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Off-label prescribing in the pediatric population: perceptions and practices of community pharmacists in Kosovo – a cross-sectional survey

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Off-label drug prescribing in pediatric populations is a common practice worldwide due to the limited availability of approved formulations and clinical data for children. While often necessary, it raises concerns regarding safety, efficacy, and ethical considerations. Pharmacists play a key role in ensuring the safe use of off-label drugs; however, their perspectives in low-resource settings like Kosovo remain under-investigated. A cross-sectional, questionnaire-based survey was conducted among 296 community pharmacists across Kosovo between December 2024 and January 2025. The 27-item structured survey collected demographic data and assessed pharmacists' familiarity, practices, and perspectives on pediatric off-label use. Data were analyzed using IBM SPSS 22.0. Of the pharmacists surveyed, 49% reported moderate familiarity with pediatric off-label use, and 79% had not received formal training. Nearly all participants (99%) had encountered off-label prescriptions, most commonly involving anti-infectives and respiratory medications. Although 98% acknowledged that off-label use is sometimes necessary, many expressed concerns about safety and effectiveness. Only 21% had observed adverse drug reactions, while 96% reported no treatment failures. Communication with prescribers was rated as good by 49% of respondents, though 71% emphasized the need for stronger interdisciplinary collaboration. This study provides the first national insight into community pharmacists' perspectives on pediatric off-label prescribing in Kosovo. The findings highlight the urgent need for targeted pharmacist education, the development of standardized national guidelines, and enhanced collaboration between pharmacists and prescribers to improve medication safety in pediatric patients.

1. Introduction

Off-label prescribing-the use of medications outside their approved indications, dosages, age groups, or routes of administration-is a common and often necessary practice in pediatric medicine. This practice largely arises from the limited number of clinical trials involving children and the regulatory challenges in obtaining pediatric-specific drug approvals, making off-label use the most feasible therapeutic option in many cases (Gore et al. 2017; Petkova et al. 2023; Allen et al. 2018). The pharmaceutical industry has historically focused on adult populations due to the ethical, methodological, and financial barriers associated with conducting pediatric trials and the complexities of developing age-appropriate formulations (Domingues et al. 2023; Rose 2019). Consequently, many pediatric treatments rely on evidence extrapolated from adult studies, leading to frequent off-label prescribing (Kimland and Odlind 2012; Yuan et al. 2024).

Multiple studies across Europe and beyond have highlighted the widespread nature of off-label prescribing in children. A recent meta-analysis found that more than half of hospitalized pediatric patients receive at least one off-label or unlicensed medication, with even higher rates observed in neonatal intensive care units (Yuan et al. 2024). Evidence further suggests that such use is associated with an increased risk of adverse drug reactions, influenced by developmental differences in pharmacokinetics and pharmacodynamics as well as institutional and clinical factors (Rashed et al. 2012; Belayneh et al. 2022). In community settings, off-label prescribing also remains common, particularly for respiratory, neurological, and infectious diseases (Schaffer et al. 2022).

Pharmacists play a critical role in promoting medication safety, particularly in pediatric care. Their responsibilities include reviewing prescriptions, validating dosages, identifying potential drug-related problems, and counseling both prescribers and caregivers (Keuler et al. 2021). These functions become even more essential in off-label scenarios, where dosing guidelines and safety data are often limited (Kimland and Odlind 2012). The ability of pharmacists to intervene effectively depends on their clinical competence, access to reliable pediatric-specific information, and awareness of the legal and ethical aspects of off-label use (Eiland et al. 2018).

Across Europe, there is growing recognition of pharmacists as key stakeholders in addressing the complexities of off-label prescribing. Community pharmacists are increasingly involved in evaluating and managing such prescriptions, underscoring their expanding role in promoting rational medicine use (Kalaivani et al. 2017; Jîtcă et al. 2024). However, the extent of their involvement varies widely between countries, shaped by factors such as the maturity of healthcare systems, regulatory clarity, and access to continuing professional development opportunities in pediatric pharmacotherapy (Balan et al. 2015; Gelayee et al. 2018).

