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Analysis of pharmacy organisation staff awareness of pharmacovigilance

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The aim of the study was to investigate the awareness of pharmacists' knowledge of the pharmacovigilance basics in pharmacy organisations (PhOs) of the Russian Federation and to identify the factors influencing their participation in the drug safety monitoring system.

Materials and methods. A single-point survey study was conducted in the form of a single solid group online questionnaire survey of 513 pharmaceutical specialists from different regions of Russia. A specially designed 14-item questionnaire aimed was used to assess their knowledge of the pharmacovigilance system. Retrospective, comparative, statistical, and logical analysis methods were applied.

Results. A comprehensive assessment of the level of pharmaceutical specialists' pharmacovigilance knowledge in Russia was carried out. The factors influencing the specialists' awareness were determined. The necessity of educational activities to increase the involvement of PhOs employees in the drug safety monitoring system was justified. The insufficient level of pharmaceutical specialists' knowledge about the basic concepts and procedures of pharmacovigilance was revealed. Specialists with secondary specialized education and less work experience demonstrated a lower level of awareness. Only 13% of the participants had received training on pharmacovigilance, while the majority (about 80%) considered it necessary to increase the number of training programmes. The influence of education, work experience and job position on the awareness of professionals was established. Most respondents recognize the need to report adverse drug reactions (ADRs) occurring when taking a medicine, but in practice the level of reporting remains low.

Conclusion. Insufficient knowledge of the pharmacovigilance basics among pharmacy workers causes a low level of ADRs reporting by them. A comprehensive approach, including educational initiatives and the development of targeted interventions, is required to improve specialists' engagement in the drug safety monitoring system. Further research is necessary to develop and evaluate the effectiveness of educational programmes and motivational models to increase pharmaceutical specialists' pharmacovigilance activities.

Keywords: pharmacovigilance; pharmaceutical specialists; pharmacy organisations; adverse drug reactions; drug safety

Abbreviations: ADR – adverse drug reaction; HP – health professional.

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Анализ осведомлённости персонала аптечной организации об основах фармаконадзора

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Цель. Исследование осведомлённости знаний фармацевтических работников аптечных организаций (АО) Российской Федерации об основах фармаконадзора и выявление факторов, влияющих на их участие в системе мониторинга безопасности лекарственных средств.

Материалы и методы. Проведено одномоментное опросное исследование в форме однократного сплошного группового онлайн-анкетирования 513 фармацевтических работников из различных регионов России с использованием специально разработанной анкеты из 14 вопросов, направленных на оценку знаний о системе фармаконадзора. Применялись методы ретроспективного, сравнительного, статистического и логического анализа.

Результаты. Проведена комплексная оценка уровня знаний фармацевтических работников России в области фармаконадзора. Определены факторы, влияющие на осведомлённость специалистов. Обоснована необходимость образовательных мероприятий для повышения вовлечённости сотрудников АО в систему мониторинга безопасности лекарственных средств. Выявлен недостаточный уровень знаний фармацевтических работников об основных понятиях и процедурах фармаконадзора. Специалисты со средним специальным образованием и меньшим стажем работы продемонстрировали более низкий уровень осведомлённости. Лишь 13% участников проходили обучение по фармаконадзору, при этом большинство (около 80%) считают необходимым увеличение количества обучающих программ. Установлено влияние образования, стажа работы и должности на осведомлённость специалистов. Большинство респондентов признаёт необходимость в сообщении нежелательных реакций (НР), возникающих при приёме того или иного препарата, однако на практике уровень репортирования остаётся низким.

Заключение. Недостаточные знания основ фармаконадзора среди фармацевтических работников АО обуславливают низкий уровень репортирования ими НР. Для повышения вовлечённости специалистов в систему мониторинга безопасности лекарств необходим комплексный подход, включающий образовательные мероприятия и разработку целевых интервенций. Требуются дальнейшие исследования по разработке и оценке эффективности образовательных программ и мотивационных моделей повышения активности фармацевтических работников в сфере фармаконадзора.

Ключевые слова: фармаконадзор; фармацевтические работники; аптечные организации; нежелательные реакции; безопасность лекарственных средств

Список сокращений: АО — аптечная организация; НР — нежелательная реакция; ЛП — лекарственный препарат; МР — медицинский работник.

INTRODUCTION

Pharmacovigilance plays a key role in ensuring the drug safety. As defined by the World Health Organization (WHO), pharmacovigilance is a set of scientific studies and activities aimed at detecting, analyzing, understanding and preventing adverse effects of pharmacotherapy[1].

The Eurasian Economic Union (EAEU) Rules of Good Pharmacovigilance approved by Decision of the Council of the Eurasian Economic Commission No. 87[2] are in force in our country. The EAEU rules establish common approaches to the organization of drug

[1] World Health Organization. WHO: Pharmacovigilance: ensuring the safe use of medicines; 2004, No. WHO/EDM/2004.8. Available from: https://www.who.int/publications/i/item/WHOEDM2004.8

[2] Decision of the Council of the Eurasian Economic Commission No. 87 dated 03.11.2016 (as amended on 19.05.2022). “On approval of the Rules of good practice of pharmacovigilance of the Eurasian Economic Union”. Russian

safety monitoring, define the procedures for collecting and analyzing information on adverse drug reactions (ADRs) [1, 2]. At the national level, Federal Law No. 61-FZ "On Circulation of Medicines"[3] dated 12.04.2010 obliges all subjects of the pharmaceutical market to report to Roszdravnadzor any identified risks to patient life or health associated with the use drugs [3]. The legislation stipulates liability for a concealment or an untimely transfer of such information. The key role in the functioning of the pharmacovigilance system belongs to the pharmacy organisation (PhO). Professional standards for "Pharmacists", "Pharmacy Technicians" and "Specialists in Pharmacy Management" stipulate the duties of pharmaceutical specialists to collect information on ADRs, inform authorized bodies and advise consumers on the drug safety [5–7]. Pharmacy managers are responsible for a proper organization of pharmacovigilance in their subordinate institutions.

The effectiveness of the pharmacovigilance system aimed at detecting, evaluating and preventing ADRs of medicines depends on the involvement of all subjects of the medicines circulation, including pharmacy staff [4]. In modern conditions, when the availability of primary health care is not always fully ensured [5], and some part of the population (from 18 to 27%) is not satisfied with the quality of medical services [6, 7], the role of pharmaceutical specialists in the health care system is significantly increasing. Pharmacists and pharmacy technicians in pharmacies become the most important link between patients and the drug safety monitoring system, as they have a direct and regular contact with drug consumers. We believe that pharmacists and pharmacy technicians can play a key role in the drug safety monitoring system, as they are the ones who directly interact with consumers and are the primary link for collecting information on safety violations, including ADRs. However, despite a detailed regulation of pharmacovigilance, there remains a practical issue of insufficient awareness and engagement among pharmacy staff in this system [8–10]. This leads to a low level of the ADRs reporting by them and, as a consequence, an incomplete collection of data on the drug safety [11].

