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## ALBANIAN PHARMACISTS' PERSPECTIVES ON GALENIC PREPARATIONS IN THE TREATMENT OF PEDIATRIC ATOPIC DERMATITIS

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**Abstract:** Atopic dermatitis is a form of eczema and a chronic inflammatory state of the skin that touches million of people around the world, mainly the pediatric age being influenced by a number of internal or external factors. For the treatment of this pathology in the pediatric group, where the toxicology aspect of the topical pharmaceutical forms is essential, the pharmacist can participate in giving recommendations as well as in the preparation of some galenic preparations. The pathology of atopic dermatitis is a widespread pathology among children and the interest in topical formulations is high. Therefore, in the Albanian pharmaceutical market there are many alternatives of ready-made formulations. Despite the multitude of forms available on the market, in many cases alternatives of 'tailored'-to-the-patient or without preservatives may be required or with different concentrations of active substances from the finished forms. Pharmacists are the only professionals with the legislation in force in Albania who can carry out galenic preparations in the premises of the pharmacy according to the regulations of the preparations. For this, they are based on the Pharmaceutical Formulary, the Therapeutic Formulary, the European Pharmacopoeia and academic literature. Access to the European Pharmacopoeia or contemporary European literature is difficult for Albanian pharmacists. So, the academic literature remains the main reference for them. The purpose of the study is to research the compounding preparations of pediatric atopic dermatitis described in the literature and to investigate the approach of Albanian pharmacists to these types of preparations. A questionnaire was designed and shared to pharmacist professionals in different regions of Albania. The questionnaire designed in the Albanian language in Google Forms has questions focused on the pharmacist category developed in three sections including demographic information, inclusion of galenic preparations in professional practice, pharmacists' knowledge of pediatric atopic dermatitis. The pharmacists that accepted to be part in the study were 106. The data obtained from the survey were then extracted to primary data and analyzed with Microsoft Office 365. The results showed pharmacists' dedication to the treatment of atopic dermatitis with the proper recommendation and their knowledge and commitment to the specialty. While there is a good approach to these preparations, the results of the survey shows a lack of practice by pharmacists to perform galenic preparations, more than 50% of the responders didn't practice this specialty. This kind of attitude was claimed due to some difficulties encountered during their work such as lack of access to raw materials, time spent, material costs, physical space. Even though all the difficulties, the pharmacists share a good perspective for the development of this specialty within the pharmacy practice by ensuring a stable regulatory framework and continuous education programs dedicated to the issue.

**Keywords:** Galenic Preparations, Compounding, Pharmacist, Albania.

### 1. INTRODUCTION

Atopic dermatitis is a form of eczema and a chronic, relapsing, inflammatory skin condition that affects millions of people worldwide, mostly affecting the pediatric population of all skin types (Torrelo, 2014). It has a complex manifestation of symptoms, acute outbreaks of eczematous lesions, followed by itching on the surface of the skin (Nutten, 2015). This chronic, pruritic, inflammatory skin condition starts before the age of 1 year (usually between 3 and 6 months of age) with a continuation into childhood in 2%–3% of the cases (Pellefigues, 2020).

While there are consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children, unique treatment protocols are not recommended and topical corticosteroids remain the mainstay of therapy along with tacrolimus and pimecrolimus for long-term usage and sensitive skin areas (Wollenberg et al., 2018a). Adjuvant therapy includes UV irradiation antipruritic therapy and antimicrobial therapy, systemic anti-inflammatory treatment, and immunotherapy (Wollenberg et al., 2018b). According to studies, compounded antibacterial, steroids, and moisturizers appear to be effective in the management of atopic dermatitis and may offer additional benefits for patients who have stabilized with standard therapies (Lakhani, Lee, & Lio, 2017). According to Food and Drug Administration (FDA), 'compounding is defined as the process of combining, mixing, or modifying ingredients to create a medication tailored to the needs of an individual patient' even though galenic

preparations includes magisterial preparation, officinal preparation, extemporaneous preparations, preparations from raw materials and preparations to modify already marketed medicines (van der Schors et al, 2021). Compounded preparations are non-FDA approved (U.S. Food and Drug Administration, 2024) and they have issues with safety but they can be many times a therapeutic option in dermatology. Recent review studies recall that there is a gap between community pharmacy practice and their training and education to respond successfully to the needs of atopic dermatitis patients in practice (Sánchez-Regaña et al., 2013). The pharmacist can contribute to the well treatment through their recommendations during the treatment by increasing adherence, managing over the counter drugs, as well as preparing galenic preparations or compounding for specific pediatric patients, form dose or needs. Their interventions to optimize the management of atopic dermatitis and patients' responses to treatment include pharmacy preparations, known as galenic preparation in the Albanian pharmacy setting.

