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OFF LABEL USE OF HUMAN DRUGS IN VETERINARY SMALL PRACTICE IN REPUBLIC OF NORTH MACEDONIA

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ABSTRACT

“Off-label use” is defined as the use of a medicinal product that is not in accordance with the summary of the product characteristics, which includes the use of a medicine for unapproved species, disease, route of administration, or dosage. This is widespread practice in veterinary medicine, especially “off-label use” of human-approved drugs for the treatment of small animals. The data was collected from a private veterinary practice in North Macedonia. Veterinarians were asked to collect data on every off-label prescription or application of human drugs during a 3-month period. In both cats and dogs, oral antibacterial drugs were the most prescribed drugs, and oral application of amoxiclav was most commonly used in both species. The reasons all over the world why veterinarians frequently use “off-label” drugs from human medicine may be different: low price, no medicines available for treatment of a specific condition, more suitable drug formula. Antibacterial drugs are the number one ‘off-label use’ drug in small animal practice in our country, and these data are similar to results from other countries. The main concern for off-label use of human drugs in veterinary medicine is the risk to public health, especially off-label use of antimicrobial drugs and potential impacts on public health due to antimicrobial resistance. The findings of this study indicate that in small animal veterinary practice in North Macedonia, the off-label use of human medicinal products, particularly antibacterial drugs, remains a widespread and routine clinical practice. Clearer professional guidelines and better regulation are needed to provide veterinarians with clear and standardized protocols, thereby justifying the use of human drugs.

Keywords: off-label, veterinary medicine, drugs, antibiotics

1. INTRODUCTION

“Off-label use” is defined as the use of medicinal product that is not in accordance with the summary of the product characteristics (EMA/CVMP 2017) which includes the use of a medicine for unapproved species for which it is not authorized, using it for an unapproved disease or indication, applying it via a different route of administration, or prescribing it at a dosage or treatment duration not stated in the official labelling. Off-label prescribing is widespread and common practice in veterinary medicine, especially “off label use” of human approved drugs for treatment of small animals is often necessary to manage clinical condition successfully.

The primary reasons of off-label use of drugs in small animal practice in veterinary medicine are the limited registration of veterinary drugs and non-availability of certain drugs (Grand View Research 2025). Many therapeutic drugs needed for the treatment of dogs and cats are unavailable in veterinary-specific formulations, forcing veterinarians to lean on human pharmaceuticals to fill these therapeutic gaps.

In many countries there are regulatory frameworks where there are legal pathways for off-label prescription of human drugs in veterinary medicine. Veterinarians in European Union and the United States are allowed to prescribe off-label uses of human drugs under controlled conditions like when the health or welfare of the animal is threatened, or suffering or death may result from failure to treat animals and when no suitable veterinary drugs is available (EMA/CVMP 2018, FDA 2023). If this regulation is respected by veterinarians, a balance can be made between animal welfare and responsible prescription. Veterinarians are ones who should be insured that off-label occurs only when it is clinically justified and in accordance with professional guidelines.

In European Union and United Kingdom there are principles of the *prescribing cascade*, this principle can provide and help veterinarians in making decision for appropriate

treatment. According to these principles, always the first and preferred treatment choice should be a veterinary medicinal product approved for the use in the target animal species and for the relevant paralogical condition. If there is no available suitable veterinary product to treat a condition, treatment option should be- second choice are veterinary drugs for use in another animal species or for a different condition in the same species. Only when neither of these alternatives are available, veterinarians may consider about human drugs use in animals respectively last choice is a medicinal drug authorized for human use (Veterinary medicines guidance 2013).

Despite these recommendations, there are currently no comprehensive official data for the frequency or clinical justification for off label use of human drugs in veterinary medicine by veterinarians and no requirement for systematic monitoring of this practices (EMA/CVMP2015). This lack of monitoring makes it difficult to overview and evaluate the real extent of off-label prescribing, and its potential impacts for animal and human health (One Health).

Also veterinarians who are working in small animal practice have fewer regulatory limitation compared to those veterinarians who are treating food-producing animals. Because animals in small animal practice do not enter the human food chain, concerns related to consumer safety, withdrawal periods, and drug residues are not applicable. As a result, veterinarians in small animal practice may have greater flexibility in selecting off-label treatments for companion animals, provided that such decisions are made responsibly and in the best interest of the animal's health and welfare.