Although the pharmacy employees may occupy a key position in the ADRs reporting chainthe studies show that they are not sufficiently involved in the pharmacovigilance system [12]. It has been reported that only a small proportion of pharmacy professionals (about 5%) complete notifications of identified ADRs, while almost 1/5th (19%) of the employees never do so [13]. The established facts indicate the need to find effective ways to increase the participation of pharmacists and pharmacy technicians in drug safety monitoring which is an urgent scientific and practical task.

Similar trends are noted in the works by other authors [14, 15]. They point to significant differences in the level of participation between the representatives of the pharmaceutical industry (registration certificate holders and legal entities with clinical trial approvals), who actively identify ADRs, and PhOs staff, who treat this responsibility rather formally [14, 15]. The key problem in the organization of the ADRs data collection is a low motivation of specialists to fill in relevant notifications. The experts attribute a low activity of health professionals (HPs) in this area to a number of factors. First, it is the difficulty of identifying causal links between the intake of a particular medicine and the occurrence of ADRs. Second, it is an insufficient level of knowledge in the field of drug safety monitoring. Third, these are psychological aspects, including the fear of damaging the reputation of a medical organization or a pharmaceutical company. Finally, the lack of financial incentives to do additional work on pharmacovigilance plays an important role.

Foreign studies also confirm that one of the main reasons for a low ADRs reporting rate is the lack of awareness of pharmacovigilance among medical and pharmaceutical professionals [16–19]. A study conducted in Shiraz, Iran, showed that pharmacists have little knowledge about the process, purpose and importance spontaneous ADR reporting system. The authors concluded that education and training courses would be important to maintain, improve and enhance ADR reporting by pharmacists [20].

A survey among pharmacy students in Romania found out that 92% of future pharmacists planned to report identified ADRs, but only 48% of the final year students and 37% of the fourth-year students considered themselves sufficiently prepared or ready to do so [21]. The same Romanian study indicated that fewer than half (45.7%) of student-pharmacists had studied pharmacovigilance and 95% agreed that pharmacovigilance should be included as a separate course in their curriculum.

A Ghanaian study of doctors, nurses and pharmacists showed that although 82.8% had encountered ADRs, only 52.6% had reported them, with the pharmacists accounting for 66.7% of this population [22]. In the Ghanaian study, 85.8% of the HPs were aware of the ADRs reporting procedure and had a positive attitude, suggesting that other factors besides the awareness may influence under-reporting.

[3] Federal Law No. 61-FZ dated 12.04.2010 (latest edition) "On the Circulation of Medicines". Russian

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A systematic review by V. Paudyal et al. showed that financial incentives and face-to-face educational interventions improved the quality and quantity of ADR reports compared to interventions without a face-to-face interaction [23]. The authors focus on the need to develop and test training programmes based on the principles of behavioural psychology. It is noted that most of the research has been focused primarily on HRs, while the role of patients in pharmacovigilance remains poorly understood.

Thus, the problem of the insufficient involvement of pharmacy workers in the pharmacovigilance system is relevant not only for Russia, but also for many other countries. Consequently, it is critically important to evaluate the knowledge level of pharmacy workers in Russia regarding the safety monitoring of drugs.

THE AIM of the study was assessing the knowledge level of pharmacy workers in the Russian Federation regarding pharmacovigilance fundamentals and to identify factors influencing their awareness and participation in the drug safety monitoring system.

MATERIALS AND METHODS

The authors conducted a single-point survey study in the form of a solid group online questionnaire survey. This method was chosen for a rapid collection of the primary information, as it allows interviewing a large number of respondents in a short period of time and with minimal material costs. To conduct the study, an anonymous online questionnaire was developed to collect and analyze the responses of pharmaceutical specialists. The following is a typical form of the questionnaire, consisting of 14 questions with suggested answer options (Table 1).

The survey was conducted online by Sechenov University between September 13 and 30, 2023. The information about the opportunity to voluntarily participate in the questionnaire, an invitation to participate and a link to the questionnaire were emailed to 700 pharmacy workers (from 18 Russian regions) who had undergone training or certification at Sechenov University. Prior to the main study, a pilot test involving 10 pharmacy workers (5 pharmacists and 5 pharmacy technicians) was conducted. In the course of the pilot test, the following were evaluated: a comprehensibility of the questions wording, an unambiguous interpretation of the terms used, and a logical structure of the questionnaire. Based on the results of preliminary testing, the sequence of questions in the questionnaire was optimized, the validity of the questionnaire and the adequacy of the terms used were confirmed.

This study did not require a submission of a biomedical ethics committee approval or other documents because it contained anonymized data. The questions whose content did not meet ethical standards had not been included in the study. Completed anonymous questionnaires were considered as an informed consent from pharmacy workers to participate in the study and a permission to process the provided data. The anonymity of respondents was a mandatory condition of the survey; no personal information (surname, name, patronymic, gender, age) and contact details were collected in the course of the study.

To determine a statistically representative number of respondents (a number of questionnaires), a random non-repeat sampling method was used. The margin of error was set at 5%. To ensure reliable results, at least 400 questionnaires needed to be processed [24, 25]:

$$n = \frac{22}{(4 \times 0.052)} = 400$$

As a part of the survey, 700 emails were sent to potential respondents. The authors received 550 completed questionnaires, which was 78.6% of the total number of questionnaires sent out. The questionnaires were selected for the analysis according to the following criteria: 1) “completeness” – presence of responses to all mandatory question 2) “correctness” – a logical consistency of answers, the absence of obvious mistakes in filling in. As a result of applying these criteria, 37 questionnaires with incomplete or incorrect answers were excluded. Thus, the final sample for the analysis was 513 questionnaires (73.3% of the initially sent ones).

The non-parametric Pearson’s chi-square test (χ^2) was used to assess the statistical significance of differences between the groups. This method had been chosen as the most appropriate for analyzing the categorical data obtained from the questionnaires. The differences between the responses of different groups were investigated using conjugation tables. For each comparison, null and alternative hypotheses were formulated. The null hypothesis implied the absence of differences between the groups, while the alternative hypothesis implied the presence of statistically significant differences. A significance level of p=0.05 was set for all statistical tests. At p <0.05 the differences were considered statistically significant, which allowed rejecting the null hypothesis about the absence of differences between the groups. The data analysis was performed using MS Excel 2019 software package (Microsoft Corp., USA).

RESULTS AND DISCUSSION

Based on the analysis of the received questionnaires, the characteristics of the study participants were compiled (Table 2). The majority of the respondents (53.0%) had secondary specialized education, 39.8% had higher pharmaceutical education, and 7.2% were students of medical universities and colleges. The average work experience of the survey participants was 13.86 years. The sample of the respondents is represented by various categories of pharmaceutical specialists, including front desk specialists (62.0%), supervisors (32.0%), representatives of other job positions (pharmacy technologists, pharmacy analysts, consultants). More than half of the respondents (56.9%) work in private pharmacies. The vast majority (94.0%) are employees of pharmacy chains, only 6.0% of the respondents work in individual PhOs; 89.0% of the participants work in urban areas, 11.0% in rural settlements.

