

## Consumer rights and product safety in Albania's pharmaceutical industry

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### Abstract

This study examines the effects of product safety practices on consumer rights in the Albanian pharmacy sector. In particular, it is aimed to analyze the perceptions of pharmacy personnel, examine regulatory frameworks and identify deficiencies in safety communication and reporting practices. Cross-sectional survey design is employed in the study to assess the perceptions and practices of pharmacy staff across Albania. Descriptive and inferential statistical analyses provide a comprehensive understanding of the factors affecting product safety and consumer rights protection in Albanian pharmacies. The findings of the study highlight the strengths of the Albanian pharmacy sector, especially in terms of staff awareness and proactive safety measures, while revealing that there is a serious need for positive steps in areas such as communication, personnel management and leadership practices. Therefore, the findings in this study contribute to the establishment of a more reliable and effective healthcare system by providing a basis for improving safety practices and protecting consumer rights.

**Keywords:** Consumer rights, Product safety, Regulatory control, Pharmaceutical industry, Albania.



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## 1. Introduction

The pharmacy sector has a very important and critical role in global health systems by addressing health problems, improving quality of life and providing essential products that improve public health outcomes. As consumer health needs increase day by day, the demand for protection of consumer rights in the pharmacy sector also increases. Among these rights, access to safe, effective and high-quality medicines stands out as a fundamental element of public health systems. Ensuring product safety in the pharmacy sector minimizes possible risks, increases consumer confidence and protects individual rights.

In Albania, the interaction between product safety, regulatory control and consumer rights continues to be an important issue in the pharmacy sector in particular and in the health sector in general. The pharmacy sector, which is vital for public health in the country, faces challenges such as counterfeit medicines, lack of regulatory compliance and limited pharmacovigilance practices (Ministry of Health and Social Protection of Albania, 2023). These challenges in the sector have direct impacts on the health and safety of consumers who rely on pharmacies as the primary point of access to medicines. The aim of this study was to investigate the status of product safety in Albanian pharmacies and its broader implications for consumer rights in the context of staff perceptions, demographic influences and existing regulatory frameworks.

Of course, product safety on a global scale is not only a regulatory requirement but also a public health imperative. The World Health Organization (2019) has found that ensuring safety standards in medicines prevents potential harm to public health, reduces side effects and promotes accountability in healthcare systems. In Albania, there are limited studies on product safety practices in the pharmacy sector and their impact on consumer rights. It is critical to fill the literature gap on the subject in order to improve public health outcomes, ensure ethical practices and align the Albanian pharmacy sector with international standards.

### 1.1. Justification for the Topic

The issue of product safety in the Albanian pharmaceutical sector is of great importance in many respects. For example, from a public health perspective, pharmaceutical products are essential for the prevention, management and treatment of diseases, and for these reasons, product safety is fundamental to the provision of healthcare services. On the other hand, from a consumer rights perspective, individuals have the right to access safe, effective and reliable medicines. Although regulatory frameworks and safety protocols are improving in Albania, they are inadequate to address current challenges such as counterfeit medicines and inconsistent quality control, and therefore there is significant progress to be made in this regard.

The safety of pharmaceutical products in Albania is a critical concern, especially due to the prevalence of counterfeit medicines and difficulties in quality control. The World Health Organization (WHO) has identified counterfeit medicines as a significant threat to public health, especially in low- and middle-income countries where regulatory systems are weak (Almuzaini, Choonara & Sammons, 2013).

Furthermore, the European Directorate for the Quality of Medicines and Healthcare (EDQM) emphasizes the importance of strict quality standards and regulatory measures to prevent the distribution of counterfeit medical products throughout Europe. In Albania, procedures for



reporting adverse drug reactions (ADRs) are not yet in line with European Union standards, despite ongoing legislative reforms (Hoxha, Zappacosta & Franco, 2024; Shkreli, Dhamo, Haloçi & Tabaku, 2023; Hoxha, Spahiu, Spahiu & Zappacosta, 2024). These findings highlight the need to strengthen pharmaceutical regulatory frameworks and quality assurance protocols to ensure the safety and efficacy of medicines offered to consumers in Albania. Therefore, this study provides a multi-faceted view of product safety assessment in the Albanian context, addressing the regulatory, ethical and practical dimensions of the issue. The research highlights the high need for robust quality assurance mechanisms, improved regulatory oversight and ethical accountability in the Albanian pharmaceutical industry, focusing on how product safety impacts consumer rights.

## 1.2. Research Gap

Although extensive research has been conducted on pharmaceutical safety and consumer rights on a global scale, it appears that there is not enough work specifically for Albania. Existing studies address regulatory compliance and public health issues in the region, but do not provide a focused analysis of how product safety practices in pharmacies directly affect consumer rights. Furthermore, the role of pharmacy staff perceptions, demographic factors and communication practices in ensuring product safety has not been sufficiently investigated. Therefore, this study aims to fill this gap in the literature by comprehensively analyzing product safety practices in Albanian pharmacies and their impact on consumer rights.

