			

The subject of prescription errors was also researched through a survey of pharmacists, where

it was highlighted that "dispensing medicinal products on prescriptions with prescription errors" was considered one of the most frequent and problematic situations encountered in pharmaceutical activity. These data were complemented by information obtained through the real-time monitoring technique where, when asked about the frequency of errors in medical prescriptions presented by patients, 100% of respondents stated that they encounter such situations "very often".

To separate errors of omission from those of commission, the weight of each type of error was calculated, table 3.

**Table 3. The weight of each type of error**

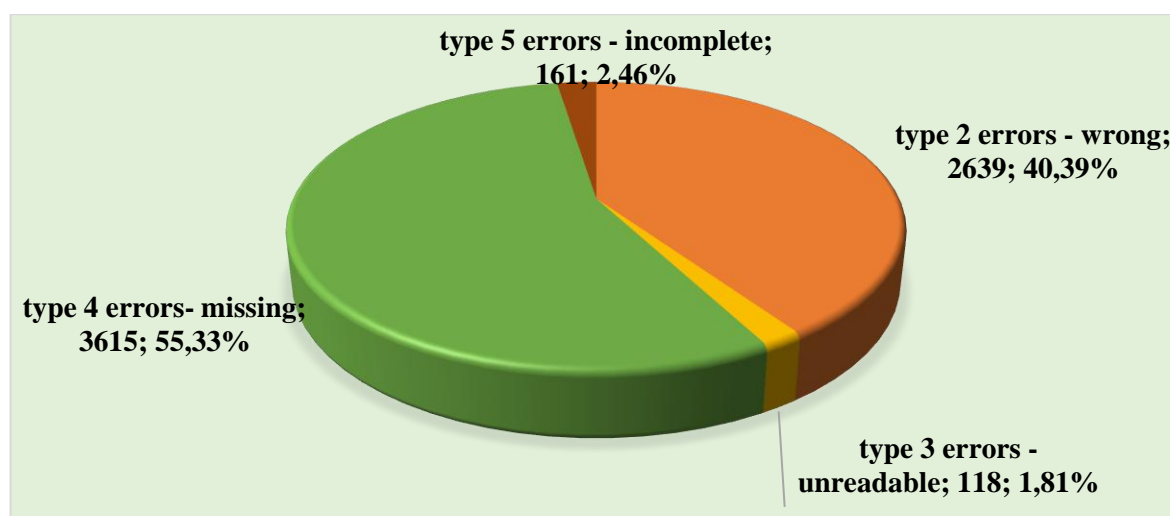
	Min.	Max.	Total	Sym. avg.	%	Confidence interval 95%	
						Lower limit	Upper limit
Number of type 2 errors - wrong	0	6	2639	1,76	40,39	39,21	41,58
Number of type 3 errors - unreadable	0	4	118	0,08	1,81	1,48	2,13
Number of type 4 errors - missing	0	8	3615	2,41	55,34	54,13	56,54
Number of type 5 errors - incomplete	0	2	161	0,11	2,46	2,09	2,84
<b>Total</b>			6533		100		

For type 2 errors – “wrong,” the minimum proportion is 0, meaning that in some cases no such errors were recorded, while the maximum proportion is 6, indicating that in certain situations multiple incorrect errors occurred. In total, 2639 errors of this type were recorded (40,39%, 95% CI: 39,21 – 41,58).

For type 3 errors – “illegible,” the minimum proportion is 0, and the maximum proportion is 4, reflecting a lower occurrence of this type of error. In total, 118 errors of this type were recorded (1,81%, 95% CI: 1,48 – 2,13).

For type 4 errors – “missing,” the minimum proportion is 0, and the maximum proportion is 8, indicating a significant presence of this type of error. In total, 3615 errors of this type were recorded (55,34%, 95% CI: 54,13 – 56,54).

For type 5 errors – “incomplete,” the minimum proportion is 0, and the maximum proportion is 2, representing a lower occurrence of this type of error, figure 3. In total, 161 errors of this type were recorded (2,46%, 95% CI: 2,09 – 2,84).



**Figure 3. Chart of the weight of each type of error, %**



To verify whether there are significant differences between the average errors of each type (2, 3, 4 and 5), the ANOVA technique with repeated measures was applied, table 4.

A requirement for applying the ANOVA technique is the sphericity condition, which assumes homogeneity of variances within all experimental moments and within the differences between these moments. This condition is verified in SPSS by the Mauchly test of sphericity W, table 5, which presents significant results for the researched situation ( $W=0.351$  for  $p(\text{sig.})=0.000<0.05$ ). Therefore, the sphericity condition is not met and since the Epsilon coefficients are less than 0.75, the Greenhouse-Geisser correction will be used for the main F results of the ANOVA technique in the Tests of Within-Subjects Effects table.

Table 4. Average of each error type

Average of each error type			
Number of type 2 errors - wrong	1,76	1,002	1500
Number of type 3 errors - unreadable	,08	,325	1500
Number of type 4 errors - missing	2,41	1,061	1500
Number of type 5 errors - incomplete	,11	,324	1500

Table 5. Mauchly Test of Sphericity

Mauchly Test of Sphericity					Greenhouse-Geisser	Huynh-Feldt	Lower-bound
errors	,351	1569,134	5	,000	,721	,722	,333

From table 6 Tests of Within-Subjects Effects, we have that  $F(2,162) = 3789,508$ , for  $p(\text{sig.}) = 0,000 < 0,05$ . Therefore, there are significant differences between the means of the 4 types of errors investigated.

Table 6. Tests of Within-Subjects Effects

Source		Type III Sum of Squares	df	Mean Square	F	Sig.
errors	Sphericity Assumed	6268,246	3	2089,415	3789,508	,000
	Greenhouse-Geisser	6268,246	2,162	2899,903	3789,508	,000
	Huynh-Feldt	6268,246	2,165	2895,577	3789,508	,000
	Lower-bound	6268,246	1,000	6268,246	3789,508	,000
errors	Sphericity Assumed	2479,504	4497	,551		
	Greenhouse-Geisser	2479,504	3240,143	,765		
	Huynh-Feldt	2479,504	3244,984	,764		
	Lower-bound	2479,504	1499,000	1,654		

Therefore, it makes sense to separate errors of omission (type 4 - missing) from those of commission (type 2 - wrong, type 3 - unreadable, type 5 - incomplete) and analyze the differences in means between them.

The testing of differences was performed using the t-test for paired samples Paired Samples Test.

Following the analysis, we can say that there are significant differences between the average of errors of omission and the average of errors of commission, with significantly more errors of omission (2.41) - missing information in prescriptions, compared to errors of commission (1.95) - wrong, incomplete or unreadable information), table 7.

As a method of solving the problem of prescription errors, an Operational Procedure for dispensing medicines and other healthcare products from the pharmacy was developed and

included in Chapter V of the Guide on the Implementation of risk management in community pharmacies.