In countries like Kosovo, where the pharmaceutical regulatory infrastructure is still evolving, pharmacists may encounter additional challenges, including inconsistent prescribing practices, limited availability of pediatric formulations, and the absence of formal guidance on off-label use. A recent study conducted in a Neonatal Intensive Care Unit in Kosovo highlighted the frequent use of off-label and unlicensed medications, underscoring the relevance of this issue in local clinical practice (Koshi et al. 2023).

However, to date, no published research has explored the perspectives, practices, and challenges faced by community pharmacists in Kosovo regarding pediatric off-label prescribing.

This study provides the first national insight into the knowledge, attitudes, and practices of community pharmacists in Kosovo regarding pediatric off-label drug use. By addressing this previously unexplored area, the research fills a critical gap in understanding the pharmacist's role in pediatric medication safety within a developing healthcare system. The findings aim to inform targeted pharmacist education, strengthen inter-professional collaboration, and support the development of standardized national guidelines to improve medication safety in pediatric patients.

2. Investigations and results

2.1. Study population and response rate

Questionnaires were distributed to a randomly selected sample of community pharmacies across Kosovo. After the two-month data collection period, a total of 296 completed questionnaires were returned, yielding a response rate of 59%. Fifty-four percent of respondents were between the ages of 25 and 34, and the majority were female (n = 237, 80%). Additionally, 47% (n = 140) had less than 6 years of job experience (Table 1).

Table 1: Characteristics of community pharmacists

Characteristics	n	Frequency (%)
1. Gender		
Male	59	19.93
Female	237	80
2. Age		
18-24	36	12.16
25-34	161	54.39
35-44	92	31.08
45-54	6	2.02
>55	1	0.34
3. Experience (years)		
0-5	140	47.29
6-10	117	39.53
11-15	27	9.12
16-20	10	3.38
21-25	2	0.67

2.2. Awareness, attitudes, and perceived challenges

The majority of pharmacists (49%) reported moderate familiarity with the concept of pediatric off-label prescribing, though several indicated gaps in understanding (Q4). Our data suggest that the majority of respondents either support or are neutral towards pediatric off-label prescribing, with a negligible proportion holding a negative view (Q5). Nearly half of respondents (47%) expressed concern about both efficacy and safety in pediatric off-label prescribing, while 38% were primarily concerned with safety alone. Only 15% cited efficacy issues exclusively (Q6). In terms of prevalence, off-label prescribing was identified as a common practice: 27% of respondents encountered it often while 46% occasionally (Q7). When assessing its impact on pediatric health outcomes, 74% of pharmacists believed off-label use had a positive effect (Q8). The main reason cited for off-label prescribing in children included unapproved indications (47%) while the least common reason was modification in the route of administration (3%) (Q9) (Table 2).

2.3. Practical experience and confidence

Almost all respondents (99%) indicated that they had encountered pediatric off-label prescriptions in their professional practice, highlighting the widespread nature of such prescribing in community pharmacy settings (Q10). Most respondents (33%) viewed collaboration with doctors as the key aspect in managing off-label prescribing, followed by the inclusion of families in decision-making (23%). Fewer participants emphasized dose regulation or regulatory compliance, highlighting that communication and teamwork are seen as the most critical elements in safely managing pediatric off-label use (Q11). Pharmacists' confidence in identifying off-label pediatric prescriptions varied, with the majority of them (40%) feeling moderately confident (Q12). Similar trends were observed in their confidence levels when counseling parents or caregivers about such prescriptions: 46% reported moderate confidence (Q13). These findings indicate a generally strong but not uniform level of professional assurance in handling off-label pediatric prescribing. Regarding the frequency of pediatric prescriptions in daily practice, responses were nearly evenly split (Q14). In the open-ended

Table 2: Awareness, attitudes, and perceived challenges regarding pediatric off-label prescribing (n = 296)