Approximately half of the respondents, regardless of the level of education, experience, position, or pharmacy type correctly identified that the term "pharmacovigilance" refers to the type of activities aimed at identifying, assessing, understanding and preventing undesirable consequences of the drug (Fig. 1). However, more than 40% of respondents incorrectly believed that pharmacovigilance is a body of a state supervision and control over compliance with the legislation of the Russian Federation in the sphere of drug circulation. Only a small proportion of the respondents chose other answer options, such as: "the science that studies (using epidemiological methods), the efficacy, safety and specifics of the drug use in real-life conditions at the level of a population or large groups of people" (3.43% with higher education and 6.62% with secondary specialized education) and "the research and activities related to the consideration of any problems associated with a medicinal product" (2.45 and 1.84%, respectively).

Herewith, about 55% of specialists with higher education were well acquainted with the term "adverse drug reaction" (Fig. 2), compared to 37.50% of those with secondary specialized education (χ^2=26.28; p <0.05). The analysis of the answers depending on the work experience showed that the level of familiarity with the term "adverse drug reaction" increases as the professional experience is acquired. Among the specialists with the work experience up to 1 year, only 25% indicated that they were well acquainted with the term, whereas among the professionals with more than 10 years of work experience – 52.69% (χ^2=18.09; p <0.05).

This trend indicates that practical experience and the accumulation of knowledge in the course of work contribute to a better understanding of the basic concepts of pharmacovigilance. Pharmacy supervisors demonstrated greater familiarity with the term "adverse drug reaction" (54.88% were well acquainted) than front desk specialists (37.54%, χ^2=27.30; p <0.05). The analysis of responses according to the pharmacy location (urban or rural) showed that the level of familiarity with the term "adverse reaction" was slightly lower among rural pharmacy specialists (38.60% were well familiar) compared to urban pharmacy (44.08% χ^2=6.95; p <0.05). The proportion of those who had never heard of the term was also higher among the specialists in rural pharmacy (8.77 *vs.* 2.41% in urban PhOs).

The level of familiarity with the ADR reporting (Fig. 3) form varies according to the education, experience, position, pharmacy ownership, pharmacy chain affiliation and location. Among the respondents with higher education, 75% were familiar with the form, whereas among those with secondary specialized education the figure was 55.15% (χ^2=20.22, p <0.05). The differences in the level of familiarity with the increasing work experience and between the employees of individual and chain pharmacies were not statistically significant (χ^2=4.783, p >0.05 and χ^2=1.80, p >0.05). Pharmacy supervisors show a higher level of familiarity with the form (76.22%) compared to the front desk specialists (56.47%; χ^2=18.73, p <0.05). In public PhOs, 68.33% of the employees were familiar with the form, while in private PhOs, 58.90% were familiar with the form (χ^2=4.83, p <0.05).

A similar trend was observed with regard to the awareness of where to obtain an adverse drug reaction reporting form (Fig. 4). The level of awareness of where to obtain the adverse drug reaction reporting form is higher among the people with higher education (68.14%) compared to the people with secondary specialized education (41.54%; χ^2=33.50, p <0.05). The percentage of the pharmacy specialists familiar with the reporting form increased with experience, from 55.26% among the specialists with the experience up to 1 year, to 67.31% among those with more than 10 years of experience (χ^2=21.05, p <0.05). The study found out that pharmacy supervisors showed higher awareness than front desk specialists regarding familiarity with the form (76.22 *vs.* 56.47%; χ^2=18.27, p <0.05) and how to obtain it (67.68 *vs.* 43.85%; χ^2=24.66, p <0.05). The employees of public and non-chain pharmacies were more aware of how to obtain an adverse drug reaction reporting form (63.80 and 77.42%) than the employees of private and chain pharmacies (42.47 and 50.00%; χ^2=27.91, p <0.05). Pharmaceutical specialists from the urban pharmacies were more familiar with the form (63.60%) and knew where to obtain it (53.07%) compared to the pharmacy staff from the rural areas (57.89% and

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40.35%, respectively), but the differences were not statistically significant (χ^2=0.6821, p >0.05 and χ^2=3.3095, p >0.05).

The majority of pharmacy professionals recognize the need to report identified ADRs (Fig. 5). Among the respondents with higher education, 61.76% believed that ADRs should be always reported, while among the specialists with secondary specialized education this figure was slightly lower – 58.82% (χ^2=1.739, p >0.05, the differences not significant). The pharmaceutical specialists with 2 to 5 years of work experience showed the highest willingness to always report ADRs – 74% (χ^2=12.70, p <0.05). The pharmacy supervisors and front desk specialists equally recognized the need to report ADRs (60.37 and 60.25%, respectively). No statistically significant difference was found out between the private and public pharmacy employees (χ^2=3.43, p <0.05). However, it was established that in the individual pharmacy chains, 67.74% of employees believed that ADRs should be always reported, while in the chain pharmacies this figure was only 32.16% (χ^2=19.229, p <0.05). At the same time, it should be noted that 34.02% of the employees in the chain pharmacies believe that it is not necessary to report ADRs, which is an alarming signal.

When asked to correctly identify the government body collecting information on ADRs in Russia, the majority of the respondents correctly stated that it was Roszdravnadzor. However, the level of awareness varied depending on several factors. Among the specialists with higher education, 87.25% gave a correct answer, while among the specialists with secondary specialized education this figure was 70.22% (χ^2=20.85, p <0.05). The work experience also influenced their awareness: with the increasing work experience, the percentage of pharmacists who correctly identified Roszdravnadzor, increased (from 63.16% among those with up to 1 year of experience to 81.92% among those with more than 10 years of experience; χ^2=19.96, p <0.05). The Pharmacy supervisors showed higher awareness (85.37%) compared to the front desk specialists, 71.29% (χ^2=12.29, p <0.05).

The level of pharmacy professionals' awareness about the pharmacovigilance regulation at the EAEU level varies depending on different factors (Fig. 6). Specialists with higher education are better informed on this issue – 38.24% are well aware of it, while 37.25% have superficial knowledge. Among the specialists with secondary specialized education, only 25% are well informed, 37.13% have superficial knowledge and 37.87% have no knowledge at all (χ^2=13.10, p <0.05). The work experience has a positive effect on the level of knowledge. While among the employees with up to 1 year of experience only 22.37% have good knowledge of pharmacovigilance regulations at the EAEU level, among the specialists with more than 10 years of experience this indicator reaches 33.46%. At the same time, with the increasing work experience, the share of those who do not know about it at all decreases (χ^2=8.76, p >0.05). The Pharmacy supervisors are significantly better informed (39.02% are well aware) than ordinary first desk specialists – 24.29% (χ^2=13.16, p <0.05). The differences in awareness between public and private, individual and chain, urban and rural pharmacy specialists are not statistically significant (χ^2=5.34, p >0.05; χ^2=4.01, p >0.05; χ^2=2.56, p >0.05).