Table 7. **Paired error statistics**

		Mean	N	Std. Deviation
Pair 1	Number of type 4 errors - missing	2,41	1500	1,061
	Number of commission errors	1,95	1500	1,137

#### **4.2. Identification and management of risks associated with medicines with similar names**

The analysis of the regulations in the Republic of Moldova highlighted a gap in the regulatory framework regarding similar names of medicines. The Order of the Ministry of Health of the Republic of Moldova on regulating the authorization of medicinal products for human use and the introduction of post-authorization amendments: no. 739 of 23.07.2012, does not impose strict measures to avoid the risks associated with medicines that have similar names or packaging [26].

To address the issue concretely, a detailed analysis of the SNM of the Republic of Moldova was conducted. Following this analysis, 36 pairs of drug names with significant similarities were identified, highlighting the possibility of visual or auditory confusion.

The topic of risks associated with similar drug names was also addressed by surveying pharmacists. According to the results, "similar drug names" were ranked third as a factor that can increase the incidence of medication errors. It is worth highlighting the fact that 197 respondents (71.6%, 95%CI: 66,31% – 76,96%) reported having had at least one confusion related to similar drug names.

Among the most risky pairs of drug names identified by pharmacists are Somnol (Zopiclonum) and Sonmil (Doxylaminum) with a percentage of 57.8% (95%CI: 51,9% – 63,7%), Leodex (Dexketoprofenum) and Leponex (Clozapinum) with 39.6% (95%CI: 39,6% – 33,8%), followed by Dedal (Ibuprofenum + Paracetamololum) and Defal (Deflazacortum) with an alarming percentage of 38.2% (95%CI: 32,4% – 44,0%), and in fourth place Verfen (Fentanylum) and Valfen (Valeriana officinalis + Phenobarbitalum) which were considered threatening by 36% (95% CI: 30,3% – 41,7%) of pharmacists, figure 4.

Also, the real-time monitoring technique of pharmaceutical risks was applied to directly observe situations in which similar trade names of drugs can cause errors in practice. This experimental approach allowed highlighting similar names as one of the most frequent risks in the drug release stage.

As a method of solving the problem, stricter standards for drug names were included in the regulatory framework of the Republic of Moldova. The changes were materialized by updating the Order of the Ministry of Health No. 739/2012 “On the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments” (Official Gazette of the Republic of Moldova, 2012, No. 254-262, Art. 1555).

The additions were validated by an Implementation Act issued by the Agency for Medicines and Medical Devices, which confirmed that the changes were made based on the results of scientific research carried out within this project. Following this approach, the Order of the Ministry of Health no. 1041 of November 15, 2021, “On amending the Order of the Ministry of Health no. 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization changes” was developed and approved [28].

Looking ahead, it is essential to adopt a prevention-oriented approach, by establishing a

functional system of continuous monitoring and early intervention, which allows medication errors to be transformed from ignored incidents into valuable sources of learning and improvement of patient safety.

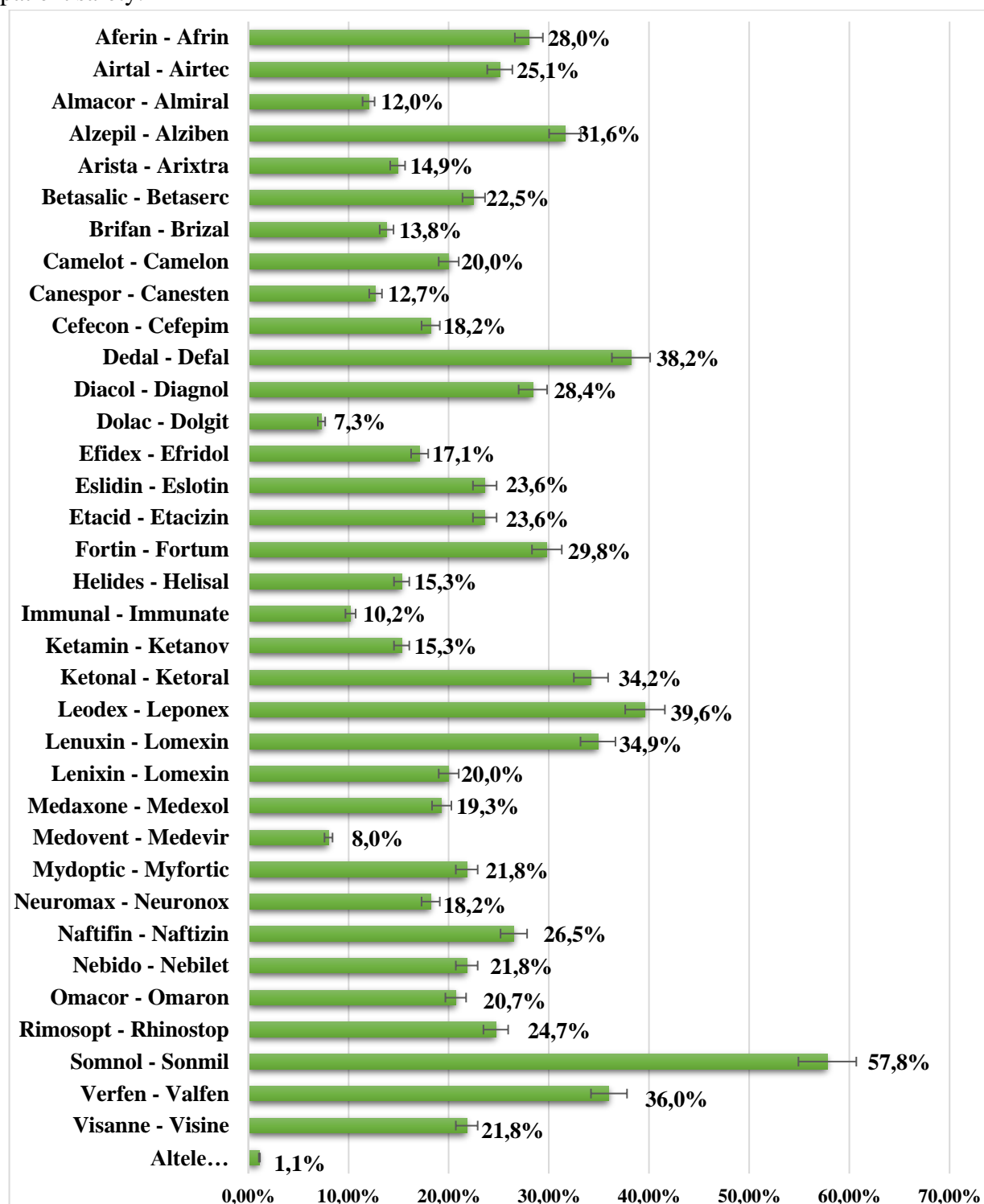


Figure 4. **Pharmacists' responses regarding similar drug names that may cause a medication error, %**

By questioning pharmacists, it was highlighted that 85% (236, 95%CI: 81,69% – 89,94%) of respondents considered the implementation of risk management to be a pressing need within community pharmacies. Also, 86.2% (237, 95%CI: 82,10% – 90,26%) of pharmacists indicated the need to improve and strengthen this system to effectively address risks and prevent medication

errors. These data confirmed that pharmacists recognize the importance of risk management, but that there is a lack of formal structures to support its implementation in a systematic way [10].