Since the fall of the communist area in Albania, where galenic preparations were an important source of medicine in the pharmacy practice, now days there is this feeling among pharmacists of limited interest for this specialty and no real information and quantification of this service due to the increasing imported medicine. Even though specific preparations could be needed to be prepared by the pharmacist for the pediatric age group with atopic dermatitis in case of allergy to some ingredient, shortage of drugs, different form dose products (Salzmann, Salzmann, & Staubach, 2020) (Torres, Almeida, & Oliveira, 2024).

In Albania, the pharmacist is the only healthcare professional who can practice galenic preparations according to the doctor recommendations or formal literature with no restriction in the current law (Republic of Albania. (2022). *Law No. 95/2022*) but these preparations are not yet included in the Health Insurance Program. For applying this practice, pharmacists are based on the Pharmaceutical Formulary, the Therapeutic Formulary, the European Pharmacopoeia and academic literature. Access to the European Pharmacopoeia or contemporary European literature is difficult for Albanian pharmacists. So, the academic literature remains the main reference for them. The study aims to explore the Albanian pharmacists' attitudes as well as perspectives on galenic preparations in pediatric atopic dermatitis in a small pharmaceutical market but in constant development, in search of a regulatory framework for this field.

## 2. MATERIALS AND METHODS

To investigate the Albanian pharmacists' perspective and approach on galenic preparations of pediatric atopic dermatitis, a cross sectional study was designed. The questionnaire was developed in Google Form in the native language for better understanding of the questions and shared electronically through different pharmacists across different regions of Albania over a 5 months period of time. The questionnaire was structured in 22 questions that include demographic information, education and training, level of knowledge, future perspectives to the topic. Approval was requested ahead the filling along with confidentially notes. The first 5 responders were requested to be part of the focus group to validate the questionnaire. The data obtained from the survey were then extracted to primary data and analyzed by descriptive and inferential statistic with Microsoft Excel 365.

## 3. RESULTS

### Demographic data

The Order of Pharmacists of Albania states that there are a total of 3108 active pharmacists (Order of the Pharmacists of Albania, 2023) with the majority centered in the capital of the country (Mehmeti et al, 2023). A total of 106 pharmacist participated in the study (Table 1). Due to the promptness of responding the questionnaire in the electronically way, the main participants were young professionals, from 20 to 30 years old (76.4%) which defined also lower years in experience at work with less than 5 years (68.9%). The role in the pharmacy varied, nearly half of the responders were Full-time employed pharmacist (47.2%) and a part were Technical Director of the pharmacy (23.6%) followed by Part time Employed Pharmacist (15.1%). The pharmacists in the study were located in the urban areas (95.3%) and distributed mainly in the city of Tirana, the capital (72.6%).

**Table 1 Demographic information of the pharmacists that participated in the study**

<i>Gender</i>	No.	%	<i>Location</i>	No.	%
Female	89	84,0%	Rural	5	4,7%
Male	17	16,0%	Urban	101	95,3%
Total	106	100,0%	Total	106	100,0%

<i>Age (years old)</i>	No.	%	<i>City</i>	No.	%
20-30	81	76,4%	Tiranë	77	72,6%
31-40	17	16,0%	Durrës	5	4,7%
41-50	6	5,7%	Korçë	5	4,7%
51-60	1	0,9%	Vlorë	5	4,7%
61-70	1	0,9%	Other	14	13,2%
Total	106	100,0%	Total	106	100,0%

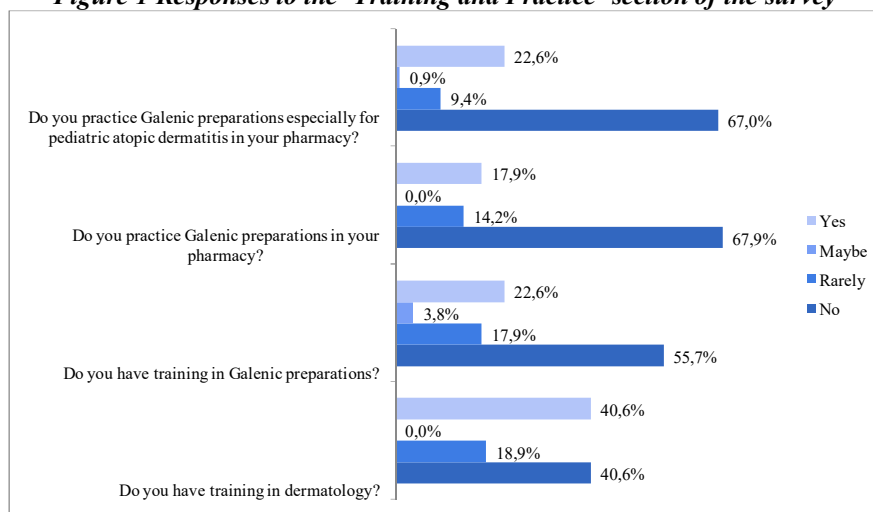
<i>Experience (year)</i>	No.	%	<i>Role in Pharmacy</i>	No.	%
<5	74	69,8%	Full-time employed pharmacist	50	47,2%
5-10	19	17,9%	Technical Director	25	23,6%
11 - 15	5	4,7%	Pharmacist employed part-time	16	15,1%
16-20	5	4,7%	Assistant pharmacist	11	10,4%
21-25	2	1,9%	Pharmacy manager	3	2,8%
25-30	1	0,9%	Pharmaceutical consultant	1	0,9%
Total	106	100,0%	Total	106	100,0%