Question	Response option	Number (n)	Frequency (%)
4. How familiar are you with the concept of pediatric off-label prescribing?	A lot	75	25.3
	Average	144	48.6
	A little	75	25.3
	Not at all	2	0.7
5. What is your general attitude towards pediatric off-label prescribing?	Positive	141	47.6
	Neutral	150	50.7
	Negative	3	1.0
6. What are the main concerns regarding the off-label use of drugs in children?	Efficacy issues	43	14.5
	Safety issues	113	38.2
	Both efficacy and safety issues	140	47.3
7. Is pediatric off-label prescribing a common practice in your community?	Frequently	81	27.4
	Occasionally	135	45.6
	Rarely	76	25.7
	Never	4	1.4
8. What is the overall impact of pediatric off-label prescribing on children's health outcomes?	Positively affects	218	73.6
	No significant impact	61	20.6
	Negatively affects	16	5.4
9. Why are drugs prescribed off-label to children?	Indication not approved	138	46.6
	Age restrictions	95	32.1
	Dosage adjustments	55	18.6
	Route of administration	8	2.7

Table 3: Practical experience and confidence regarding pediatric off-label prescribing (n = 296)

Question	Response option	Number (n)	Frequency (%)
10. Have you encountered pediatric off-label prescribing in your practice?	Yes	292	98.6
	No	4	1.4
11. What aspects are important in managing off-label prescribing?	Dose regulation and monitoring	4	1.4
	Collaboration and communication with doctors	98	33.1
	Inclusion of patients and family in decision making	18	6.1
	Dose regulation, monitoring and communication with doctors	17	5.7
	Dose regulation, communication, inclusion of family	23	7.8
	Communication with doctors and inclusion of family	69	23.3
	Communication with doctors and compliance with regulations	22	7.4

12. Confidence in identifying off-label drug use?	A lot	108	36.5
	Moderate	120	40.5
	A little	68	23.0
	None	0	0
13. Confidence in counseling patients/parents?	A lot	116	39.2
	Moderate	135	45.6
	A little	23	7.8
	Not at all	22	7.4
14. Estimated % of pediatric off-label prescriptions?	≥ 25%	141	47.6
	< 25%	155	52.4
15. Most common therapeutic classes prescribed off-label?	Anti-infectives	150	50.7
	Medicines for acute respiratory diseases	120	40.5
	Medicines used in psychiatric field	70	23.6
16. Have you ever refused to dispense off-label drugs for children?	Yes	6	2.0
	No	284	95.9
	Have not encountered off-label use	6	2.0

question, pharmacists were asked to provide examples of drugs they had dispensed off-label to children. The most frequently mentioned therapeutic class was antibiotics, followed by antiasthmatics and analgesics/antipyretics. Fewer respondents also cited gastrointestinal agents and antihistamines (Q15).

Finally, when asked whether they had encountered any treatment failures in children following off-label use, the majority (96%) reported no such experiences. While this could reflect a low incidence of adverse outcomes, it may also point to limited opportunities for pharmacists to monitor long-term therapeutic results in pediatric patients (Q16) (Table 3).

2.4. Communication, collaboration, and ethical considerations

Communication between pharmacists and doctors regarding pediatric off-label prescribing was generally rated as good by 49% of respondents (Q17). A significant majority (71%) agreed that collaboration among healthcare professionals should be enhanced, underscoring the importance of interdisciplinary communication (Q18). Ethical considerations were addressed by 76% of respondents to a large extent, suggesting most pharmacists are attentive to these issues, though practices vary (Q19). Regarding responsibility for informing parents about off-label drug use, 61% of respondents felt it lies with the prescribing doctor (Q20). In terms of safety, the majority of respondents (55%) believed off-label use slightly increases the likelihood of side effects, while 6% thought it greatly increases the risk (Q21).

Only 21% of respondents encountered side effects from off-label use, while 77% did not report such cases (Q22) (Table 4).

Table 4: Communication, collaboration and ethical considerations regarding pediatric off-label prescribing

Question	Response option	Number (n)	Frequency (%)
17. How would you rate the collaboration between pharmacists and physicians?	Very good	79	26.7
	Good	145	49.0
	Poor	67	22.6
	Very poor	5	1.7
18. Should off-label drug use in children be communicated clearly among healthcare professionals?	Agree	210	70.9
	Neutral	86	29.1
	Do not agree	0	0.0
19. Should parents/caregivers be informed when a drug is used off-label in a child?	A lot	224	75.7
	Average	69	23.3
	A little	3	1.0
	Not at all	0	0
20. Who should inform parents/caregivers about off-label drug use?	Physician	180	60.8
	Pharmacist	92	31.1
	Both	24	8.1
	No need to inform	0	0
21. Does off-label use increase the likelihood of adverse reactions in children?	Yes, major increase	16	5.4
	Yes, some increase	164	55.4
	No increase	116	39.2
22. Have you reported any adverse effects related to pediatric off-label use?	Yes	63	21.3
	No	227	76.7
	Have not encountered off-label use	6	2.0