#### **4.3. Implementation of the integrated risk management methodology**

By applying the real-time monitoring technique of pharmaceutical activity, we highlighted a significant gap: 81.8% (9, 95%CI: 59,03% – 100,00%) of pharmacists mentioned the absence of clear procedures for managing risks in key stages of pharmaceutical activity, such as procurement, receipt, storage, preparation and dispensing of medicines. These results showed the need for a standardized framework of procedures to mitigate vulnerabilities and reduce medication errors.

The detailed analysis of 1500 medical prescriptions, carried out as part of the research, indicated the frequent presence of prescribing errors. The frequent incidence of medication errors was also confirmed by pharmacists, with concrete examples from pharmaceutical practice, but this is in discrepancy with the official findings provided by the Agency for Medicines and Medical Devices, according to which no cases of medication errors have been reported in the last five years. This suggests an underreporting of errors and a lack of effective mechanisms for reporting and documenting safety issues in pharmaceutical activity.

In order to modernize and streamline the training of future pharmacists and develop their skills in managing pharmaceutical risks, the Pharmaceutical Risk Management discipline (Implementation Act) was introduced in their initial training, in the curriculum of the Faculty of Pharmacy, starting with the 2021-2022 academic year. As curricular tools for this discipline, a Pharmaceutical Risk Management Course Support and Methodological Recommendations was developed, which provides students with essential knowledge about identifying and managing risks, both theoretical and practical, addressing aspects such as risks in the health system, drug quality management, economic and financial risks and error prevention measures in community pharmacies [10].

The research results were also included in the didactic process of improving pharmacists in a course entitled "Specialized pharmaceutical care for high-risk patients", with a duration of 3 weeks (90 hours/credits). The course is included in the teaching program of the "Vasile Procopișin" Department of Social Pharmacy within the "Nicolae Testemițanu" State University of Medicine and Pharmacy (Implementation Act).

At the same time, another fundamental element of the research was the approval of Order No. 686 of August 19, 2024 of the Ministry of Health of the Republic of Moldova, which formalized the practical application of the Guide for the implementation of risk management in community pharmacies. This guide was designed to provide complete and detailed methodological support for pharmaceutical risk management, providing concrete instructions on risk management at each stage of pharmaceutical activity within community pharmacies. The guide includes a description of the risk management cycle, which includes the identification, assessment, response and monitoring of risks, all of which are essential for creating a safety framework for patients and for ensuring quality in community pharmacies.

The implementation of this guide was supported by relevant healthcare institutions, including the Agency for Medicines and Medical Devices, and the "Nicolae Testemițanu" University of Medicine and Pharmacy, thus ensuring the application of standards and good practices throughout the community pharmacy network.

A central aspect of the Guide is chapter V, which contains Model Operating Procedures for each stage of pharmaceutical activity. These operational procedures represent a model of good practice that pharmacists should follow to carry out their pharmaceutical activity in accordance

with the highest safety standards. This chapter covers procedures for the supply of the pharmacy, the receipt of medicines, their correct storage, the safe preparation of medicines and the correct dispensing of medicines and healthcare products. In addition, it also includes the Risk Management Strategy, a document that guides pharmacists in the identification and assessment of risks, as well as in the implementation of mitigation and prevention measures.

The scientific relevance, originality, and practical applicability of the research results in the field of pharmaceutical risk management were also confirmed by the Silver Medal mention in the 4th Edition of the International Exhibition of Innovation and Technology Transfer - Excellent Idea - 2025.

At the heart of the research is the integrated pharmaceutical risk management algorithm, developed within the research, which allows for the identification, assessment, classification and prioritization of risks at specific stages of the pharmaceutical process, figure 5. For the development of this algorithm, an Innovation Implementation Act and an Innovator Certificate were obtained, thus recognizing the methodological and applicative contribution made to the pharmaceutical field.

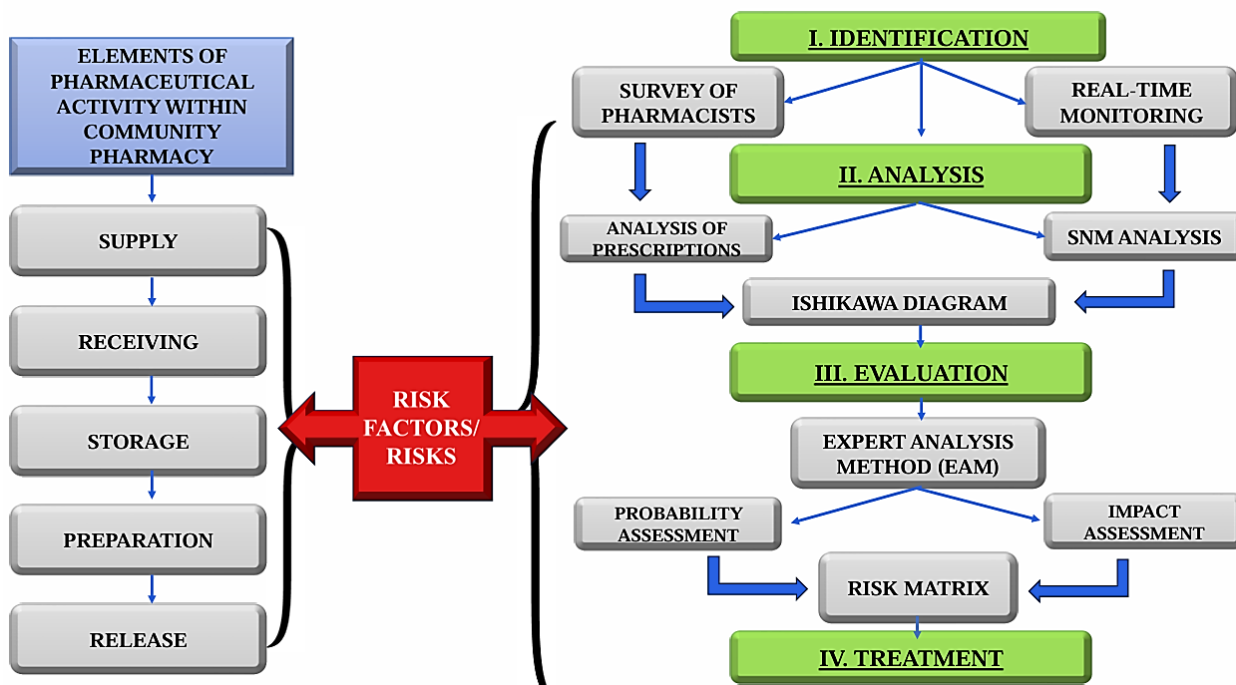


Figure 5. **Integrated pharmaceutical risk management algorithm**

The research demonstrated that integrated risk management, combined with standardization of procedures and continuous training of pharmaceutical staff and future pharmacists, leads to a significant decrease in the incidence of medication errors. Thus, the research hypothesis was confirmed, highlighting the importance of implementing a risk management system.

