



Off-Label and Extra-Label Drug Use in Veterinary Medicine: From Clinical Necessity to Rational Pharmacological Decision-Making

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Abstract: Off-label and extra-label drug use represents an essential component of contemporary veterinary medicine due to species diversity and the limited availability of authorized veterinary medicinal products. These practices allow therapeutic adaptation in complex clinical situations but are associated with significant pharmacological uncertainty caused by interspecies variability. Rational prescribing therefore requires integration of pharmacological knowledge, evidence-based medicine, patient monitoring, and risk-benefit assessment. This review summarizes the principal determinants, clinical benefits, pharmacological risks, and decision-making strategies associated with off-label and extra-label therapies in veterinary medicine.

Material and method

- This study was designed as a narrative review focused on the pharmacological, clinical, and regulatory aspects of off-label and extra-label drug use in veterinary medicine. Scientific literature, veterinary pharmacology references, and current international regulatory guidelines were analyzed to evaluate the principal determinants, benefits, risks, and clinical implications associated with these practices.
- Particular emphasis was placed on interspecies pharmacokinetic and pharmacodynamic variability, therapeutic decision-making, and representative clinical applications in companion animal medicine.

Results and discussions

- 1. Main determinants of off-label and extra-label use**
 - Limited availability of authorized veterinary medicines
 - Species diversity and interspecies pharmacological variability
 - Therapeutic urgency in severe clinical conditions
 - Transfer of human pharmacotherapy into veterinary medicine
 - Economic and accessibility considerations
- 2. Major pharmacological challenges**
 - Unpredictable pharmacokinetic and pharmacodynamic responses
 - Risk of toxicity and inaccurate dose extrapolation
 - Limited species-specific clinical evidence
 - Drug interactions and variable therapeutic efficacy
 - Antimicrobial resistance concerns
- 3. Clinical benefits**
 - Expansion of therapeutic possibilities
 - Individualized and patient-oriented therapy
 - Improved multimodal pain management
 - Access to innovative therapeutic strategies
 - Improved quality of life and disease control

Main Clinical Benefits of Off-Label and Extra-Label Use	
Clinical benefit	Clinical relevance
Expansion of therapeutic options	Access to therapies when approved alternatives are unavailable
Individualized therapy	Adaptation of treatment to patient-specific needs
Multimodal analgesia	Improved pain management and patient comfort
Access to innovative therapies	Early integration of emerging treatments
Improved quality of life	Better control of chronic and complex diseases

Major Pharmacological Risks and Limitations	
Risk factor	Potential consequence
Interspecies pharmacokinetic variability	Unpredictable drug exposure and toxicity
Incorrect dose extrapolation	Therapeutic failure or overdose
Pharmacodynamic variability	Variable clinical response
Drug interactions	Adverse effects and altered efficacy
Antimicrobial resistance	Public health and stewardship concerns

Representative Off-Label and Extra-Label Therapies in Veterinary Medicine		
Drug	Veterinary use	Main concern
Gabapentin	Neuropathic pain and anxiety	Sedation in cats
Amlodipine	Feline hypertension	Variable hypotensive response
Trazodone	Behavioral disorders	Excessive sedation
Omeprazole	Gastric ulceration	Variable bioavailability
Remdesivir	Feline infectious peritonitis	Limited safety data