## 1.3. Problem Statement

Product safety in the Albanian pharmaceutical sector is of great and vital importance in protecting public health and consumer rights. However, deficiencies in safety protocols, weak regulatory oversight and limited pharmacovigilance systems pose serious risks to consumers. Of course, without a comprehensive study of these issues, the healthcare system lacks the necessary tools to develop effective policies and practices that are appropriate for Albania's unique challenges. Therefore, this study aims to contribute to the solution of these problems in the sector by examining the product safety situation in pharmacies, analyzing the perceptions and demographic effects of staff and evaluating the effectiveness of existing safety protocols. In this context, this study provides actionable insights that will protect consumer rights and improve public health outcomes.

## 1.4. Purpose and Objectives of the Study

The main objective of this study is to analyze the effects of product safety practices on consumer rights in the Albanian pharmacy sector. In particular, it is aimed to analyze the perceptions of pharmacy personnel, examine regulatory frameworks and identify deficiencies in safety communication and reporting practices.

Therefore, the objectives of the study can be listed as follows:

- **Evaluation of quality assurance procedures:** To analyze the effectiveness of existing protocols in ensuring product safety in the sector.
- **Examination of regulatory frameworks:** To examine the compliance of existing regulatory mechanisms in the Albanian pharmacy sector with international standards.
- **Case study analysis:**
  - Examination of product safety practices in Albanian pharmacies

- Examination of the impact of these practices on consumer rights.
- To investigate the effects of demographic factors on safety perceptions.
- To analyze practices related to safety communication and reporting.
- To understand organizational learning, dynamics affecting teamwork and personnel competence.

In line with these objectives, this study aims to provide insights into the relationship between product safety and consumer protection and to identify areas for improvement in the Albanian pharmaceutical sector.

### 1.5. Research Questions

To achieve the objectives of this study, the following research questions will be addressed:

1. What are the main elements of the legal framework regulating pharmaceutical products in Albanian pharmacies?
2. How do product safety practices in Albanian pharmacies affect the protection of consumer rights?
3. How effective are safety communication, reporting practices and managerial expectations in promoting product safety in Albanian pharmacies?

### 1.6. Hypotheses

The study is guided by two hypotheses:

The study was guided by the following two hypotheses:

- **Hypothesis 1:**
  - **Null Hypothesis (H<sub>0</sub>):** There is no significant difference in the perception of product safety practices and their impact on consumer rights among different demographic groups in Albanian pharmacies.
  - **Alternative Hypothesis (H<sub>1</sub>):** There is a significant difference in the perception of product safety practices and their impact on consumer rights among different demographic groups in Albanian pharmacies.
- **Hypothesis 2:**
  - **Null Hypothesis (H<sub>0</sub>):** Safety communication, reporting frequency and manager/supervisor expectations do not significantly affect product safety practices in Albanian pharmacies.
  - **Alternative Hypothesis (H<sub>1</sub>):** Safety communication, reporting frequency, and manager/supervisor expectations significantly influence product safety practices in Albanian pharmacies.

## 2. Literature Review

The literature review section starts from a global perspective and moves to the specific context of Albania, addressing the regulatory framework, consumer rights and specific challenges faced by the pharmaceutical industry. The main objective of this section is to provide literature to create a conceptual framework for analyzing the product safety situation in pharmacies, the perception of safety among pharmacy staff and the impact of this perception on consumer rights.



## 2.1. Global Perspective on Product Safety Assessment and Consumer Rights

The pharmaceutical industry operates within complex regulatory frameworks on a global scale to ensure product safety and protect consumer rights. According to Ilardo & Speciale (2020), consumer rights such as access to safe and effective medicines, transparency, and accountability are of utmost importance and critical importance in building public trust. The World Health Organization (WHO, 2021) emphasizes the importance of harmonized standards in ensuring product safety, recommending the adoption of Good Manufacturing Practices (GMP), pharmacovigilance systems, and standardized labeling protocols.

Studies on the subject reveal the critical role of pre-market testing, post-market surveillance systems, and risk management plans in protecting the integrity of pharmaceutical product. Sami et al. (2021) and Chen et al. (2011) highlight advanced methods, such as machine learning and Bayesian neural networks to enhance side effect detection. For example, the Bayesian neural network approach developed by Bate et al. (1998) has contributed to global safety monitoring by significantly improving signal detection.

Despite advancements, regulatory harmonization challenges remain. Atkinson (2022) notes that differences in national policies, resource limitations, and evolving technologies make it difficult to adopt universal safety standards. On the other hand, international collaborative efforts, such as the pharmacovigilance programs of the Uppsala Monitoring Center cited by Olsson (1998), play an important role in improving safety protocols and communication.

Consumer trust in pharmaceutical products is, of course, directly related to strong safety measures and regulatory transparency. Wu et al. (2021) found that safety vulnerabilities can undermine consumer confidence, endanger public health, and undermine consumer rights. Therefore, proactive risk management and accountability are critical. Desselle et al. (2018) emphasize the need for evidence-based policy development and stakeholder engagement to address safety concerns and enhance consumer rights protection.

Internationally, agreements such as the TRIPS Agreement facilitate regulatory harmonization and safety assurance to ensure equal access to high-quality medicines (WHO, 2019). Tools such as MedDRA (Medical Dictionary for Drug Regulatory Activities), with the support of WHO-ART, have increased consistency in regional adverse reaction reporting (Olsson, 1998).