## GENERAL CONCLUSIONS

1. The analysis of the specialized literature on risk management and risk factors in the pharmaceutical field highlights the interdependence between these two terms, which support each other in the process of effective risk management. International comparative studies – from the USA, Canada, the European Union and other countries with consolidated pharmaceutical systems – highlight the existing shortcomings in the national system of the Republic of Moldova. Among the most important deficiencies are the lack of relevant statistical

data on medication errors and the absence of a coherent national reporting system. These aspects emphasize the need to adopt an integrated and standardized approach to pharmaceutical risk management, aligned with international good practices.

2. The integrated pharmaceutical risk management algorithm, developed within this research, constitutes a complex methodological structure intended to systematize and streamline the processes of identification, assessment, classification and management of risks and risk factors in pharmaceutical activity. This tool offers a coherent and phased approach, based on scientifically validated qualitative and quantitative methods.
  - a) The application of the algorithm allowed the identification of 56 risks/risk factors that can generate medication errors, distributed as follows: drug ordering stage: 8 risks (all with priority 3 - medium level), reception stage: 1 risk with priority 4 (low level), 5 risks with priority 3 and 2 risks with priority 2 (high level), storage stage: 6 risks with priority 3, preparation stage: 1 risk with priority 4, 12 risks with priority 3 and 4 risks with priority 2, release stage: 1 risk with priority 4, 9 risks with priority 3 and 7 risks with priority 2.
  - b) Based on the values calculated for each risk factor and using the Risk Matrix, they were classified into four priority levels for intervention: priority 1 – very high risk (no situation identified), priority 2 – high risk (13 risks), priority 3 – medium risk (40 risks), priority 4 – low risk (3 risks).
3. The analysis of a sample of 1500 medical prescriptions revealed the universal presence of errors, with none of the prescriptions being completely free of errors. The number of identified errors ranged from a minimum of one error (0,9%, 95% CI: 0,40 – 1,34) to a maximum of 12 errors (0,1%, 95% CI: 0,00 – 2,20). On average, the most frequent were errors of omission (2.41 per prescription), followed by errors of commission (1.95 per prescription), reflecting significant differences between the typologies of errors. A statistically significant correlation was identified between the number of drugs prescribed on a prescription and the total number of associated errors. According to the correlation coefficient interpretation scale (absolute value  $r > 0.5$ ), the relationship was considered strong, indicating that prescriptions with a higher number of drugs are associated with an increased probability of medication errors.
4. The analysis of the risks associated with similar names of medicines has highlighted their significant impact on the frequency of medication errors in community pharmacies. Following a detailed examination of the SNM, 36 pairs of similar names were identified, which create an increased risk of confusion and error. As a result of the research, a major gap was highlighted in the national regulations on the management of risks associated with similar names. This finding led to the formulation of legislative recommendations, which were subsequently approved by the Order of the Ministry of Health of the Republic of Moldova no. 1041 of November 15, 2021, amending Order no. 739/2012 on the regulation of the authorization of medicinal products for human use and post-authorization changes.
5. The results obtained through the pharmacist survey, corroborated with real-time monitoring of pharmaceutical risks, confirmed the lack of clear risk management procedures in community pharmacies. These findings highlighted the urgent need to develop standardized protocols, designed to support pharmaceutical staff in the prevention and effective management of medication errors.

In response to this need, the Guide on the implementation of risk management in community pharmacies was developed, a document that proposes practical strategies for preventing medication errors, integrated into a coherent system of six standardized operational procedures.

These procedures cover all stages of pharmaceutical activity: from ordering and receiving medicines, to storage, preparation and dispensing, providing pharmacists with a clear framework for identifying and reducing risks.

The Guide was approved and recommended for application in pharmaceutical practice by the Ministry of Health of the Republic of Moldova, through Order No. 686 of august 19, 2024, and awarded the Silver Medal at the 4th Edition of the International Exhibition of Innovation and Technology Transfer EXCELLENT IDEA – 2025.

6. The scientific problem solved in the research consists in the substantiation and development of an innovative model of integrated pharmaceutical risk management, through which a systemic and coherent approach to the processes specific to community pharmacies was achieved. The research demonstrated that the identification, classification and assessment of risk factors, followed by the development and implementation of a complex algorithm, associated with the standardization of the stages of the pharmaceutical process and the continuous training of specialists, represent effective methodological tools for significantly reducing medication errors in community pharmacies.

## **RECOMMENDATION**

1. In the context of discrepancies between identified medication errors and the lack of official reporting, AMMD should implement a national online medication error reporting system, which would allow for the continuous and systematic collection of data on medication errors from community pharmacies and medical institutions.
2. AMMD to develop and implement a feedback system that allows pharmacists to receive information on the measures taken following the reporting of medication errors.
3. The Dean's Office of the Faculty of Pharmacy should integrate aspects related to Pharmaceutical Risk Management into continuing education programs, in order to respond to the constant evolution of risks and adapt the professional training of pharmacists to the requirements of the pharmaceutical market.
4. It is recommended to organize joint conferences between doctors and pharmacists, aimed at facilitating the exchange of professional experience and promoting a constructive interdisciplinary dialogue, events that could contribute to the identification and analysis of prescribing and dispensing errors as well as to the development of common solutions to reduce them.
5. Community pharmacies to implement periodic audit procedures to assess compliance with risk management guidelines and standards.
6. The Ministry of Health of the Republic of Moldova and the Agency for Medicines and Medical Devices should periodically review and update regulations on drug names and packaging to prevent risks associated with LASA confusion.
7. The Ministry of Health of the Republic of Moldova should develop a national patient education and information program to raise awareness of the risks associated with medication errors and preventive measures.
8. The Ministry of Health of the Republic of Moldova should implement an integrated IT system for electronic prescribing of medicines, including automatic checks for dosage, interactions, and contraindications, thereby helping to reduce prescribing errors.
9. The institutions covered by the Order of the Ministry of Health of the Republic of Moldova no. 686 of august 19, 2024, which approves the application of the Guide "Implementation of risk

management in community pharmacies", including AMMD, the Directorate of health services quality management, the "Nicolae Testemițanu" State University of Medicine and Pharmacy and others, fully comply with the provisions of this order.

