

Pediatric drugs and the "off-label" concept in pharmaceutical practice

1. Please specify your professional practice experience:
 - a) 1-5 years
 - b) 5-10 years
 - c) 10-15 years
 - d) >15 years
2. How well do you rate your knowledge of off-label medication?
 - a) Good
 - b) Very well
 - c) A little bit
 - d) Not at all
3. What was the circumstance in which you were introduced to this concept?
 - a) Academic environment
 - b) Experience
 - c) Through professional colleagues
 - d) Vocational training courses
4. To the best of your knowledge, the off-label practice in Romania is:
 - a) Legal but unrecognized
 - b) Legal and recognized
 - c) Illegal, but generally accepted
 - d) Illegal and unrecognized
5. In your daily practice, have you identified off-label pediatric drug prescriptions?
 - a) Never
 - b) Daily
 - c) Weekly
 - d) Monthly
6. If your answer to question 5 indicates that you encountered off-label prescriptions, what was their origin?
 - a) Family physician
 - b) The specialist doctor
7. If your answer to question 5 indicates that you encountered off-label prescriptions, what were the most commonly prescribed drug categories?

- a) Medicines used in acute respiratory diseases
 - b) Antibiotics
 - c) Medicines used in the psychiatric field
 - d) Others
8. Could you provide specific examples of medicinal substances that reflect the answers to question 7?
9. If your answer to question 5 indicates that you have encountered off-label prescriptions, in which of the following off-label categories would you place those prescriptions, in terms of frequency?
- a) Indication
 - b) Age
 - c) Dose
 - d) Route of administration
 - e) Pharmaceutical form
10. If your answer to question 5 indicates that you encountered off-label prescriptions, what was your professional attitude?
- a) You have informed the parent/legal tutor
 - b) You have contacted the prescribing doctor in order to request more information about the therapeutic choice
 - c) You dispensed the prescription without informing the prescriber
 - d) You refused to dispense the prescription
 - e) You dispensed the prescription without informing the parent/legal tutor
11. 11. In your daily practice, have you identified situations where parents have requested OTC medications to be dispensed, that meet off-label criteria?
- a) Never
 - b) Daily
 - c) Weekly
 - d) Monthly
12. If your answer to question 11 indicates that you encountered off-label requests, what were the most frequently requested drug categories?
- a) Medicines used in acute respiratory diseases
 - b) Antihistamines/other OTC substances with sedative properties, used to calm the child
 - c) Others

13. Could you provide concrete examples of drug substances that reflect the answers to question 12?

14. If your answer to question 11 indicates that you have encountered off-label requests, in which of the following off-label categories would you place those requests, in terms of frequency?
- Indication
 - Age
 - Dose
 - Pharmaceutical form
 - Route of administration
15. If your answer to question 11 indicates that you encountered off-label requests, what was your professional attitude?
- You searched for OTC, on-label therapeutic alternatives
 - You have informed the parent/legal tutor that the request is for an off-label treatment
 - You dispensed the medication based on your professional experience, following a careful anamnesis
 - You have consulted a pediatrician or a clinical pharmacist in order to make an informed decision
 - You have refused the dispensing of that medicine
16. In your daily practice, have you identified situations where parents have requested a prescription drug without having a prescription that meets off-label criteria?
- Never
 - Daily
 - Weekly
 - Monthly
17. If your answer to question 16 indicates that you encountered off-label requests, what were the most frequently requested drug categories?
- Antibiotics
 - Medicines used in acute respiratory diseases
 - Topical corticosteroids
 - Medicines used in gastrointestinal disorders
 - Antihistamines/other OTC substances with sedative properties, used to calm the child
 - Others
18. Could you provide concrete examples of medicinal substances that reflect the answers to question 17?

19. If your answer to question 16 indicates that you have encountered off-label requests, in which of the following off-label categories would you place those requests, in terms of frequency?
- Indication
 - Age
 - Dose
 - Pharmaceutical form
 - Route of administration
20. If your answer to question 16 indicates that you encountered off-label requests, what was your professional attitude?
- You have informed the parent/legal tutor that the request is for an off-label treatment
 - You dispensed the medication based on your professional experience, following a careful anamnesis
 - You searched for OTC, on-label therapeutic alternatives
 - You have refused the dispensing of that medicine
 - You have consulted a pediatrician or a clinical pharmacist in order to make an informed decision
21. Have you encountered situations in which, following the dispense based of an off-label prescription, the patient experienced adverse reactions?
- Yes
 - No
 - Don't know
22. Have you encountered situations in which, following the dispense of an OTC medication off-label, the patient experienced adverse reactions?
- Yes
 - No
 - Don't know
23. When do you think a doctor should resort to off-label prescribing?
- When his experience with that treatment is extensive and has been used successfully in several patients
 - When the respective treatment is well documented in the literature or treatment guidelines
 - Only when other on-label therapeutic options have been ineffective

24. What do you consider to be the benefits associated with off-label practice in pediatrics?
- It meets the therapeutic needs in the pediatric sphere, as there are not enough medicinal substances/pharmaceutical forms for pediatric use
 - It supports research in the field, as successful off-label treatments can be documented and serve as the scientific basis for approval of the indication for pediatric use
 - It allows the doctor to act knowingly, in full professional capacity and experience, for the good of the patient
25. What do you think are the risks associated with off-label practice in pediatrics?
- Occurrence of acute, potentially serious adverse effects, difficult to manage therapeutically
 - The occurrence of unwanted long-term effects that could interfere with the normal development of the child
 - Implications for the license to practice, as off-label can be associated with malpractice
 - Violation of the patient's right to benefit from a treatment that can be settled by the National Health Insurance House
26. What are your sources of information when it comes to pediatric drugs?
- Summary of product characteristics
 - The drug leaflet
 - Specialty sites, such as DrugBank, Medscape, Drug List, etc.
 - Other sources; please specify _____
27. Considering that off-label practice is a large-scale phenomenon in the pediatric sphere, what do you think would be the most appropriate actions in the patient's interest?
- Existence of a database or guidelines containing information on off-label drugs
 - An increased level of knowledge on the status of the drugs used in pediatrics by the pharmacist, continuous information and documentation through access to specialty courses
 - Development and approval of medicines for pediatric use, for the total avoidance of off-label practice
 - Off-label practice cannot be totally avoided

- e) Refusal to dispense the drug by the pharmacist and encourage the doctor to find alternatives

28. Considering that off-label practice is a large-scale phenomenon in the pediatric sphere, which cannot be completely eliminated due to unmet therapeutic needs, in your opinion, what would be the most appropriate actions to achieve therapeutic success?
- a) A good doctor-pharmacist collaboration, in order to optimize the treatment
 - b) Informing parents about the respective treatment and obtaining their informed consent
 - c) Treatment monitoring, documentation and reporting of adverse reactions
 - d) Informing the parents is not necessary, as it may cause them to become alarmed and refuse treatment, even though it may be the only therapeutic option for the child