As a result, global practices emphasize the importance of harmonization, transparency, and proactive risk management in product safety assessment. These efforts will not only protect public health but also strengthen consumer trust and rights in the pharmaceutical industry.

## 2.2. Regulatory Frameworks and Product Safety

Ensuring product safety in the pharmaceutical sector is critical to protecting consumer health and rights. According to the World Health Organization (2018), unsafe or counterfeit medicines pose serious risks. These risks include side effects and treatment failures. Regulatory oversight through strict product safety measures can minimize these risks and increase public confidence in the pharmaceutical sector.

The Albanian pharmaceutical regulatory system has undergone significant reforms to align with EU directives. Indeed, the Albanian Ministry of Health and Social Protection (2023) reports a focus on the adoption of Good Manufacturing Practices (GMP) and the modernization of quality assurance mechanisms. On the other hand, ongoing challenges such



as counterfeit medicines, lack of quality control, and monitoring inconsistencies clearly indicate that safety protocols need to be further strengthened.

The European Medicines Agency (EMA) highlights pharmacovigilance as a critical mechanism to identify and reduce risks associated with medicines (Jooanne, 2021). Pharmacovigilance systems remain inadequate in Albania; there are deficiencies in side effect reporting and inadequacies in the organizational framework (World Bank, 2020)

### 2.3. Consumer Rights and Product Safety

Consumer rights underpin pharmaceutical safety by ensuring access to safe and effective medicines and transparent product information. The World Health Organization (WHO) emphasizes the need for strong regulatory frameworks to protect these rights, highlighting the importance of clear labeling, pharmacovigilance systems and post-market surveillance (Ofori-Parku & Park, 2022).

In Albania, consumer trust in pharmacies is increasingly undermined by concerns about counterfeit and expired medicines. The prevalence of counterfeit medicines poses a serious public health risk; these medicines may contain incorrect dosages or harmful ingredients, which can lead to treatment failures or side effects (Pathak, Gaur, Sankrityayan & Gogtay, 2023).

Weak enforcement of safety regulations in this sector further endangers consumer rights and thus increases public health problems. Solving these issues requires comprehensive strategies that include public awareness campaigns, stringent safety protocols, and training of pharmacy staff on consumer protection and safety issues. Such measures and activities are vital to both promote accountability and increase consumer confidence in the pharmaceutical industry (Roshi et al., 2023).

### 2.4. Challenges in the Albanian Context

The pharmaceutical sector in Albania is faced with serious challenges and problems due to economic constraints, fragmented regulatory oversight, and limited resources. The prominent problems in the sector are as follows:

- ◆ **Counterfeit Medicines:** The presence of poor-quality medicines undermines consumer confidence in the sector while also posing serious health risks (Marjo, 2021).
- ◆ **Regulatory Compliance:** Uncertainties and inadequacies continue to exist regarding the implementation of regulations such as ensuring that product leaflets are in Albanian (World Bank, 2020).
- ◆ **Personnel Perceptions:** A study conducted by Saric et al. (2021) assessed the quality of primary health care in Albania. This study revealed deficiencies in areas such as infrastructure, service delivery, and patient satisfaction. This situation reflects systemic weaknesses in the sector and negatively affects the trust of pharmacy staff in quality control mechanisms.

### 2.5. Improving Safety Protocols

Ministry of Health and Social Protection of Albania (2023) emphasizes and emphasizes the critical role of regulatory reforms in improving safety protocols. Initiatives within the scope of these regulatory reforms include streamlining licensing procedures and aligning drug



registration processes with EU standards. Close and strong cooperation is essential between regulatory authorities, healthcare providers and industry stakeholders for the effective implementation of these measures within the framework of the reforms.

The World Health Organization (WHO) actively supports cooperation between government bodies, healthcare providers and international organizations to improve healthcare quality and patient safety in Albania. An example of these efforts is the visit of an Albanian high-level technical delegation to Greece in April 2023. This visit, organized by the WHO Office for Quality and Patient Safety in Athens, aimed to share knowledge and experience in order to improve the quality of healthcare in Albania (WHO, 2023).

Additionally, the Albanian Association of Pharmaceutical Companies (SHPF) strives for a regulatory system in line with European standards, emphasizing the need for cooperation between stakeholders to ensure access to safe and effective medicines (AAPC, 2024).

### 3. Methodology

#### 3.1. Rationale for the Research Method

This study investigates the status of product safety in pharmacies in Albania and its impact on consumer rights in the sector. The study examines the perception of safety among pharmacy staff, the impact of demographic factors and the effectiveness of safety protocols. By adopting a comprehensive approach, the study aims to identify actionable insights and provide recommendations to improve safety standards and protect consumer rights in the Albanian pharmacy sector.

Ensuring the safety of pharmaceutical products is vital to protecting public health, maintaining trust in healthcare systems and ensuring consumer rights. Therefore, the study aims to address gaps in product safety practices by evaluating existing protocols, identifying influencing factors and presenting improvement strategies.