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## LIST OF PUBLICATIONS ON THE THESIS TOPIC

- **Articles published in journals from abroad:**

- ✓ **articles in ISI journals, SCOPUS and other international databases**

1. **Cheptanari-Bîrta N.**, Brumărel M., Safta V., Spinei L., Aduji S. The analysis of prescriptions and distribution of medicines in the prevention of medication errors in community pharmacies. In: *Farmacia*. România, 2022; 70(4): 760-766. <https://doi.org/10.31925/farmacia.2022.4.25> (IF: 1.6) <https://farmaciajournal.com/issue-articles/the-analysis-of-prescriptions-and-distribution-of-medicines-in-the-prevention-of-medication-errors-in-community-pharmacies/>

- **Articles published in accredited national scientific journals:**

- ✓ **articles published in B+ category journals**

2. **Cheptanari-Bîrta N.** General provisions on medication errors committed by pharmacists. In: *The Moldovan Medical Journal*. 2020; 63 (1): 61-65. DOI: 10.5281/ zenodo. 3685669. ISSN 2537-6373 (Print), ISSN 2537-6381 (Online). [https://ibn.idsi.md/ro/vizualizare\\_articol/97786](https://ibn.idsi.md/ro/vizualizare_articol/97786)
3. **Cheptanari-Bîrta N.** Management of pharmaceutical risk factors -warranty of patient's safety. In: *The Moldovan Medical Journal*. 2020; 63 (2): 49-53. DOI: 10.5281/ zenodo .3666023. ISSN 2537-6373 (Print), ISSN 2537-6381 (Online). [https://ibn.idsi.md/ro/vizualizare\\_articol/105788](https://ibn.idsi.md/ro/vizualizare_articol/105788)

- ✓ **Articles published in B category journals**

4. **Cheptanari-Bîrta N.**, Aduji S., Brumărel, M. Risk management – component part of the quality assurance system of pharmaceutical care. In: *Revista de Științe ale Sănătății din Moldova/Moldovan Journal of Health Sciences*. 2022; 30(4): 52-60. ISSN 2345-1467. <https://doi.org/10.52645/MJHS.2022.4.09>. <http://repository.usmf.md/handle/20.500.12710/24222>

- **Articles published in journals in the accreditation process:**

5. **Cheptanari-Bîrta N.**, Moiseev D., Brumărel M., Sîbii L. Sisteme de evaluare ale performanțelor farmacistului în cadrul farmaciilor comunitare. În: *Revista farmaceutică a Moldovei*. 2020; 1-4: 6-8. ISSN 1812-5077. <http://repository.usmf.md/handle/20.500.12710/16278>
6. **Cheptanari-Bîrta N.**, Safta V., Aduji S., Brumărel M. Rolul farmacistului în asigurarea farmacoterapiei eficiente și sigure. În: *Revista Farmaceutică a Moldovei*. 2023; 52(2): 24-33. ISSN 1812-5077. <http://repository.usmf.md/handle/20.500.12710/28361>

- **Articles published in scientific conference proceedings:**

- ✓ **international events abroad**

7. **Cheptanari-Bîrta N.**, Brumarel M., Safta V., Aduji S. Discipline of Pharmaceutical risk management- integrated component in the training of specific professional competences of pharmacists. In: *Materialele celei de-a VII-a Conferințe științifico-practice internaționale dedicate aniversării a 10 ani de la fondarea Catedrei de farmacie socială “Соціальна фармація: стан, проблеми та перспективи”*. Harkov, Ucraina: 23-24 septembrie 2021; pp.199-208. УДК: 615.15:378.14. <https://drive.google.com/file/d/1I-9abWIGzWa8BBBeAV4FtR2YvT52UxWT8/view> [https://ibn.idsi.md/ro/vizualizare\\_articol/222495](https://ibn.idsi.md/ro/vizualizare_articol/222495)

- **Abstracts published for national and international scientific conferences:**

8. **Cheptanari-Bîrta N.** Technical and organizational risk reduction measures in the community pharmacy. În: *Матеріали XXVIII міжнародної науково-практичної конференції молодих вчених та студентів «Topical issues of new medicines development» присвяченої 150-річчю з дня народження М.О. Валяшка. Ucraina, Haricov;* 18-19 martie 2021, pp. 450-452.
9. **Cheptanari-Bîrta N.,** Mistreanu N. Prevenirea erorilor de medicație în farmaciile comunitare. Analiza erorilor de prescripție. În: *Materialele Conferinței științifico-practice dedicate memoriei profesorului universitar Vasile Procopișin în contextul anului Lucrătorului medical 2020 și Aniversării a 75-a de la fondarea USMF "Nicolae Testemițanu" "Farmacistul și rolul lui în sistemul de sănătate. Revista farmaceutică a Moldovei. Chișinău;* 20 octombrie 2020, nr. 1-4, pp. 52-53. ISSN 1812-5077. <http://repository.usmf.md/handle/20.500.12710/16466>
10. **Cheptanari-Bîrta N.,** Ursachi V., Brumărel M. Consecințele consumului abuziv de medicamente promovate pe site-urile farmaciilor comunitare. În: *Materialele conferinței științifico-practice cu participare internațională „Sistemul de asigurare a calității medicamentului – probleme și soluții”. Revista farmaceutică a Moldovei. Chișinău;* 29 septembrie 2021, 4 (48), pp. 30-31. ISSN 1812-5077. [https://ibn.idsi.md/sites/default/files/imag\\_file/30-31\\_38.pdf](https://ibn.idsi.md/sites/default/files/imag_file/30-31_38.pdf)
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12. Sîbii L., Aduji S., **Cheptanari-Bîrta N.** Evaluarea rolului farmacistului comunitar în utilizarea rațională a medicamentelor OTC. În: *Materialele conferința științifico-practice naționale cu participare internațională „Actualități și perspective în studiul farmaceutic al plantelor medicale”. Chișinău;* 01-02 octombrie 2021, pp. 115. ISBN 978-9975-56-909-5. [https://ibn.idsi.md/ro/vizualizare\\_articol/143069](https://ibn.idsi.md/ro/vizualizare_articol/143069)
13. **Cheptanari-Bîrta N.** Aspecte privind gestionarea riscurilor în procesul circulației medicamentului. În: *Abstract Book, Conferința științifică anuală: Cercetarea în biomedicină și sănătate: Calitate, Excelență și Performanță. USMF "Nicolae Testemițanu". Chișinău;* 20-22 octombrie 2021, pp. 432. ISBN: 978-9975-82-223-7. <http://repository.usmf.md/handle/20.500.12710/18768>
14. Usafii D., **Cheptanari-Bîrta N.** Importanța aplicării etichetării braille pe ambalajele medicamentelor pentru persoane cu deficiență de vedere. În: *Culegere de rezumate ale Conferinței științifice anuale „Cercetarea în biomedicină și sănătate: calitate, excelență și performanță. USMF „Nicolae Testemițanu”. Chișinău;* 18-20 octombrie 2023, vol. 10(3), anexa 1, pp. 653. ISSN 2345-1467. [https://ibn.idsi.md/vizualizare\\_articol/195205](https://ibn.idsi.md/vizualizare_articol/195205)
15. Carmanovici F., **Cheptanari-Bîrta N.** Evaluarea impactului farmacoterapiei asupra calității vieții pacienților. În: *Culegere de rezumate ale Conferinței științifice anuale „Cercetarea în biomedicină și sănătate: calitate, excelență și performanță. USMF „Nicolae Testemițanu”. Chișinău;* 18-20 octombrie 2023, vol. 10(3), anexa 1, pp. 672. ISSN 2345-1467. [https://ibn.idsi.md/vizualizare\\_articol/195286](https://ibn.idsi.md/vizualizare_articol/195286)
16. **Cheptanari-Bîrta N.** Riscurile asociate mediilor de muncă proprii farmaciei comunitare.