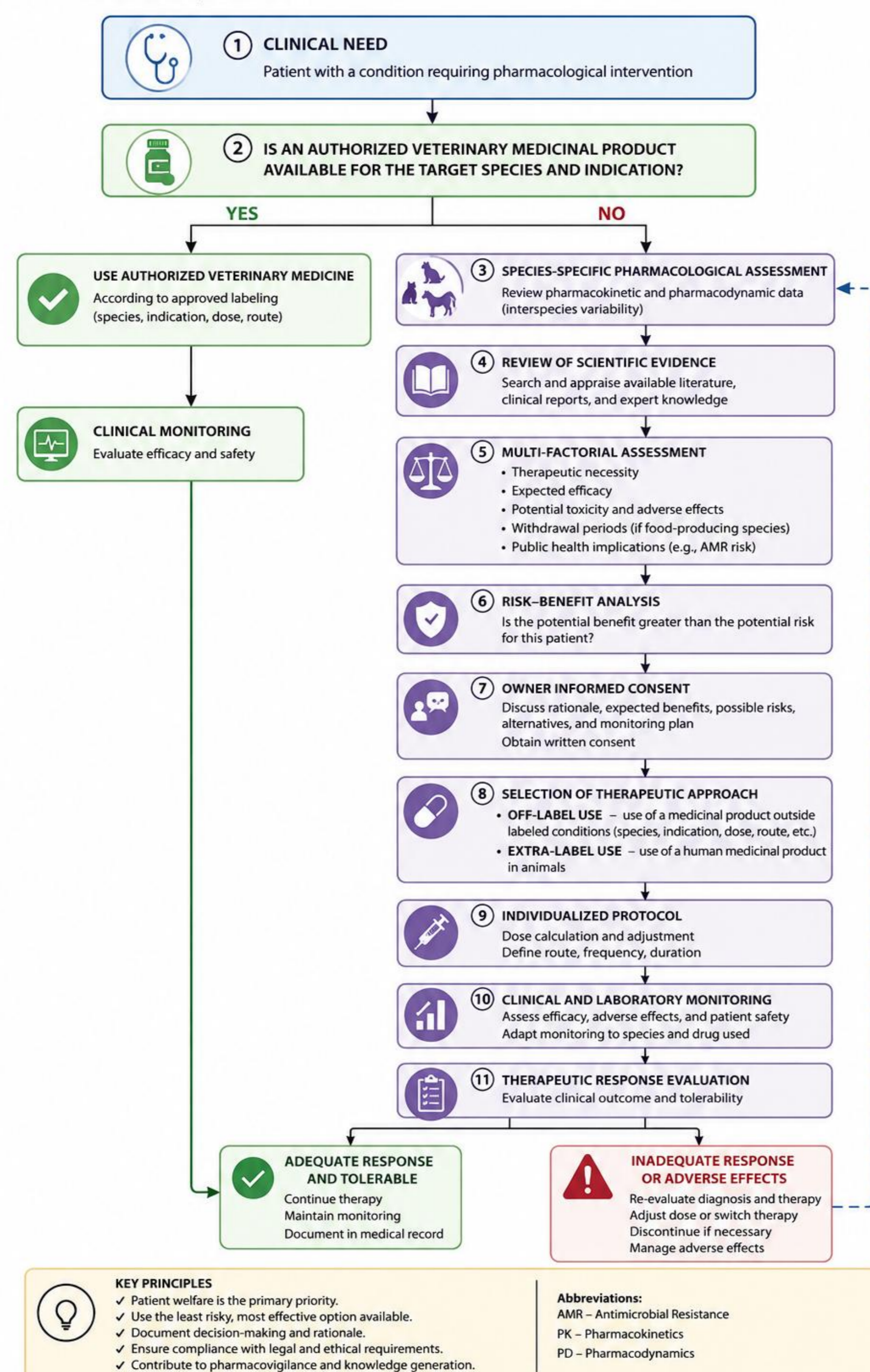


Figure 1. Proposed clinical decision-making model for off-label and extra-label drug use in veterinary medicine

Conclusions

- Off-label and extra-label prescribing has become an integral component of contemporary veterinary medicine.
- Interspecies pharmacokinetic and pharmacodynamic variability remains the principal source of therapeutic uncertainty.
- These practices expand therapeutic possibilities and support individualized patient-oriented therapy.
- Rational use requires evidence-based pharmacological assessment, continuous monitoring, and structured clinical decision-making.
- Future progress depends on comparative pharmacology research and standardized evidence-based therapeutic guidelines.