#### Objectives

The objectives of the study are as follows:

- ◆ To assess the level of product safety practices in Albanian pharmacies.
- ◆ To examine the impact of product safety on consumer rights.
- ◆ To identify factors affecting safety practices.
- ◆ To provide recommendations to improve product safety and protect consumer rights.

#### Variables

This study focuses on the following variables:

- **Dependent Variable:**

#### Consumer Rights Protection

This variable measures the extent to which consumer rights are protected in Albanian pharmacies. It includes elements such as security, transparency, and effectiveness of security protocols. Higher scores indicate stronger protection of consumer rights.

- **Independent Variables:**

1. **Perception of Product Safety Practices**

This variable, one of the independent variables, assesses the attitudes of pharmacy personnel towards safety practices. It covers issues such as prioritization of safety in the sector, communication, frequency of reporting, managerial actions, organizational learning, teamwork, and staff competence.

2. **Demographic Factors**

Another group of independent variables, this variable, examines the impact of characteristics such as age, gender, job title, and years of experience on the perception of product safety and consumer rights in the pharmacy sector. For example, there may be differences in perceptions between younger and more experienced professionals or between different roles in this sector.

By examining the relationships between these variables, the study aims to evaluate the effectiveness of current security practices and their impact on the protection of consumer rights in the pharmacy sector in Albania.

### 3.2. Empirical Data and Their Collection

#### 3.2.1. Study Design

This study employs a *cross-sectional survey design* to assess the perceptions and practices of pharmacy staff across Albania. This method is an appropriate approach to assess the current status of product safety practices in the sector and to identify the main factors affecting safety and consumer rights.

#### 3.2.2. Population and Sample Size

The target population includes all staff working in pharmacies throughout Albania. The target population includes pharmacists, pharmacy technicians, assistants and other staff involved in the administration and distribution of pharmaceutical products.

A *sample size of 200 participants* was selected for the study based on the ratio of approximately 86 pharmacists per 100,000 people in Albania, to provide sufficient statistical power and to represent different perspectives. Participants were selected by *random sampling* from various geographical regions in order to reduce selection bias and increase generalizability of the findings.

#### 3.2.3. Survey Questionnaire

This study uses an adapted questionnaire based on the Patient Safety Culture Questionnaire (PSCQ-4), which was translated into Albanian to ensure linguistic and cultural compatibility. The questionnaire consists of 26 questions and is designed in the following sections:

- 1) **Demographic Information** (5 questions): It covers age, gender, job title, place of work and years of experience.
- 2) **General Assessment of Security Perception** (3 questions): It examines the prioritization of security in the sector and the effectiveness of security protocols.
- 3) **Communication on Security Issues** (3 questions): It investigates the flow of information and the comfort of staff in discussing security concerns.





- 4) **Frequency of Reporting** (3 questions): It assesses how frequently security incidents are reported in the sector.
- 5) **Managerial Actions** (3 questions): It assesses the role of managers in promoting security.
- 6) **Organizational Learning** (3 questions): It focuses on continuous improvement in security practices.
- 7) **Teamwork** (3 questions): It examines cooperation and mutual support.
- 8) **Personnel and Working Conditions** (3 questions): It analyses staff competence and its impact on security.
- 9) **Impact on Consumer Rights** (3 questions): Evaluates the impact of security practices on sectoral consumer safety and transparency.

### 3.3. Data Collection

In this survey study, the data was collected using a dual-mode survey distribution strategy:

- 1) **Online Surveys:** Facilitated for participants with internet access.
- 2) **Physical Surveys:** Distributed to pharmacies with limited digital access or where this strategy was thought to motivate participation.

The data collection process was carried out between March 1 and May 1, 2024, and sufficient participation was achieved. Responses were collected from pharmacy staff across Albania, focusing on large cities, especially Tirana.

### 3.4. Data Analysis

The collected data was analyzed using SPSS 25 using the following statistical methods:

- **Descriptive Statistics:** Used to summarize demographic information and identify missing data.
- **Reliability Analysis (Cronbach's Alpha):** Measures the internal consistency of the survey. Cronbach's Alpha was found to be 0.912 (n=30) and 0.915 (n=200), indicating excellent reliability.
- **T-Test:** Compares means between two independent groups (e.g., perceptions of gender differences).
- **ANOVA:** Determines significant differences in key variables between three or more groups (e.g., job titles or years of experience).
- **Pearson Correlation Coefficient:** Evaluates the strength and direction of the relationship between variables. This coefficient ranges from +1 (strong positive relationship) to -1 (strong negative relationship).

### 3.5. Ethical Considerations

This study was conducted in accordance with strict ethical standards:

- **Voluntariness:** Participation is completely voluntary and participants can withdraw from the study at any time without any consequences.



- *Informed Consent*: Informed consent was obtained from participants by ensuring transparency about the purpose, procedures and potential risks of the study.
- *Data Confidentiality*: Confidentiality of data was meticulously maintained and findings were reported collectively to protect individual identities.
- *Ethical Approval*: Approval for the study was obtained from the relevant institutional ethics committee.