În: *Program și rezumate. A XXVIII-a Reuniune Națională de Istoria Farmaciei. Sibiu*; 2019, pp. 18.

17. **Cheptanari-Bîrta N.** Riscuri informaționale în consilierea consumatorului de medicamente. În: *Culegere de rezumate ale Conferinței științifico-practice „Importanța consilierii pacientului în utilizarea rațională a medicamentelor”, ediția a XII-a. Chișinău*; 28 noiembrie 2023, pp. 19-22. ISBN 978-9975-89-295-7. [https://ibn.idsi.md/vizualizare\\_articol/195952](https://ibn.idsi.md/vizualizare_articol/195952).
18. **Cheptanari-Bîrta N.** Metode de determinare a factorilor de risc în farmaciile comunitare. *Congresul consacrat aniversării a 75-a de la fondarea USMF “Nicolae Testemițanu”. Abstract Book. Chișinău*; 21-23 octombrie 2020, pp. 654. [https://ibn.idsi.md/ro/vizualizare\\_articol/126907](https://ibn.idsi.md/ro/vizualizare_articol/126907)
19. Iurcenco T., **Cheptanari-Bîrta N.**, Brumărel M. Managementul interacțiunilor medicamentoase în prevenirea erorilor de medicație în cadrul farmaciilor comunitare. În: *Moldovan Journal of Health Sciences, USMF “Nicolae Testemițanu”. Chișinău*; 2022, pp. 494. ISSN 2345-1467. [https://ibn.idsi.md/ro/vizualizare\\_articol/206135](https://ibn.idsi.md/ro/vizualizare_articol/206135)
20. Midoni E., **Cheptanari-Bîrta N.**, Brumărel M. Incidența și cauzele erorilor de eliberare a medicamentelor în farmaciile comunitare În: *Moldovan Journal of Health Sciences, USMF “Nicolae Testemițanu”. Chișinău*; 2022, pp. 475. ISSN 2345-1467. [https://ibn.idsi.md/ro/vizualizare\\_articol/169555](https://ibn.idsi.md/ro/vizualizare_articol/169555)
21. **Cheptanari-Bîrta N.** Risk management - component of the pharmaceutical quality system. În: *MedEspera: the 9th International Medical Congress for Students and Young Doctors: abstract book. Chișinău*; 12-14 mai 2022, pp. 326. <http://repository.usmf.md/handle/20.500.12710/21141>
22. **Cheptanari-Bîrta N.** Availability and impact of information on medicines on community pharmacy sites from Moldova. În: *MedEspera: the 9th International Medical Congress for Students and Young Doctors: abstract book. Chișinău*; 12-14 mai 2022, p. 301. <http://repository.usmf.md/handle/20.500.12710/21108>

- **Innovator Certificate:**

23. Algoritm integrat de management al riscurilor farmaceutice. Autori: **Cheptanari-Bîrta Nicoleta**, asist. univ.; Brumărel Mihail, conf. univ., dr. șt. farm.; Adauji Stela, conf. univ., dr. hab. șt. farm.; Safta Vladimir, prof. univ., dr. hab. șt. farm.; Spinei Larisa, prof. univ., dr. hab. șt. med. Certificat de inovator nr. 6352 din 22.04.2025.

- **Participation in the Parliamentary Exhibition:**

24. Prezentarea proiectului de cercetare: Managementul factorilor de risc în prestarea serviciilor farmaceutice. 28-29 iulie 2022.

- **Active participation with oral presentations within scientific forums:**

- ✓ **international**

25. **Cheptanari N.** Riscurile asociate mediilor de muncă proprii farmaciei comunitare. *A XXVIII-A Reuniune națională de istoria farmaciei. Sibiu*, 3-5 Octombrie 2019.
26. **Cheptanari-Bîrta N.** Technical and organizational risk reduction measures in the community pharmacy. *XXVIII міжнародна науково-практичної конференції молодих вчених та студентів «Topical issues of new medicines development», Присвяченої 150-Річчю з дня народження М.О. Валяшка. Haricov, Ucraina*, 18-19 martie 2021.

✓ **national**

27. **Cheptanari N.** Riscuri specifice activității farmaceutice- erori comise de către farmaciști. *Conferința științifică anuală a cadrelor științifico-didactice, doctoranzilor, masteranzilor, rezidenților și studenților, USMF “Nicolae Testemițanu”*. Chișinău, 17-18 Octombrie 2019.
28. **Cheptanari-Bîrta N.** Evaluarea de către farmaciști a riscurilor apariției erorilor de medicație. *Conferința științifică cu participare internațională ”Obținerea și cercetarea farmaceutică a unor molecule și produse farmaceutice cu potențial terapeutic. În Cadrul Proiectului Bilateral Internațional Moldo-Belarus. USMF “Nicolae Testemițanu”*. Chișinău, 31 ianuarie 2020.
29. **Cheptanari-Bîrta N.,** Brumărel M., Safta V., Adauji S. Evaluarea rezultatelor privind identificarea factorilor de risc și impactul lor în prevenirea erorilor de medicație. *Conferința științifico-practică on-line dedicată memoriei profesorului universitar “Vasile Procopișin” ”Farmacistul și rolul lui în sistemul de sănătate”*. Chișinău, 20 noiembrie 2020.
30. **Cheptanari-Bîrta N.** Metode de determinare a factorilor de risc în farmaciile comunitare. *Congresul consacrat aniversării a 75-a de la fondarea USMF “Nicolae Testemițanu”*. Chișinău, 21-23 Octombrie 2020.
31. **Cheptanari-Bîrta N.** Aspecte privind gestionarea riscurilor în procesul circulației medicamentului. *Conferința științifică anuală: Cercetarea în biomedicină și sănătate: calitate, excelență și performanță. USMF “Nicolae Testemițanu”*. Chișinău, 20-22 octombrie 2021.
32. Sîbii L., **Cheptanari-Bîrta N.,** Șchiopu T. Riscuri în utilizarea rațională a medicamentelor la copii și vârstnici. *Conferința științifico-practică cu participare internațională ”Sistemul de asigurare a calității medicamentului- probleme și soluții”*. Chișinău, 29 septembrie 2021.
33. **Cheptanari-Bîrta N.** Activități ale farmaciștilor pentru minimizarea riscului farmaceutic. *Conferința științifico-practică ”Abordarea sistemică- metodologie în cercetarea farmaceutică”*. Chișinău, 16 aprilie 2021.
34. **Cheptanari-Bîrta N.,** Brumărel M., Safta V. Rolul factorului uman în erorile de prescripție și identificarea soluțiilor de prevenire ale acestora. *Conferința științifico-practică on-line “Relații medic-farmacist în promovarea serviciilor farmaceutice avansate”, USMF „Nicolae Testemițanu”*. Chișinău, 26 noiembrie 2021.
35. Șchiopu T., Sîbii L., **Cheptanari-Bîrta N.,** Adauji S., Brumărel M. Rolul farmacistului comunitar în evaluarea calității serviciilor farmaceutice avansate prestate copiilor și vârstnicilor. *Conferința științifico-practică on-line “Relații medic-farmacist în promovarea serviciilor farmaceutice avansate”, USMF „Nicolae Testemițanu”*. Chișinău, 26 noiembrie 2021.
36. **Cheptanari-Bîrta N.** Risk management- component of the pharmaceutical quality system. *The 9 th International medical congress for students and young doctors. Medespera*. Chișinău, 12-14 mai 2022.
37. Midoni E., **Cheptanari-Bîrta N.** Incidența și cauzele erorilor de eliberare a medicamentelor în farmaciile comunitare. *Conferința științifică anuală “Cercetarea în biomedicină și sănătate: Calitate, Excelență și Performanță”*. USMF “Nicolae Testemițanu”. Chișinău, 19-21 octombrie 2022.