The results of the study showed that only 13.24% of the respondents with higher education and 14.71% with specialized secondary education had received full-fledged training on pharmacovigilance during their professional career. The majority of the specialists either had not studied pharmacovigilance at all (59.80% with higher education and 62.13% with secondary education) or attended only separate lectures (26.96 and 23.16%, respectively). The analysis of the data according to the work experience revealed that only 11.84% of the staff with up to 1 year of experience had received training in pharmacovigilance. With the increasing work experience, the situation improves somewhat, but even among the specialists with more than 10 years of service, the share of those who have received training is only 13.85%, while the share of those who have not received training is 58.08%. Nevertheless, the differences between the groups by work experience are not statistically significant (χ^2=8.64, p >0.05). Pharmacy supervisors are more likely to be trained in pharmacovigilance (15.85%) than the rank and file first desk specialists (12.93%). However, among the supervisors, more than half (51.83%) had never received training on pharmacovigilance either (χ^2=9.15, p <0.05). A comparison of responses from the employees of public and private PhOs showed that the employees in private PhOs are more likely to be trained in pharmacovigilance (17.81 *vs.* 8.60% in public PhOs; χ^2=9.18, p <0.05). However, the proportion of the untrained employees was higher in public PhOs (66.06%) than in private pharmacies (57.53%). It is worth noting that individual pharmacies had a significantly higher rate of pharmacovigilance training (25.81%) than chain pharmacies (13.07%) (χ^2=4.29, p <0.05). At the same time, the proportion of those who had attended only separate lectures was lower in individual pharmacies (12.90 *vs.* 25.73% in chain pharmacies; χ^2=4.53, p <0.05). The differences in the number of people trained in pharmacovigilance and attending individual lectures between urban and rural pharmacies are not statistically significant (χ^2=1.92, p >0.05). However, the overall situation is about the same – more than half of the workers in both urban and rural PhOs have not been trained in pharmacovigilance at all.

Table 1 – Questionnaire form for respondents' survey

No	Question	Answer options
	First of all, we ask you to tell us a little bit about yourself:	
1	What kind of pharmaceutical education do you have?	☐ Higher; ☐ Secondary specialized; ☐ Medical student: University, college.
2	What is your work experience in the speciality (years)?	Specify: _____
3	What is your "job position" in the pharmacy	☐ Supervisor; ☐ Front desk specialist; Other (specify): _____.
	What pharmacy are you working in?	
4	By ownership form:	☐ Public; ☐ Private.
5	In relation to pharmacy chains:	☐ Chain; ☐ Individual.
6	By location:	☐ City; ☐ Rural settlement.
	Further on, we ask you to answer a number of questions related to pharmacovigilance:	
7	Do you think pharmacovigilance is…	☐ A science that studies the efficacy, safety, and patterns of medicines use in real-world settings at the population or large group level using epidemiological methods; ☐ A type of activity aimed at identifying, assessing, understanding and preventing adverse drug reactions; ☐ Research and activities related to taking into account any concerns about drugs; ☐ The body of state supervision and control over compliance with the legislation of the Russian Federation in the sphere of the drug circulation.
8	How are you familiar with the term "adverse drug reaction"?	☐ Well acquainted – I have a full understanding; ☐ Familiar – I have a basic understanding; ☐ Heard of the term – I can't define it; ☐ Never heard of the term.
9	Are you familiar with the adverse drug reaction reporting form for medical professionals?	☐ Yes; ☐ No.
10	Do you know of a location where this form can be obtained?	☐ Yes; ☐ No.
11	What body collects information on adverse drug reactions in the Russian Federation?	☐ Ministry of Health of Russia; ☐ Rospotrebnadzor; ☐ Roszdravnadzor; ☐ Rosstat.
12	Do you know that pharmacovigilance is regulated at the EAEU level?	☐ Yes; ☐ No. ☐ I know, but only superficially.
13	Have you received training in pharmacovigilance?	☐ Yes; ☐ No; ☐ Attended separate lectures.
14	Do you think there is a need for more training programmes for pharmaceutical specialists in the identification and reporting of adverse drug reactions?	☐ I agree; ☐ I disagree.

Note: PhO – pharmacy organization.

Table 2 – Characteristics of study participants

Survey question		Response	Number and proportion of respondents, *n* (%)
What kind of pharmaceutical education do you have?		Higher	204 (39.8%)
		Secondary specialized	272 (53.0%)
		Medical student: University, college	37 (7.2%)
What is your position' in the PhO?		Supervisor	318 (62.0%)
		Front desk specialist	164 (32.0%)
		Other (specify)	31 (6.0%)
What PhO are you working in?	By ownership form:	Public	221 (43.1%)
		Private	292 (56.9%)
	In relation to pharmacy chains:	Chain	482 (94.0%)
		Individual.	31 (6.0%)
	By location:	City	457 (89.0%)
		Rural settlement.	56 (11.0%)

Note: PhO – pharmacy organisation.