### 3.6. Limitations of the Study

Despite the efforts made to ensure a robust methodology, this study encountered some limitations:

- 1) **Participation Challenges**: Recruiting a sufficient number of participants required significant effort, as pharmacy staff were faced with time constraints and other pressing tasks.
- 2) **Translation Limitations**: In adapting the PSCQ-4 to Albanian, care was taken to preserve the original meaning and cultural relevance of the questions.

Addressing these limitations in a transparent manner strengthens the validity and reliability of the study results and contributes to a deeper understanding of product safety practices and consumer rights in Albanian pharmacies.

**Table-1: Enhanced Reliability of Survey Instrument**

Questionnaires	Cronbach's Alpha (n=30)	Cronbach's Alpha (n=200)	Number of Questions
Assessing product safety in Albanian pharmacies	0.912	0.915	26

The reliability coefficient above 0.9 indicates excellent internal consistency and confirms the suitability of this instrument for assessing safety practices and consumer rights.

## 4. Results

This section presents the analysis of data collected from a survey conducted with pharmacy staff in Albania. The aim is to assess product safety practices in the sector and their impact on consumer rights. The findings focus on the following topics, covering the objectives of the study:

- 1) Examining the perceptions of pharmacy staff on product safety practices.
- 2) Evaluating the frequency of reporting safety incidents.
- 3) Analyzing the impact of safety practices on consumer rights.
- 4) Exploring how demographic factors shape attitudes towards product safety and consumer rights.

Descriptive and inferential statistical analyses provide a comprehensive understanding of the factors affecting product safety and consumer rights protection in Albanian pharmacies.



#### 4.1. Demographics and Professional Characteristics

The sample size consisted of 200 participants representing a variety of demographic and professional profiles. Key findings are as follows:

##### 4.1.1. Age Distribution

Participants were relatively evenly distributed across age groups. The largest groups were those aged  $\leq 24$  and 36–45, representing 32.0% (64 people). Those aged 25–35 were represented at 20.5% (41 people), and those aged  $\geq 46$  at 14.5% (29 people).

##### 4.1.2. Gender

The sample was predominantly female; 82.0% (164 people) were female and 18.0% (36 people) were male. This gender distribution is consistent with the gender representation in the pharmacy profession in Albania.

##### 4.1.3. Educational and Professional Background

Most of the participants were pharmacy technicians, representing 60.0% (120 people). Pharmacists were represented by 22.0% (44 people) and technicians or assistants by 18.0% (36 people).

##### 4.1.4. Years of Professional Experience

A significant proportion of participants had limited professional experience. 32.0% (64 people) reported 2–3 years of experience, 27.0% (54 people) reported  $\leq 1$  year of experience. Participants with 4–7 years of experience were represented by 23.0% (46 people). Those with 8–10 years of experience and  $\geq 11$  years of experience were represented by 9.0% (18 people) each.

**Table-2: Summary Table of Demographics**

Variable	Frequency	Percentage (%)
Age $\leq 24$	64	32.0
Age 25–35	41	20.5
Age 36–45	64	32.0
Age $\geq 46$	29	14.5
Female	164	82.0
Male	36	18.0
Pharmacy Technicians/Owners	120	60.0
Pharmacists	44	22.0
Technicians/Assistants	36	18.0
$\leq 1$ year	54	27.0
2–3 years	64	32.0
4–7 years	46	23.0
8–10 years	18	9.0
$\geq 11$ years	18	9.0

## 4.2. Perceptions of Product Safety Practices

The analysis of perceptions regarding safety practices revealed the following:

### 1. Prioritization of Safety Over Efficiency:

- Mean = 3.5 (moderate-positive perception).
- Responses ranged from 1 (strong disagreement) to 5 (strong agreement), with a *standard deviation of 1.118*, indicating variability among respondents.

### 2. Effectiveness of Safety Procedures:

- Mean = 3.2, reflecting mixed perceptions of procedural effectiveness.
- The standard deviation of 1.061 suggests moderate variability.

### 3. Belief in Chance Avoidance of Serious Safety Issues:

- Mean = 3.4, with variability (SD = 1.033) indicating differing opinions on whether safety issues are preventable or occur by chance.

**Table-3: Summary Table of General Perceptions of Safety**

Aspect	Mean	SD
Pharmacy prioritizes safety over efficiency	3.5	1.118
Effectiveness of procedures in preventing safety incidents	3.2	1.061
Serious safety issues avoided by chance	3.4	1.033

## 4.3. Safety-Related Communication

Survey responses about communication revealed the following:

### 1. Informing About Safety Improvements:

- Mean = 3.4, indicating moderate satisfaction with communication practices.
- Variability (SD = 1.2) suggests differing experiences.

### 2. Comfort Questioning Safety Practices:

- Mean = 3.2, reflecting moderate comfort levels among staff.
- Variability (SD = 1.1) highlights mixed perceptions.

### 3. Encouragement to Raise Safety Concerns:

- Mean = 3.6, showing relatively positive perceptions.