38. Usatîi D., **Cheptanari-Bîrta N.** Importanța aplicării etichetării braille pe ambalajele medicamentelor pentru persoane cu deficiențe de vedere. *Conferința științifică anuală "Cercetarea în biomedicină și sănătate: Calitate, Excelență și Performanță", USMF „Nicolae Testemițanu”*. Chișinău, 18-20 octombrie 2023.

- **Poster presentations within scientific forums:**

- ✓ **national**

39. Sîbii L., Adauji S., **Cheptanari-Bîrta N.** Evaluarea rolului farmacistului comunitar în utilizarea rațională a medicamentelor OTC. *Conferința științifico-practică națională cu participare internațională "Actualități și perspective în studiul farmaceutic al plantelor medicinale"*. Chișinău, 01-02 octombrie 2021.
40. Florența A., **Cheptanari-Bîrta N.** Medii de muncă proprii unităților farmaceutice ca factor de risc profesional. *Conferința științifică anuală a cadrelor științifico-didactice, doctoranzilor, masteranzilor, rezidenților și studenților în cadrul Zilelor USMF „Nicolae Testemițanu”*. Chișinău, 15-18 octombrie 2019.
41. Ursachi V., Brumărel M., **Cheptanari-Bîrta N.** Consecințele consumului abuziv de medicamente promovate pe site-urile farmaciilor comunitare. *Conferința științifico-practică națională cu participare internațională cu genericul "Sistemul de asigurare a calității medicamentului- Probleme și soluții", USMF „Nicolae Testemițanu”*. Chișinău, 29 septembrie 2021.
42. Mistreanu N., **Cheptanari-Bîrta N.** Prevenirea erorilor de medicație în farmaciile comunitare. Analiza erorilor de prescripție. *Conferința științifico-practică on-line dedicată memoriei profesorului universitar Vasile Procopișin "Farmacistul și rolul lui în sistemul de sănătate" în contextul Anului Lucrătorului Medical 2020 și Aniversării a 75-a de la fondarea USMF „Nicolae Testemițanu”*. Chișinău, 20 noiembrie 2020.
43. Iurcenco T., **Cheptanari-Bîrta N.** Managementul interacțiunilor medicamentoase în prevenirea erorilor de medicație în cadrul farmaciilor comunitare. *Conferința științifică anuală "Cercetarea în biomedicină și sănătate: Calitate, Excelență și Performanță", USMF „Nicolae Testemițanu”*. Chișinău, 19-21 octombrie 2022: culegere de postere electronice. 2022, p. 212.
44. Carmanovici F., **Cheptanari-Bîrta N.** Evaluarea impactului farmacoterapiei asupra calității vieții pacienților. *Conferința științifică anuală „Cercetarea în biomedicină și sănătate: calitate, excelență și performanță. USMF „Nicolae Testemițanu”*. Chișinău, 18-20 octombrie 2023.
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## ADNOTARE

### Cheptanari-Bîrta Nicoleta. MANAGEMENTUL FACTORILOR DE RISC ÎN PRESTAREA SERVICIILOR FARMACEUTICE

Teză de doctor în științe farmaceutice, Chișinău, 2026

**Actualitatea cercetării.** În Republica Moldova calitatea serviciilor farmaceutice este influențată de riscurile crescând din domeniul farmaceutic precum deficitul de farmaciști, erorile de prescriere, denumirile asemănătoare ale medicamentelor, lipsa unui sistem eficient de raportare a erorilor etc. La nivel internațional, gestionarea riscurilor farmaceutice este o temă actuală, având ca obiectiv implementarea unor soluții standardizate pentru reducerea erorilor de medicație. În Republica Moldova, alinierea la aceste standarde este esențială pentru adaptarea la cerințele sistemului de sănătate european.

**Scopul lucrării.** Analiza și evaluarea factorilor de risc care afectează activitatea farmaceutică în cadrul farmaciilor comunitare, elaborarea unei metodologii integrate de management al riscurilor pentru îmbunătățirea calității serviciilor farmaceutice, reducerea erorilor de medicație și promovarea formării și educației continue în acest domeniu a farmaciștilor.

**Obiectivele cercetării.** Analiza surselor bibliografice în domeniul riscurilor, MR și MFR; Identificarea și evaluarea factorilor de risc ce influențează serviciile farmaceutice în cadrul farmaciilor comunitare; Analiza, identificarea și clasificarea erorilor de prescriere a medicamentelor; Identificarea și evaluarea riscurilor asociate cu denumirile asemănătoare ale medicamentelor; Elaborarea și implementarea unei metodologii de management al riscului în practica farmaceutică; Elaborarea programelor educaționale destinate formării și instruirii viitorilor specialiști și farmaciștilor practicieni în gestionarea riscurilor.

**Noutatea și originalitatea științifică.** Elaborarea în premieră, a unui algoritm integrat de management al riscurilor farmaceutice, care reunește într-o formă coerentă și aplicabilă în practică, un set complex de metode precum chestionarea farmaciștilor, tehnica de monitorizare în timp real a riscurilor farmaceutice, diagrama Ishikawa, metoda analizei experților, analiza erorilor de prescriere și analiza NSM.

**Rezultatele majore noi obținute.** Au fost identificați 56 de factori de risc care influențează apariția erorilor de medicație în farmaciile comunitare. Analiza a 1.500 de prescripții medicale a evidențiat 6.533 de erori, fără nici o rețetă lipsită de greșeli. S-au identificat 36 de perechi de denumiri asemănătoare de medicamente care generează confuzii în procesul de eliberare a medicamentelor. A fost elaborat un algoritm integrat de management al riscurilor și un set de proceduri operaționale, aplicabile practic, care contribuie la reducerea erorilor de medicație.