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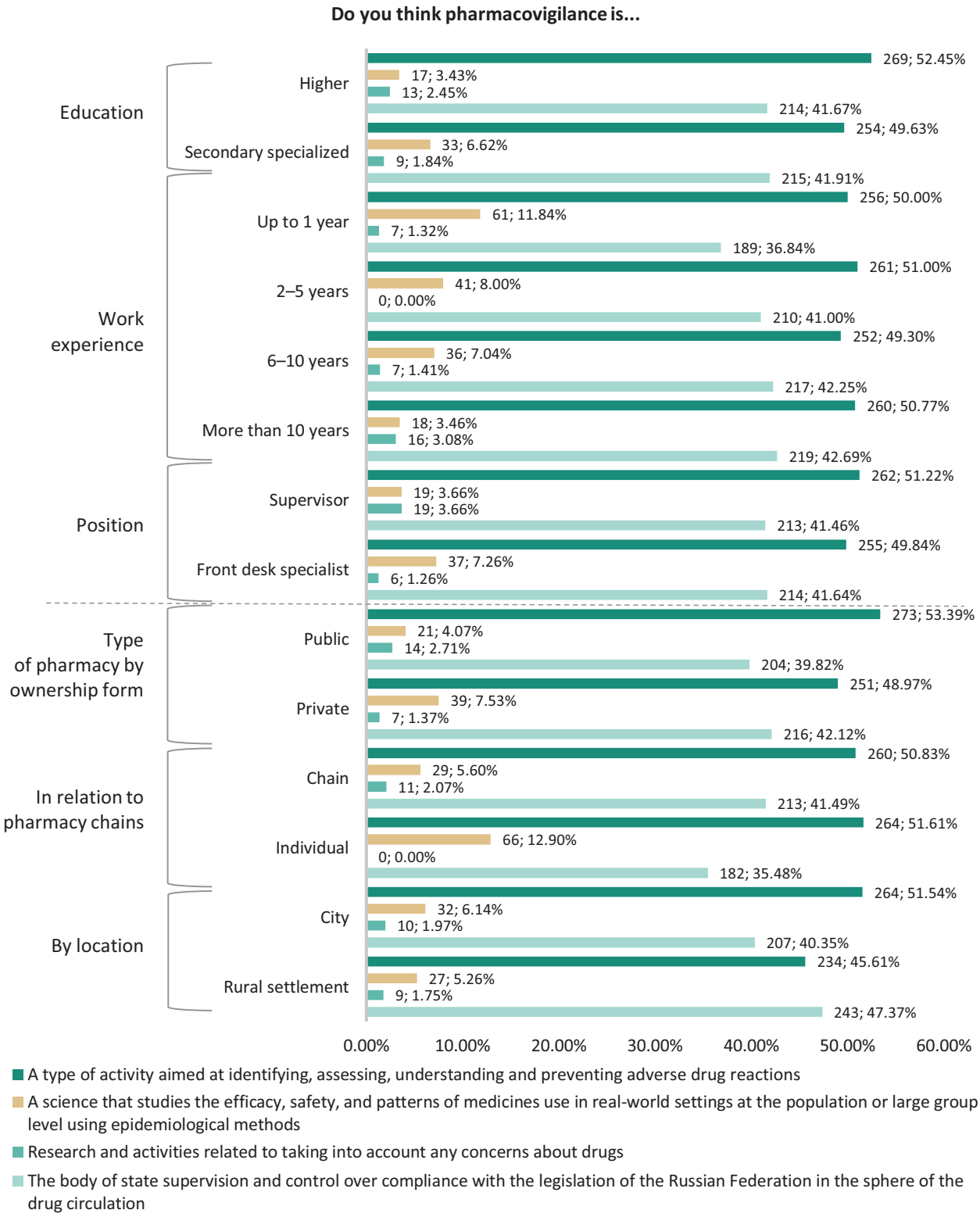

Figure 1 – Distribution of respondents' answers to the question: "Do you think pharmacovigilance is..."

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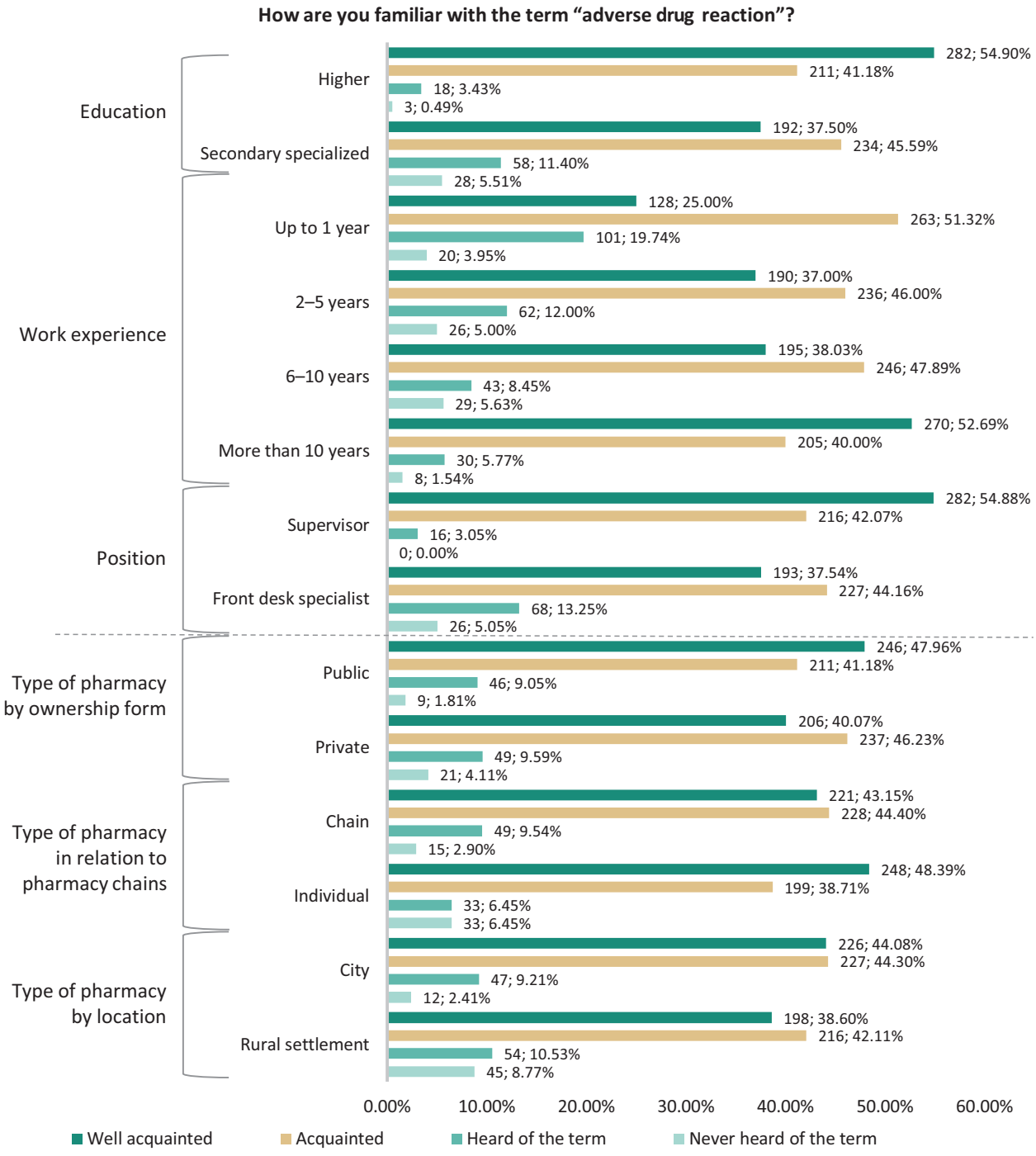

Figure 2 – Distribution of respondents' answers to the question: "How familiar are you with the term "adverse drug reaction"?