**Table-4: Summary Table of Safety-Related Communication**

Aspect	Mean	SD
Regularly informed about safety changes	3.4	1.2
Comfortable questioning management's safety practices	3.2	1.1
Encouraged to speak up about safety issues	3.6	1.3

#### 4.4. Frequency of Event Reporting

##### Key Findings

- Reporting serious safety issues had the highest mean (3.8), reflecting proactive reporting behaviors.
- Reporting minor safety issues scored lower (3.4), indicating less frequent reporting of low-risk events.

**Table-5: Summary Table of Reporting Frequency**

Aspect	Mean	SD
Reporting identified product safety issues	3.6	1.2
Reporting minor safety issues	3.4	1.1
Reporting serious safety issues	3.8	1.3

#### 4.5. Demographic Influences on Perceptions

##### Age and Gender

- No significant differences were observed across age groups ( $p > 0.05$ ).
- Gender differences were significant ( $p = 0.043$ ), with males reporting slightly more positive perceptions of safety.

##### Job Roles and Experience

- Job role significantly influenced perceptions ( $p < 0.05$ ), with technicians/assistants showing higher scores.
- Experience levels also influenced perceptions, with participants having 8–10 years of experience reporting higher scores than those with  $\leq 1$  year.

#### 4.6. Correlation Between Product Safety Practices and Consumer Rights

##### Key Findings

A Pearson correlation analysis reveals a moderate positive relationship between perceptions of product safety practices in the industry and protection of consumer rights ( $r = 0.323$ ,  $p <$

0.01). This positive relationship indicates that improved perceptions of safety practices are associated with increased levels of protection of consumer rights.

**Table-6: Summary Table of Correlation**

Variable	Correlation Coefficient (r)	p-value
Product Safety Practices ↔ Consumer Rights Protection	0.323	0.000

#### 4.7. Hypotheses Testing

##### Hypothesis 1:

- Significant differences in perceptions were observed across gender and job roles ( $p < 0.05$ ), supporting the *alternative hypothesis* for these variables.
- No significant differences were observed across age groups, leading to the *acceptance of the null hypothesis* for age.

##### Hypothesis 2:

- A significant positive correlation between safety practices and consumer rights ( $p < 0.01$ ) supports the *alternative hypothesis*, indicating that effective safety practices enhance consumer rights protection.

## 5. Conclusions

This study comprehensively analyzed product safety practices in Albanian pharmacies and their impact on consumer rights. The findings of the study reveal that pharmacy staff generally have positive perceptions of safety practices, communication and consumer protection. However, significant differences between responses highlight the different experiences and perspectives among staff members, influenced by organizational dynamics, demographic factors and individual roles.

### 5.1. Key Findings

#### 1. General Perceptions of Safety

Participants exhibited moderately positive perceptions of safety such as the priority of safety over efficiency in the sector and the effectiveness of safety procedures. However, differences between responses indicate that there is room for improvement, especially in ensuring that security protocols are consistently followed.

#### 2. Communication and Reporting

Although communication and incident reporting regarding safety were evaluated positively, there were deficiencies in creating an environment that encouraged personnel to raise safety concerns. While proactive reporting was common for serious safety issues, minor issues were reported less frequently.





### 3. Leadership and Organizational Learning

Support for safety initiatives by managers and supervisors was perceived positively, but concerns were expressed about efficiency overtaking security in busy work environments. Organizational learning practices were seen as important, and a moderately positive perception was observed regarding proactive efforts to increase safety and learning from past mistakes.

### 4. Teamwork and Staffing

While teamwork was evaluated positively, there were differences in the level of cooperation and mutual support among personnel. Personnel management practices raise concerns about workload management and temporary staff adequacy, and indicate that workforce planning needs to be improved.

### 5. Consumer Rights Protection

There is a strong consensus in the industry about the critical role of product safety practices in protecting consumer rights. Respondents emphasize the importance of transparent safety measures and prioritizing consumer safety in all operations. However, perceptions of consumer awareness of safety measures are mixed, indicating that communication with consumers needs to be improved.

#### 5.2. Hypotheses Testing

1. **Hypothesis 1:** The significant differences in safety perceptions observed across demographic factors such as gender and job role confirm the diversity in experiences and attitudes. However, there is no significant difference across age groups.
2. **Hypothesis 2:** Correlation analysis confirms that there is a statistically significant relationship between perceptions of safety practices and protection of consumer rights. This finding clearly emphasizes the importance of communication, reporting and managerial support in promoting safety.

#### 5.3. Comparison with Global Context

The study findings are consistent with international research results. For example, Meyers (2020) reveals the diversity in perceptions of safety in relation to organizational culture. Similarly, Ilardo & Speciale (2020) emphasizes the critical role of communication in ensuring safety. In this study, concerns about balancing safety and efficiency also emerged prominently. Therefore, proactive organizational learning and the connection between product safety and consumer rights in the sector stand out as consistent themes throughout the research.

In conclusion, this study highlights the strengths of the Albanian pharmacy sector, especially in terms of staff awareness and proactive safety measures, while revealing that there is a serious need for positive steps in areas such as communication, personnel management and leadership practices. The findings in this study contribute to the establishment of a more reliable and effective healthcare system by providing a basis for improving safety practices and protecting consumer rights.