2.5. Training, regulatory awareness, and suggested improvements

The majority of respondents indicated utilizing multiple sources to verify the appropriateness of pediatric off-label prescribing (Q23). Regarding formal training, most of the respondents (79%) reported having no formal education on pediatric pharmacotherapy and off-label prescriptions (Q24), highlighting a notable gap in formal education on this crucial topic. Regarding the awareness of regulatory guidelines concerning off-label pediatric prescriptions, the majority of respondents were very aware or moderately aware (Q25). In terms of improving the management of off-label pediatric prescriptions, a significant proportion of respondents suggested a combination of critical strategies such as clinical trials, interdisciplinary collaboration, and standardized protocols, as a potential improvement (Q26). Regarding the legal status of off-label prescribing, 59% of respondents considered it legal, indicating differing perspectives on its legality (Q27) (Table 5).

Table 5: Training, regulatory awareness, and suggested improvements regarding pediatric off-label prescribing

Question	Response option	Number (n)	Frequency (%)
23. What sources of information do you rely on regarding off-label pediatric prescribing?	Clinical guidelines and protocols	22	7.4
	Published clinical studies	33	11.1
	SPC (Summary of Product Characteristics)	50	16.9
	Combination of SPC, studies, and guidelines	191	64.5
24. Have you received formal training on off-label drug use in pediatrics?	No	235	79.4
	Yes, limited level	44	14.9
	Yes, moderate level	13	4.4
	Yes, high level	4	1.3
25. How aware are you of national/institutional regulations on pediatric off-label use?	Very aware	130	43.9
	Moderately aware	123	41.6
	A little aware	42	14.2
	Not aware	1	0.3
26. What improvements do you suggest for safer pediatric off-label prescribing?	Clinical trials	25	8.4
	Standardized protocols	30	10.1
	Pharmacovigilance systems	5	1.7
	Interdisciplinary collaboration	25	8.4
	Continuous professional education	5	1.7
	Patient education	4	1.4
	Combination of trials, protocols, collaboration	202	68.2
27. What is your perception of the legal status of off-label use in pediatrics?	Legal but not accepted	16	5.4
	Illegal but generally accepted	105	35.5
	Legal and accepted	175	59.1
	Illegal and unaccepted	0	0

3. Discussion

This research offers important perspectives on the knowledge, perceptions, and attitudes of community pharmacists in Kosovo regarding off-label prescribing in pediatric care. With a relatively high response rate of 59%, the findings reveal both promising trends and critical gaps in the management of pediatric off-label prescribing within the primary care setting.

A key observation is that while most pharmacists reported at least moderate familiarity with the concept of pediatric off-label prescribing, significant knowledge gaps remain. Nearly half of the respondents described their familiarity as moderate, suggesting a foundational awareness. However, the lack of formal training-reported by 79% of participants-highlights a critical shortfall in professional education. These findings align with Balan et al. (2015), who observed widespread off-label prescribing among healthcare professionals despite inadequate knowledge, and are further reinforced by the Albanian study by Noga et al. (2024), which reported that although 72% of community pharmacists had heard of off-label prescribing, only 40% felt confident identifying such prescriptions. Most relied on personal experience and peer communication rather than structured educational programs.

Pharmacists in our study generally held positive or neutral attitudes toward pediatric off-label prescribing, with 98% acknowledging its necessity-primarily due to the lack of child-specific drug formulations. However, safety and efficacy remain key concerns, with nearly half of participants citing both as significant issues. These concerns mirror the findings of Rosenfeld et al. (2018), who emphasized the importance of interdisciplinary collaboration in pediatric medication safety, and Stewart et al. (2007), who found that safety concerns were the primary barrier to pharmacist acceptance of off-label prescribing. Similarly, Noga et al. (2024) reported that while Albanian pharmacists supported pediatric off-label prescribing, they voiced apprehensions regarding adverse effects and the absence of clear regulatory guidance.