Source: Author

### Training and practice

The data analyzed from the survey of the section dedicated to the ‘training and practice’ issues, pharmacists reported that they have conducted training in dermatology (40.6%) and but not specifically in galenic preparations (22.6%) ( ). More than half of the pharmacists (67%) admitted that they don’t practice this field in general (67,9%) nor in the specific preparations of pediatric atopic dermatitis (67%). Additionally, 9.4% of respondents noted that they rarely prepare these formulations, while an insignificant 0.9% was unsure about their involvement in this particular practice.

**Figure 1 Responses to the ‘Training and Practice’ section of the survey**



Source: Author

### Pharmacists’ approach on first line of treatment

The pharmacists shared a common attitude for the first line treatment as 84.9% indicated that the first line treatment should be ‘emollients / humidificants’ and are hesitant about cortisonics, just 8.5% agree that they could be suitable as a first line treatment (Table 2). None of the respondents reported using hormonal therapy as a first-line treatment, indicating that this approach is not considered appropriate, even though 6.6% of them suggested that a combination therapy could be a more comprehensive approach to the therapy.

**Table 2 Opinions on first line of treatment of pediatric atopic dermatitis**

<i>First line of treatment of pediatric atopic dermatitis</i>	No	%
Emollients / humidificants	90	84,9%
Cortizonics	9	8,5%
Combination therapy	7	6,6%
Hormonal therapy	0	0,0%
Total	106	100,0%

Source: Author

### Knowledge towards galenic preparations on pediatric atopic dermatitis

The survey explored the basic knowledge of the pharmacists towards galenic preparations on pediatric atopic dermatitis through some questions, resulting in a large score. The pharmacist responded correctly, 76 out of 106 responses, to the question regarding the formulation of natural ingredient in the emollient preparations (71.7%) (Table 3). A high score, 87 out of 106 responses, was gained for the question regarding the usage of lanolin as a product with emollient properties (87%). There seems to be a general confusion on the topic about the concentration differences among cortisonics preparation where 73 out of 106 disagreed correctly about the fact that different cortisones preparations have the same effect (68.9%). Regarding the topic of practical preparation there is a vague impression that the emollients can be easily prepared (55.7%). Still, it appears that pharmacists (39.6%) find it difficult to compound the active ingredients in the ointment indicating that the task is sometimes hard and complex involved in ensuring the stability and effectiveness of compounded preparations.

**Table 3 Answers to the questions regarding knowledge towards galenic preparations on pediatric atopic dermatitis**

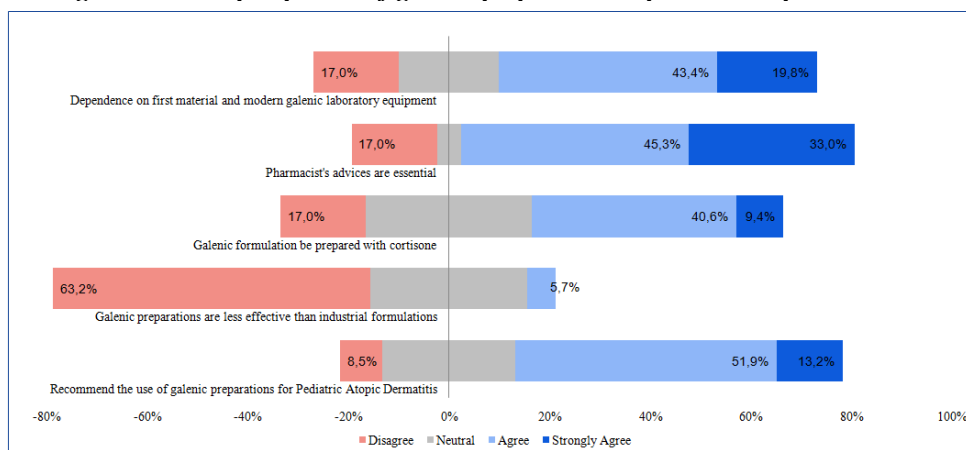
<i>Question</i>	Correct answer	No.	%
Aloe vera extract, coconut oil can be included in the formulation as a natural product with emollient properties	Yes	76	71,7%
Lanolin is an animal product with emollient properties	Yes	87	82,1%
Different cortisone formulations have the same effect, regardless of concentration	No	73	68,9%
Preparations with only emollients can be easily prepared	Yes	59	55,7%
Compounding the active ingredients in the ointment base is difficult to achieve	Sometimes	42	39,6%
Total		337	