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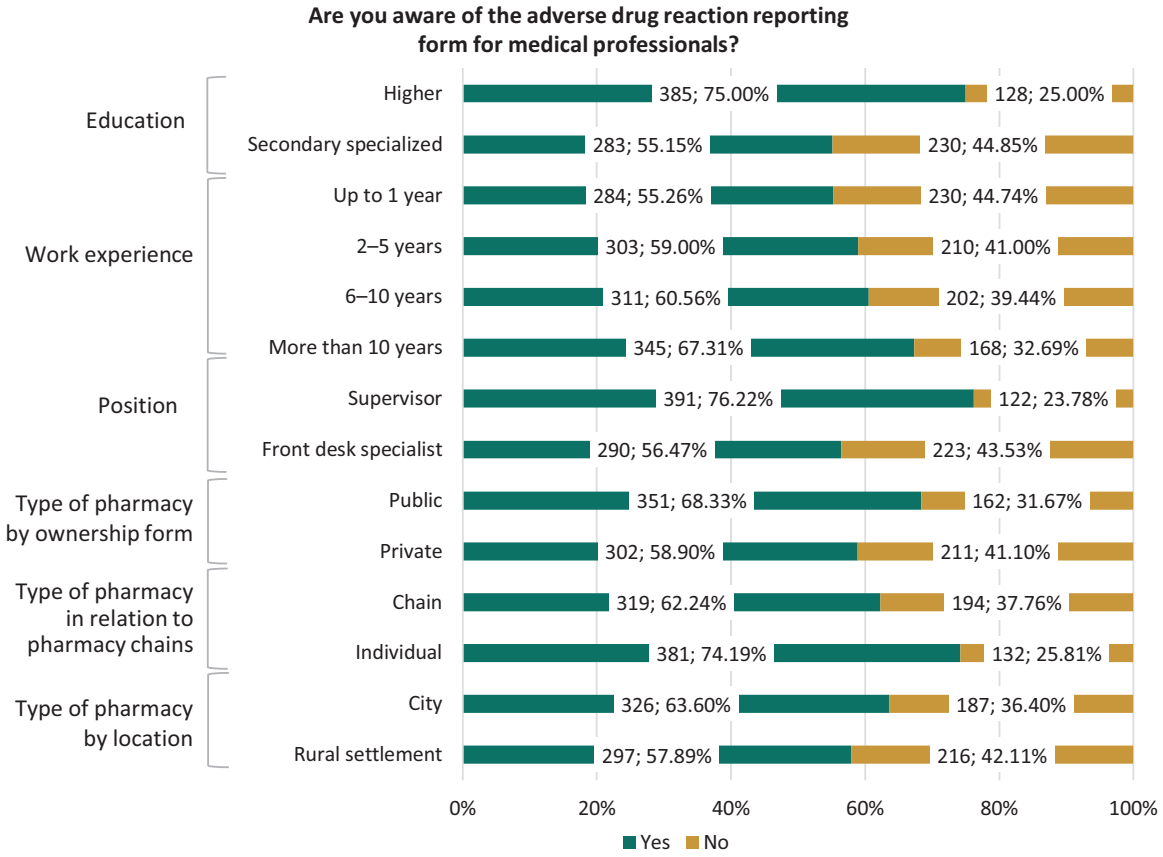

Figure 3 – Distribution of respondents' answers to the question: "Are you aware of the adverse drug reaction reporting form for medical professionals?"

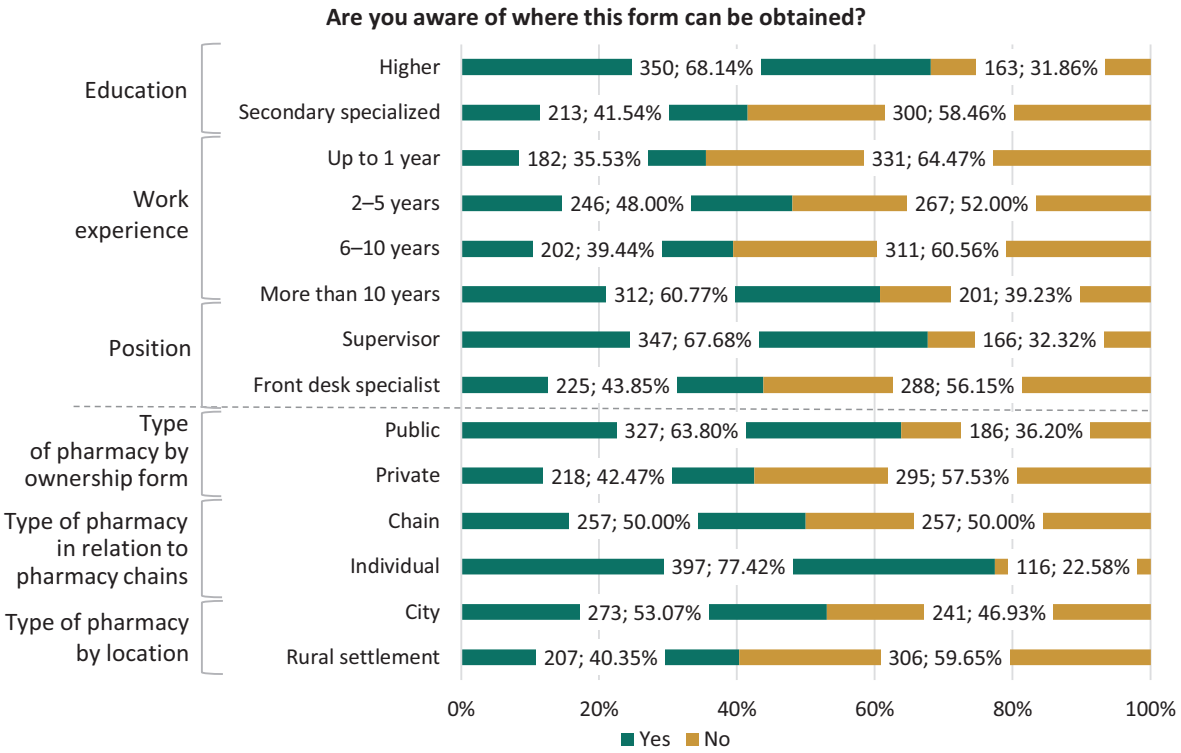

Figure 4 – Distribution of respondents' answers to the question: "Do you know where this form can be obtained?"