In our study, 27% of pharmacists reported encountering pediatric off-label prescriptions often and 46% occasionally. This reflects similar patterns reported by Jîtcă et al. (2024) in Romania, where community pharmacists frequently dealt with off-label prescribing for respiratory and anti-infective medications. Noga et al. (2024) reported that Albanian pharmacists most frequently encountered off-label prescriptions involving antibiotics and respiratory medications. These findings are consistent with those observed in other international contexts. For example, a study conducted in Shanghai, China, found that 88% of pharmacists had dispensed off-label medications, often due to the unavailability of suitable pediatric formulations (Mei et al. 2019). In the open-ended responses of our survey, pharmacists most frequently mentioned antibiotics, followed by antiasthmatics and analgesics/antipyretics as examples of off-label prescribing in children. These findings support the survey data and are consistent with reports from other countries where anti-infectives and respiratory drugs are commonly prescribed off-label in pediatric populations (Jîtcă et al. 2024; Mei et al. 2019; Noga et al. 2024). The predominance of antibiotics may reflect both the high burden of infectious diseases in children and the limited availability of pediatric formulations, highlighting the need for clear pediatric dosing guidelines and more age-appropriate medicines.

Building on these observations, although 98% of Kosovar pharmacists had encountered pediatric off-label prescribing, only 8% reported implementing a comprehensive management strategy that included dose adjustment, therapeutic monitoring, interdisciplinary communication, and caregiver engagement. Stewart et al. (2007) similarly found that while pharmacists often engaged in off-label prescribing, communication with prescribers was inconsistent. In the Albanian context, Noga et al. (2024) reported variability in how pharmacists managed off-label prescriptions, with only a minority actively involved in verifying prescriptions or counseling caregivers. These findings point to a need for structured protocols and professional training to enhance pharmacists' active role in patient safety.

These observations underscore that while pharmacists frequently encounter off-label prescriptions, effective management also depends on consistent interdisciplinary communication with prescribers to ensure patient safety.

Communication between pharmacists and prescribers is another area requiring improvement. While 49% of Kosovar pharmacists rated doctor communication as good, 71% believed interdisciplinary collaboration needs enhancement, and only 33% reported actively communicating about pediatric off-label prescribing cases. This aligns with Noga et al. (2024), who found that only 65% of Albanian pharmacists would verify off-label prescriptions with doctors. Both studies underscore that while communication is valued, it is not yet routine practice. Similar concerns are highlighted by Rosenfeld et al. (2018), who advocate for more active pharmacist engagement in collaborative decision-making in pediatric care.

In terms of clinical outcomes, 21% of pharmacists in Kosovo reported having observed side effects from pediatric off-label prescribing, while 96% reported no treatment failures. These findings suggest that off-label prescribing may be relatively safe, although the lack of formal follow-up systems could also contribute to underreporting. The findings of Lee et al. (2023) corroborate concerns regarding off-label prescribing in pediatric intensive care units, reporting an increased incidence of severe adverse drug reactions associated with such practices. In contrast, Noga et al. (2024) documented comparatively lower adverse event rates in Albania and emphasized that pharmacists who engaged in active prescription verification with prescribers achieved more favorable outcomes. These observations highlight the essential role of vigilant prescription review and monitoring strategies in mitigating risks and improving the safety of pediatric pharmacotherapy.

Participants in our study proposed several strategies to improve the management of pediatric off-label prescribing, including conducting pediatric clinical trials, enhancing inter-professional collaboration, and establishing standardized prescribing protocols. These recommendations align with international guidance, including the American Academy of Pediatrics (Committee on Drugs 2014), and resonate with the findings of Noga et al. (2021), who emphasized the importance of targeted pharmacist education and access to evidence-based decision-support tools. Additionally, Jîtcă et al. (2024) and Stewart et al. (2007) highlighted the need for improved surveillance systems and indication-specific prescribing guidelines to ensure patient safety. Implementing these measures should enhance pharmacists' competence and confidence in managing pediatric off-label prescribing, ultimately improving care quality and outcomes.