Source: Author

### Future prospective

As a mean to explore the perception of the pharmacist and their future prospective for specialty of galenic preparation in pediatric atopic dermatitis, the last section of the questionnaire was dedicated to this topic (Figure 2). There is an agreement (agree and strongly agree) between the pharmacist and their professional engagement in advising the patients during the treatment in atopic dermatitis (78%) as well as recommending the galenic preparation (65%) but in the same time having dependence on the right infrastructure and reaching to the first raw material (63.2%) to ensure quality and stability. The general consensus on the disagreement that that galenic preparation for the treatment of this pathology are less effective that industrial formulations (63.2%) giving a positive approach to this specialty. Still, there is a hesitation about the galenicals with cortisone where less than half of the pharmacists (40.6%) agree about preparing galenicals containing cortisone.

**Figure 2 Future prospective of galenic preparation in pediatric atopic dermatitis**



Source: Author

#### 4. DISCUSSIONS

The role of galenic (or also referred as compounding) has been reported to be effective in the management of the atopic dermatitis (Lakhani, Lee, & Lio, 2017) and also encouraged by the EAHP Position Paper on Pharmacy Preparations and Compounding (van der Schors et al., 2021). The results of this study give insights to the approach of Albanian pharmacists to this topic. Overall, the findings highlight a strong inclination among pharmacists to support personalized treatment, with more than half of the respondents (51.9%) agreeing and an additional 13.2% strongly agreeing that such preparations should be recommended for children with atopic dermatitis. Nearly half of the the pharmacists who participated in the study attended training programs in dermatology (40.7%) and galenic preparations (55.7%) but this did not employed their commitment in practicing the preparations of pediatric atopic dermatitis, approximately 60% was not practicing at all. This reveals a gap between education or training and practicing this specialty suggested even by Cayci, Rathbone, and Lindsey (2023) found in their systematic review that new approaches regarding education and training should be searched to boost the pharmacists' dermatological knowledge and skills. Interestingly, there is a significant level of confidence in the effectiveness of these personalized preparations compared to industrially manufactured formulations. A majority of pharmacists (63.2%) disagreed with the statement that galenic preparations are less effective than their industrial counterparts. This suggests a belief among pharmacists that the ability to tailor treatments specifically to a patient's condition can potentially result in more effective outcomes, despite the convenience and widespread availability of commercial products. The hesitancy about the cortisonic compounding with a substantial proportion (33.0%) remains neutral on their opinions of prejudices described even before in literature. The study revealed that the pharmacists are confident about their counseling role and recommendations during the treatment as discussed before by Cheong, Hie, Koh, de Souza, and Koh (2019).

This is one of the few studies conducted in Albania about galenic preparations and the only one with the focus on pediatric atopic dermatitis. The research included data obtained from the questionnaires filled by the pharmacists, so it may implies the presence of bias. The majority of the responders was located in the capital and was in young age, with a limited time frame experience and the females were considerably more involved in the study.

#### 5. CONCLUSIONS

This study investigates the perspectives of Albanian pharmacists regarding the use of personalized galenic preparations for the treatment of pediatric atopic dermatitis. The findings reveal a strong belief among pharmacists in these personalized treatments within the guidelines or official literature in support to tailored treatments to the specific needs of pediatric patients in case of allergy, shortages or form dosages. Pharmacists' confidence in the efficacy of personalized galenic preparations suggests that these formulations are viewed as valuable and effective alternatives to commercially available products, particularly in cases where standard treatments may not fully address individual patient needs. However, the study also highlights some uncertainty, particularly around the compounding of cortisone in these preparations, indicating a need for further education and standardization in this area. The essential role of pharmacists in the treatment of pediatric atopic dermatitis is strongly agreed, with many respondents emphasizing the importance of their professional advice in managing this condition but with difficulties

on ensuring first materials and modern laboratory equipment in ensuring the safety and efficacy of compounded preparations, pointing to the need for continued investment in these areas to support the compounding process and also to an updated legal framework to regulated the procedures.

In summary, this study provides important insights into the role of pharmacists in delivering personalized care for pediatric atopic dermatitis in Albania. These conclusions contribute to the research on personalized medicine and emphasize the need for continued support and education for pharmacists engaged in the compounding of specialized treatments.

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