## 6. Recommendations

Based on the research findings, the following recommendations are made to improve product safety practices and strengthen consumer rights in Albanian pharmacies:

### 6.1. Training and Education Programs

Comprehensive training should be provided to pharmacy staff on communication strategies for safety concerns, best practices for incident reporting and resolution, and legal and ethical protection of consumer rights.

### 6.2. Standardized Reporting Systems

Clear systems should be developed for rapid reporting of safety incidents and structured investigations, and feedback loops for reported incidents and corrective actions.

### 6.3. Leadership Commitment

Leaders should be encouraged to prioritize safety, recognize compliance with safety protocols, encourage open communication about safety concerns, and develop a shared safety culture.

### 6.4. Continuous Improvement

Current safety practices should be regularly evaluated and improved, lessons learned from incidents and changes implemented, and organizational learning integrated into workflows.

### 6.5. Strengthening Communication

Internal communication should be improved through security-focused team meetings, anonymous feedback options, and regular security updates through newsletters.

### 6.6. Staff Optimization

A balanced workload and prevention of fatigue should be ensured by monitoring work schedules and adjusting required staff, and assessing the security impact of temporary staff.

### 6.7. Consumer Education

Empowering consumers through clear product labeling, informative materials on security measures and reporting, and awareness campaigns that include consumer rights.

### 6.8. Regulatory Compliance

Strengthening adherence to standards through regular audits and inspections, proactive resolution of non-compliance gaps, and updates on regulatory changes.

### 6.9. Collaborative Partnerships

Encourage and strengthen cooperation among institutions and associations to share best practices, advocate for consumer rights and safety policies, and develop common solutions to safety issues.

### 6.10. Monitoring and Evaluation

Continuous monitoring and evaluation of safety practices in the sector should be ensured through staff surveys on safety perceptions, protocol and compliance audits, and consumer feedback systems.

By implementing the above recommendations in the sector, Albanian pharmacies can improve safety practices, protect consumer rights, and thus build greater trust in the sector overall.

## **7. Implications of the Study**

### **7.1. Implications for Literature**

This study contributes to the growing body of knowledge on safety practices in the pharmacy sector, particularly in the Albanian context. While universal challenges such as balancing efficiency and safety and the need for effective communication are highlighted, context-specific issues such as staff constraints and deficiencies in regulatory practices are also highlighted.

### **7.2. Implications for Companies**

The findings of this study provide actionable insights for pharmacies to improve corporate performance. Implementing the training, communication and reporting systems listed in the recommendations section above can improve safety practices in the sector and increase consumer confidence. Prioritizing safety over efficiency and creating a culture of continuous improvement will increase both staff satisfaction and consumer loyalty.

### **7.3. Implications for Society**

Improved safety practices will directly benefit the pharmacy sector by providing consumers with access to safe and reliable medicines. Educating consumers about their rights and safety measures will empower them to make informed decisions and create stronger collaboration between pharmacies and the communities they serve.

## References

- AAPC (Albanian Association of Pharmaceutical Companies). (2024). *About us*. Albanian Association of Pharmaceutical Companies (SHPF). <https://shpf.al/about-us/>
- Almuzaini, T., Choonara, I., & Sammons, H. (2013). Substandard and counterfeit medicines: a systematic review of the literature. *BMJ Open*, 3(8), e002923. <https://doi.org/10.1136/bmjopen-2013-002923>
- Atkinson, J. (2022). Advances in pharmacy practice: A look towards the future. *Pharmacy*, 10(5), 125. <https://doi.org/10.3390/pharmacy10050125>
- Bate, A., Lindquist, M., Edwards, I. R., Olsson, S., Orre, R., Lansner, A., & De Freitas, R. M. (1998). A Bayesian neural network method for adverse drug reaction signal generation. *European Journal of Clinical Pharmacology*, 54(4), 315–321. <https://doi.org/10.1007/s002280050466>
- Chen, M., Shah, V. P., Crommelin, D. J., Shargel, L., Bashaw, D., Bhatti, M., Blume, H., Dressman, J., Ducharme, M., Fackler, P., Hyslop, T., Lutter, L., Morais, J., Ormsby, E., Thomas, S., Tsang, Y. C., Velagapudi, R., & Yu, L. X. (2011). Harmonization of regulatory approaches for evaluating therapeutic equivalence and interchangeability of multisource drug products: Workshop summary report. *The AAPS Journal*, 13(4), 556–564. <https://doi.org/10.1208/s12248-011-9294-5>
- Desselle, S. P., Hoh, R., Rossing, C., Holmes, E. R., Gill, A., & Zamora, L. (2018). The caring behaviours of Danish pharmacoconomists: Insight for pharmacy technician practice around the world. *International Journal of Pharmacy Practice*, 27(2), 157–165. <https://doi.org/10.1111/ijpp.12478>
- Hoxha, M., Spahiu, E., Spahiu, M., & Zappacosta, B. (2024). Reporting of adverse drug reactions by dentists and dental patients in Albania. *International Dental Journal*, 74(2), 242-245. <https://doi.org/10.1016/j.identj.2023.08.005>
- Hoxha, M., Zappacosta, B., & Franco, M. (2024). An overview of Albanian pharmacovigilance system and its harmonization with the European pharmacovigilance legislation, *Biomedicine & Prevention Issues*, 1(249), 1-8. <https://doi.org/10.19252/00000000F9>
- Icardo, M. L., & Speciale, A. (2020). The community pharmacist: Perceived barriers and patient-centered care communication. *International Journal of Environmental Research and Public Health/International Journal of Environmental Research and Public Health*, 17(2), 536. <https://doi.org/10.3390/ijerph17020536>
- Joanne, P. (2021). *EMA pharmacovigilance system manual. Version 1.3*. European Medicines Agency. [https://www.ema.europa.eu/system/files/documents/other/ema\\_pharmacovigilance\\_system\\_manual\\_march21-en.pdf](https://www.ema.europa.eu/system/files/documents/other/ema_pharmacovigilance_system_manual_march21-en.pdf)
- Marjo, B. (2021, February 7). Siguria e Barnave, Covid-19 rriti kërkesën, ndërsa kontrollet për sigurinë u zeruan. *A2 CNN*. <https://a2news.com/siguria-e-barnave-covid-19-rriti-kerkesen-ndersa-kontrollet-per-sigurine-u-zeruan>