**Semnificația teoretică.** Prin elaborarea Suportului de curs și recomandări metodice la disciplina Managementul riscului farmaceutic și Ghidului metodologic privind implementarea managementului riscurilor în cadrul farmaciilor comunitare, teza a contribuit la dezvoltarea unui cadru teoretic riguros, care poate fi implementat în practica farmaceutică și care a fost integrat în programele de învățământ prin introducerea disciplinei opționale „Managementul riscului farmaceutic” și a cursului de perfecționare tematică „Asistența farmaceutică specializată la pacienții cu risc sporit”.

**Valoarea aplicativă.** Studiul are un impact direct și tangibil asupra sistemului farmaceutic, contribuind la creșterea calității serviciilor și la reducerea riscurilor farmaceutice. Rezultatele cercetării reprezintă instrumente aplicative privind gestionarea factorilor de risc/riscurilor în procesul autorizării medicamentelor, prestării serviciilor farmaceutice, pregătirii viitorilor farmaciști și perfecționării specialiștilor farmaciști.

**Implementarea rezultatelor științifice.** Introducerea Cursului Managementul riscului farmaceutic; modificări la Ordinul MS RM nr. 739/2012 cu privire la reglementarea autorizării produselor medicamentoase de uz uman și introducerea modificărilor postautorizare, aprobate prin Ordinul MS RM nr. 1041 din 15.11.2021; elaborarea Ghidului Implementarea managementului riscului în farmaciile comunitare; elaborarea Suportului de curs și recomandărilor metodice la disciplina Managementul riscului farmaceutic; participarea ca coautor la elaborarea Cursului de perfecționare tematică „Asistența farmaceutică specializată la pacienții cu risc sporit”; elaborarea algoritmului integrat de management al riscurilor. Rezultatele științifice au fost confirmate prin 4 Acte de implementare, un Ordin al MS RM, un Certificat de inovator și o mențiune - Medalia de Argint.

**Structura tezei:** introducere, patru capitole, sinteza rezultatelor obținute, concluzii generale și recomandări, bibliografie din 159 titluri, 9 anexe, valorificarea rezultatelor cercetării expuse pe 193 pagini, 32 figuri, 53 tabele. Rezultatele științifice la tema tezei sunt expuse în 7 articole publicate în reviste naționale și internaționale, 15 teze, 14 comunicări orale la conferințe științifice naționale și internaționale și 8 postere la conferințe științifice naționale și internaționale.

**Cuvinte-cheie:** erori de medicație, factori de risc, riscuri, managementul riscului, farmacia comunitară, farmacist, prescripții medicale, denumiri similare a medicamentelor, eliberarea medicamentelor.



## ANNOTATION

### Cheptanari-Bîrta Nicoleta. RISK FACTORS MANAGEMENT IN THE PROVISION OF PHARMACEUTICAL SERVICES

Doctoral thesis in pharmaceutical sciences, Chisinau, 2026

**Research relevance.** In the Republic of Moldova, the quality of pharmaceutical services is influenced by the growing risks in the pharmaceutical field such as the shortage of pharmacists, prescription errors, similar drug names, the lack of an efficient error reporting system, etc. At the international level, pharmaceutical risk management is a current topic, with the objective of implementing standardized solutions to reduce medication errors. In the Republic of Moldova, alignment with these standards is essential for adapting to the requirements of the European health system.

**Research goal.** Analysis and evaluation of risk factors affecting pharmaceutical activity within community pharmacies, the development of an integrated risk management methodology to improve the quality of pharmaceutical services, reduce medication errors, and promote continuous training and education of pharmacists in this field.

**Research objectives.** Analysis of bibliographic sources in the field of risks, RM and RFM; Identification and assessment of risk factors influencing pharmaceutical services within community pharmacies; Analysis, identification and classification of medication prescription errors; Identification and assessment of risks associated with similar drug names; Development and implementation of a risk management methodology in pharmaceutical practice; Development of educational programs intended for the training and education of future specialists and pharmacist practitioners in risk management.

**Scientific novelty and originality.** The development, for the first time, of an integrated pharmaceutical risk management algorithm, which brings together in a coherent and practically applicable form, a complex set of methods such as pharmacist questioning, real-time pharmaceutical risk monitoring technique, Ishikawa diagram, expert analysis method, prescription error analysis and SNM analysis.

**Major new results obtained.** A total of 56 risk factors influencing the occurrence of medication errors in community pharmacies were identified. The analysis of 1,500 medical prescriptions revealed 6,533 errors, with no prescription found to be error-free. Thirty-six pairs of look-alike drug names that cause confusion in the dispensing process were identified. An integrated risk management algorithm and a set of practical standard operating procedures were developed, contributing to the reduction of medication errors.

**Theoretical significance.** By developing the Course Support and Methodological Recommendations for the Pharmaceutical Risk Management discipline and the Methodological Guide on the Implementation of Risk Management in Community Pharmacies, the thesis contributed to the development of a rigorous theoretical framework, which can be implemented in pharmaceutical practice and which was integrated into the educational programs by introducing the optional discipline „Pharmaceutical Risk Management” and the thematic improvement course „Specialized Pharmaceutical Care for High-Risk Patients”.

**Applicative value.** The study has a direct and tangible impact on the pharmaceutical system, contributing to increasing the quality of services and reducing pharmaceutical risks. The research results represent applicable tools for managing risk factors/risks in the drug authorization process, the provision of pharmaceutical services, the training of future pharmacists and the improvement of pharmacist specialists.

**Implementation of scientific results.** Introduction of the Pharmaceutical Risk Management Course; amendments to the Order of the Ministry of Health of the Republic of Moldova no. 739/2012 on the regulation of the authorization of medicinal products for human use and the introduction of post-authorization amendments, approved by the Order of the Ministry of Health of the Republic of Moldova No. 1041 of 15.11.2021; development of the Guide to the Implementation of Risk Management in Community Pharmacies; development of Course Support and Methodological Recommendations for the Pharmaceutical Risk Management discipline; participation as a co-author in the development of the thematic advanced course „Specialized Pharmaceutical Care for High-Risk Patients”; development of the integrated risk management algorithm. The scientific results were validated through 4 Implementation Acts, an Order of the Ministry of Health of the Republic of Moldova, an Innovator’s Certificate, and an award – the Silver Medal.

**Thesis structure:** introduction, four chapters, synthesis of the results obtained, general conclusions and recommendations, bibliography of 159 titles, 9 annexes, valorisation of the research results presented on 193 pages, 32 figures, 53 tables. The scientific results on the topic of the thesis are presented in 7 articles published in national and international journals, 15 theses, 14 oral communications at national and international scientific conferences and 8 posters at national and international scientific conferences.

**Keywords:** medication errors, risk factors, risks, risk management, community pharmacy, pharmacist, medical prescriptions, similar drug names, drug dispensing.