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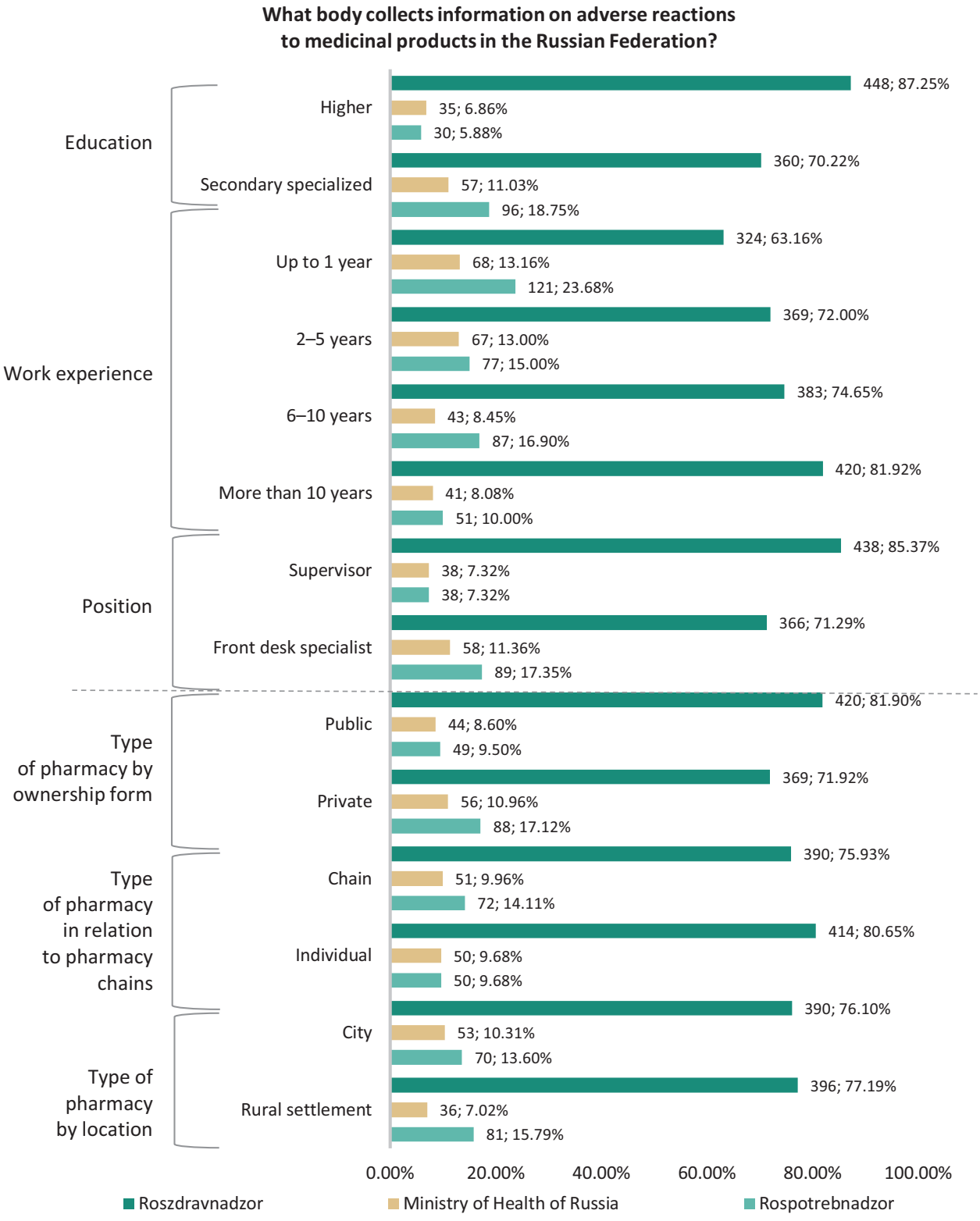

Figure 5 – Distribution of respondents' answers to the question: "What body collects information on adverse drug reactions in the Russian Federation?"

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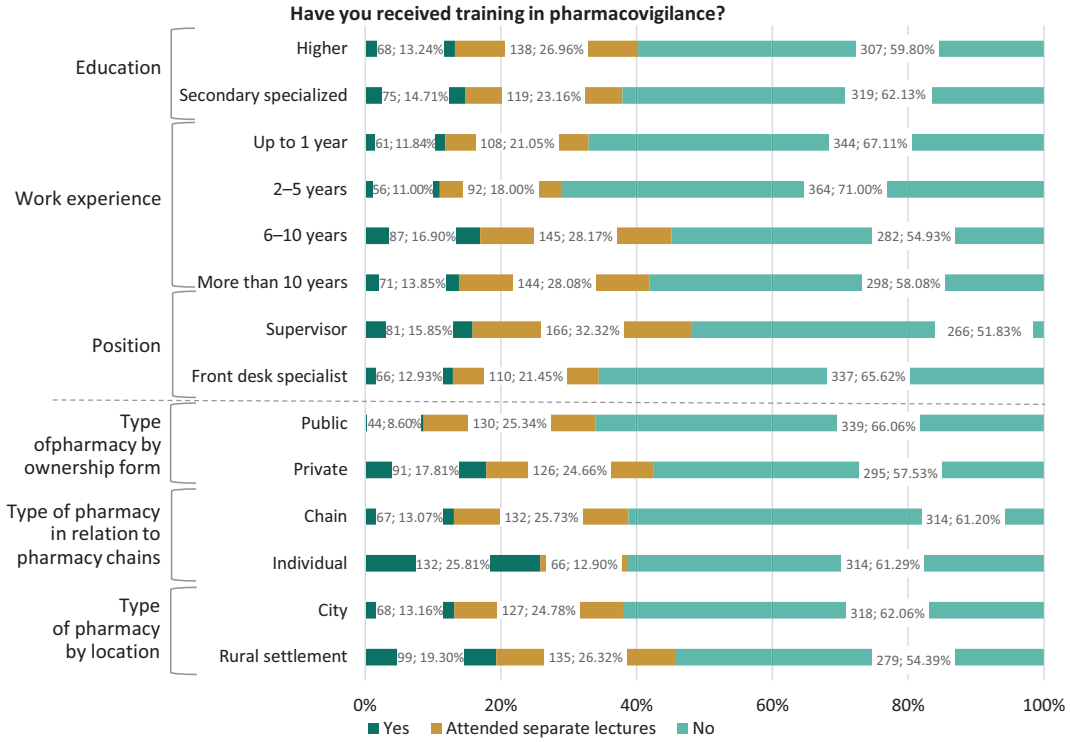

Figure 6 – Distribution of respondents' answers to the question: "Have you received training in pharmacovigilance?"