To our knowledge, this is the first study to comprehensively assess community pharmacists' knowledge, attitudes, and practices regarding pediatric off-label prescribing in Kosovo. Although the study is based on self-reported data and limited to a cross-sectional design-which restricts causal interpretation and may introduce recall or social desirability bias-it nonetheless provides unique and valuable insights into an underexplored area of pharmacy practice. While subgroup analyses could offer additional nuance, the descriptive findings highlight critical gaps in pharmacist training and practice, guiding future research and interventions to enhance pediatric medication safety.

In conclusion, this first community-pharmacist study in Kosovo demonstrates that, although nearly all pharmacists accept the role of pediatric off-label prescribing, critical deficiencies threaten patient safety and care quality. With the majority of respondents lacking formal pediatric training, under half confident in legal status or collaborative processes related to off-label prescribing, and virtually no systematic follow-up of therapeutic outcomes, immediate action is required. Establishing comprehensive educational initiatives in pediatric pharmacotherapy, clear national protocols and regulatory guidance, and building robust pharmacist–prescriber communication and monitoring systems are essential next steps to safeguard Kosovo's youngest patients.

4. Experimental

4.1. Study design

A descriptive, cross-sectional survey was conducted among male and female community pharmacists in Kosovo over a two-month period, from 1 December 2024 to 31 January 2025, to assess their knowledge, attitudes, and practices regarding pediatric off-label prescribing.

The sample size was determined using the Raosoft online calculator (2004 version), accessed on August 10, 2021, via http://www.raosoft.com/samplesize.html (Raosoft Inc. Sample Size Calculator 2004). The parameters used were a 95% confidence level, 50% response distribution, and a margin of error of ±5%, yielding an estimated sample size of 270. Ultimately, 296 pharmacists participated in the study.

The questionnaire was developed by adapting relevant items from previously validated surveys and published research (Stewart et al. 2007; Jîtcă et al. 2024; Balan et al. 2019; Mei et al. 2019; Noga et al. 2024). The questionnaire consisted of 27 items divided into five sections:

1. General information of participants;
2. Awareness, attitudes, and perceived challenges regarding pediatric off-label prescribing;
3. Practical experience and confidence regarding pediatric off-label prescribing;
4. Communication, collaboration, and ethical considerations regarding pediatric off-label prescribing;
5. Training, regulatory awareness, and suggested improvements regarding pediatric off-label prescribing.

Of these, 26 items used pre-formulated response options (closed-ended), while 1 was open-ended (*"Please specify an example of a drug you have dispensed off-label to children"*). The initial draft of the questionnaire was reviewed by faculty experts to ensure clarity and appropriateness. Prior to the full study, it was pilot-tested with ten community pharmacists to assess comprehensibility and feasibility. Minor adjustments were made based on their feedback, and pilot responses were excluded from the final analysis.

The first page of the survey explained the purpose of the study and included a consent statement.

The printed surveys were distributed in person by a member of the research team, who explained the study purpose and remained available for clarification, but did not influence responses. All questionnaires were self-administered, completed anonymously, and returned directly to the researcher in sealed envelopes.

4.2. Data collection and analysis

Statistical analyses were conducted using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp., Armonk, NY, USA). Continuous variables (e.g., age) were summarized as mean±standard deviation (SD), median, and range. Categorical variables, including gender, professional level, geographic region, years of experience, and responses related to awareness, experiences, and recommendations on pediatric off-label drug use, were described using descriptive statistics (frequencies and percentages).

The single open-ended question (*"Please specify an example of a drug you have dispensed off-label to children"*) was analyzed by reviewing responses and categorizing them into therapeutic classes (e.g., antibiotics, antiasthmatics, analgesics). Frequencies of responses within each category were then summarized descriptively.

4.3. Ethics approval

The study received ethical approval from the Institutional Ethics Committee at the Faculty of Medicine of the University of Prishtina in November 2024 (REF: 17406). This study was conducted in accordance with established ethical principles, aligning with the standards set forth in the World Medical Association's Declaration of Helsinki (2013).

Author contributions: ADG and BK were responsible for the study design. AK performed the data collection DK performed the statistical analysis. ADG and BK interpreted the results and drafted the manuscript, which RK and PBS commented on and edited. All authors read and approved the final version and take responsibility for the accuracy and integrity of the work.

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