- Meyers, R. (2020). A wish list for drug development in pediatrics. *Journal of Pharmaceutical Sciences*, 109(2), 939–943. <https://doi.org/10.1016/j.xphs.2019.10.029>
- Ministry of Health and Social Protection of Albania. (2023). *Annual report on health sector developments*. Ministry of Health and Social Protection of Albania. <https://shendetesia.gov.al/https-shendetesia-gov-al-tabelat-e-raportimit-per-intervalet-kohore-3-muaj-9-muaj-dhe-vjetore-si-dhe-relacionet-perkatese/>
- Ofori-Parku, S. S., & Park, S. E. (2022). I (Don't) want to consume counterfeit medicines: exploratory study on the antecedents of consumer attitudes toward counterfeit medicines. *BMC Public Health*, 22(1), 1094. <https://doi.org/10.1186/s12889-022-13529-7>
- Olsson, S. (1998). The role of the WHO programme on international drug monitoring in coordinating worldwide drug safety efforts. *Drug Safety*, 19(1), 1–10. <https://doi.org/10.2165/00002018-199819010-00001>
- Pathak, R., Gaur, V., Sankrityayan, H., & Gogtay, J. (2023). Tackling counterfeit drugs: the challenges and possibilities. *Pharmaceutical Medicine*, 37(4), 281–290. <https://doi.org/10.1007/s40290-023-00468-w>
- Roshi, D., Tresa, E., Lafranconi, A., Burazeri, G., Czabanowska, K., & Brand, H. (2023). Pharmaceutical policies in post-communist Albania: Progress and challenges toward European Union membership. *South Eastern European Journal of Public Health*, 16, 4604. <https://doi.org/10.70135/seejph.vi.192>
- Sami, S. A., Marma, K. K. S., Chakraborty, A., Singha, T., Rakib, A., Uddin, G., Hossain, M. K., & Uddin, S. M. N. (2021). A comprehensive review on global contributions and recognition of pharmacy professionals amidst COVID-19 pandemic: moving from present to future. *Future Journal of Pharmaceutical Sciences*, 7(1), 119. <https://doi.org/10.1186/s43094-021-00273-9>
- Saric, J., Kiefer, S., Peshkatari, A., & Wyss, K. (2021). Assessing the quality of care at primary health care level in two pilot regions of Albania. *Frontiers in Public Health*, 9, 747689. <https://doi.org/10.3389/fpubh.2021.747689>
- Shkreli, R., Dhamo, K., Haloçi, E., & Tabaku, A. (2023). Knowledge, attitude and practice towards pharmacovigilance and reporting of adverse drug reactions among health care professionals in Albania: A cross-sectional study. *Pakistan Journal of Pharmaceutical Sciences*, 36(3), 713–721. <https://doi.org/10.36721/PJPS.2023.36.3.REG.713-721.1>
- WHO. (2018). *Substandard and falsified medical products*. The World Health Organization, Geneva. <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>
- WHO. (2019). *Framework for strengthening consumer rights in the pharmaceutical sector*. The World Health Organization, Geneva.
- WHO. (2023). *Strengthening collaboration for quality of health care*, The World Health Organization (WHO), Geneva. <https://www.who.int/spain/events/item/2023/04/03/default-calendar/strengthening->



[collaboration-for-quality-of-health-care--albanian-high-level-technical-delegation-visits-health-institutions-and-who-office-on-quality-of-care-and-patient-safety-in-greece](#)

World Bank. (2020). *Study for the health sector of Albania*. Human Development Sector Unit, South East European Countries Unit, Europe and Central Asia Region. World Bank. <https://documents.worldbank.org/en/publication/documents-reports/documentdetail/658891468203362249/albania-health-sector-note>

Wu, W., Zhang, A., Van Klinken, R. D., Schrobback, P., & Muller, J. M. (2021). Consumer trust in food and the food system: A critical review. *Foods*, 10(10), 2490. <https://doi.org/10.3390/foods10102490>