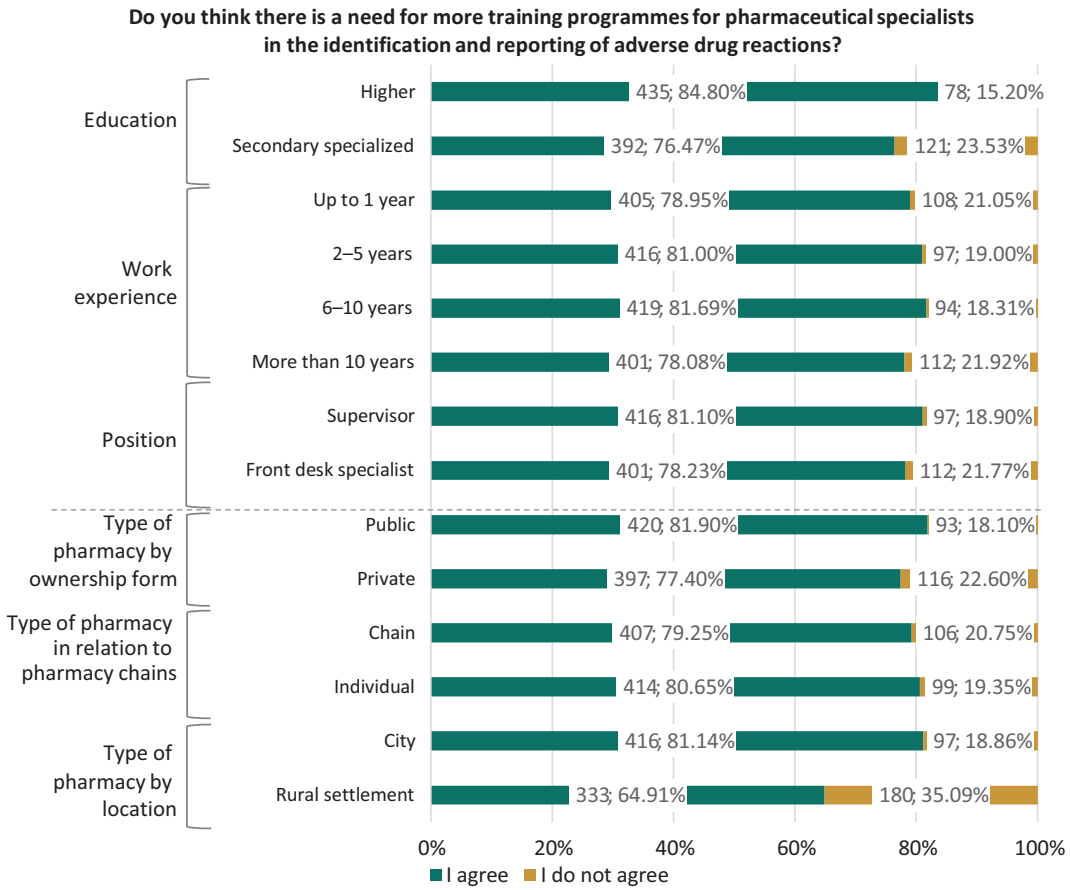

Figure 7 – Distribution of respondents' answers to the question: "Do you think there is a need for more training programs for pharmaceutical specialists on the identification and reporting of adverse drug reactions?"

The vast majority of pharmacy workers, regardless of various factors, believe that an increase in the number of training programmes aiming at the detection and reporting of ADRs is necessary (Fig. 7). Among the professionals with higher education, 84.80% agreed with this statement, and among those with secondary specialized education, 76.47% agreed (χ^2=4.57, p <0.05). The analysis of the answers depending on the work experience shows that the need for training programmes is high in all the groups. The proportion of those who agree varies slightly, from 78.08% among the specialists with more than 10 years of experience to 81.69% among the professionals with 6 to 10 years of work experience. The Pharmacy supervisors are slightly more likely to agree with the need to increase the number of training programmes (81.10%) than first desk specialists (78.23%), but this difference is not statistically significant (χ^2=0.564, p >0.05). The majority of the public and private pharmacy specialists agree on the need for more training programmes (81.90 and 77.40%). No significant differences were found out between the chain and individual pharmacies on this issue. The share of those who agree with the need for an additional training is 79.25% in the chain pharmacies and 80.65% in the individual pharmacies. Among the employees of the urban pharmacies, a support for the idea of increasing the number of training programmes is noticeably higher (81.14%) than among the employees of the rural pharmacies – 64.91% (χ^2=8.38, p <0.05).

The data gained are consistent with other studies in the field, which also show a lack of pharmacovigillance awareness among pharmacists, which negatively affects their participation in the ADRs reporting system. Knowledge of specific aspects of the drug safety monitoring system varies according to the education level, work experience and position. However, even among the specialists with higher education and extensive experience, there are still significant gaps in knowledge of the basics of pharmacovigilance, indicating the need to introduce additional educational programs at the training stage and in the postgraduate education. The availability of a large number of educational programs on pharmacovigilance does not guarantee their coverage of a wide range of specialists. Perhaps the reasons lie in the insufficient motivation, time constraints and lack of information about training opportunities or organizational barriers within pharmacies. Foreign studies show that financial incentives and face-to-face educational activities based on the principles of behavioral psychology are effective measures to increase the activities of specialists in this field. In the future, it is important to conduct additional research aimed at identifying specific barriers and developing targeted interventions for different groups of pharmaceutical professionals. A comprehensive approach combining educational, motivational and organisational measures could significantly improve the quality and quantity of ADRs reporting, which in turn, would improve the pharmacovigilance system as a whole and increase the safety of drug therapy for the public.

Study limitations

The sample was drawn from the professionals who had been trained and certified at Sechenov University (Moscow, Russia). This could lead to the sampling bias, as respondents may be more motivated or informed than the general population of pharmacy professionals in Russia. Conducting the survey in an online format may have limited the participation of professionals who do not have a regular access to the internet. The survey was based on the respondents' self-reports, so, there may be inaccuracies related to the subjective assessment of their own knowledge level. The study was cross-sectional, i.e. the data were collected at one point in time, which makes it impossible to trace the dynamics of changes in the knowledge level of pharmacy professionals over time.

CONCLUSION

The results of this study indicate inadequate knowledge of pharmacovigilance fundamentals among pharmacy workers. Education work experience and position are important factors affecting the level of their pharmacovigilance knowledge. Professionals with higher education, longer work experience and those in supervisor positions show a higher level of knowledge compared to those with secondary specialized education, shorter work experience and those in front desk positions. However, it is the PhOs front desk specialists who are in direct contact with patients and are in a position to be the first to identify ADRs. The lack of awareness of this specialists' category (only 37.54% are familiar with the term "adverse drug reaction") may significantly reduce the effectiveness of the pharmacovigilance system. This may be due to the lack of awareness of the reporting procedure, the lack of motivation and organizational barriers.

Despite the availability of educational programs, most specialists do not have special training in this area, and in practice, the ADRs reporting level remains low. The data obtained show that only 13.24% of respondents with higher education and 14.71% with specialized secondary education have been trained in pharmacovigilance. At the same time, the vast majority of survey participants (84.80% with higher education and 76.47% with secondary specialized education)

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consider it necessary to increase the number of training programs on ADR detection and reporting. The solution to this problem requires a comprehensive approach that includes educational activities, financial incentives, and the development of theoretically grounded interventions targeted at the pharmacy staff. Training should be practice-oriented and take into account the specifics of work in pharmacies of various types (public, private, chain, individual). The use of modern training technologies, including distance and online formats, will make it possible to reach more specialists and increase the effectiveness of training. Support from the pharmacy management plays a key role in creating a favorable environment for the staff training, providing the necessary resources and time to carry out their respective responsibilities. The implementation of a set of educational activities can help to improve the quality of spontaneous reports and increase their number, which will contribute to the improvement of the pharmacovigilance system in the Russian Federation.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTION

Roza I. Yagudina – development of the research concept, discussion of results, critical evaluation of the material; Olga L. Listova – development of the research concept, discussion of results, critical evaluation of the material; Adelya R. Umerova – analysis of literature sources, collection and analysis of material; Kirill A. Kopeyka – collection and analysis of material, statistical processing of results, writing and editing of the manuscript.
All the authors confirm that their authorship meets the international ICMJE criteria (all the authors have made a significant contribution to the development of the concept, research and preparation of the article, read and approved the final version before the publication).

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