Main concern for off-label use of human drugs in veterinary medicine is the potential risk for public health especially off-label use of antimicrobial drugs and potential impacts on public health due to antimicrobial resistance as resistant pathogens may circulate between animals, humans and environment (EMA 2018). The inappropriate or unregulated use of off-label antimicrobials whether through incorrect dosing, unsuitable formulations, or use in species for which pharmacokinetic and pharmacodynamic data are lacking, can contribute to the development and spread of antimicrobial resistance. This concern is for real because several studies have shown that the main group in off-label use in veterinary medicine are antimicrobial drugs (Tomanic et al. 2021, Gómez-Poveda and Moreno 2018, Bingefors 1985, Grave et al.1992). Antibiotic resistance in humans is mainly related to the wide application of antimicrobial in farm animal and foodborne transmission (Martin et al. 2015) but some authors have raised awareness about the increasing importance of direct contact transmission with pets (Guardabassi 2013, Pomb 2017). The most critical consequence of the common use of antimicrobial substances is seen in the selection and spreading of bacteria with co- or cross-resistance to antibiotics used in human medicine (Schmerold et al. 2023).

2. MATERIALS AND METHODS

The data for this study were obtained from a private small-animal veterinary practice in North Macedonia. During a three-month observation period, veterinarians at the clinic were instructed to systematically document every instance in which a human medicinal product was prescribed or administered off-label to an animal patient. Over the course of the study, a total of 45 off-label treatment records were collected, of which 35 involved dogs and 10 involved cats, reflecting the typical case distribution of the practice.

For each recorded case, the following information was gathered: the species of the animal, the brand (fabric) name of the human drug used, its pharmaceutical formulation, the prescribed dosage, the route of administration, the duration of the treatment, and the clinical indication or diagnosis that justified its use. These variables were selected to enable a detailed

assessment of prescribing patterns and to evaluate whether treatment decisions aligned with accepted principles of rational drug use.

After collection, the data were organized and categorized according to animal species (dogs vs. cats) and by therapeutic drug class. Drug classes were further subdivided based on the active pharmaceutical ingredient, allowing for a more precise analysis of trends in off-label use among different categories of medications. Routes of administration were also identified and classified to provide insight into the practical aspects of how human drugs are utilized in small-animal practice. The results obtained in this study were processed using MS Office Excel v 2007.

3. RESULTS

A total of 45 animals were included in the study, consisting of 35 dogs and 10 cats (Fig. 1). Among the canine population, 53% were male and 47% female, representing a wide age range from 6 months to 12 years, and included multiple breeds commonly presented in general practice. The feline group consisted of 58% males and 42% females, with ages ranging from 1 to 4 years, primarily domestic short- and long-haired cats.

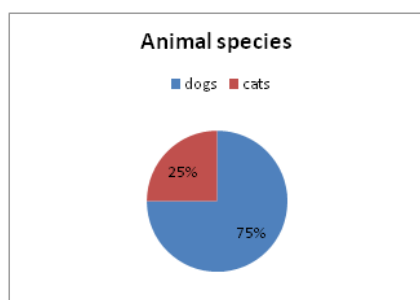


Figure 1. Distribution of human approved drugs prescription by animal species

During the three-month observation period, a total of 50 off-label human drugs were prescribed to dogs. These drugs belonged to several pharmacological classes, including 4 vitamin preparations, 4 gastrointestinal drugs, 3 antifungal drugs, 10 antibacterial drugs, 3 anticancer/chemotherapy drugs, 4 cardiac drugs, and 4 drugs affecting the central nervous system (CNS) (Fig. 2). In contrast, cats received 10 off-label prescriptions, divided into 4 analgesic drugs, 2 glucocorticosteroids, and 4 antibacterial agents (Fig. 3).

In both species, oral antibacterial medications were the most frequently used off-label drugs. Among these, amoxicillin–clavulanic acid (Amoksiklav) administered orally was the most commonly prescribed antibacterial drug in both dogs and cats. In dogs, topical formulations—particularly ophthalmic and otic preparations such as tobramycin, tyrothricin, and ciprofloxacin—were also frequently utilized (Fig. 4). Sulfonamides were often the treatment of choice for canine cystitis, and doxycycline (Vibramicin®) traditionally was used off-label for the management of *Ehrlichia canis* infection.

Several additional drug classes were used off-label in dogs, including gastrointestinal and hepatoprotective medications. Silymarin, a hepatoprotective nutritional supplement registered for human use, was administered to support liver function. Prokinetic agents such as metoclopramide were applied intravenously to manage gastrointestinal disorders. Cardiovascular drugs, including ACE inhibitors such as enalapril (orally) and diuretics like furosemide (subcutaneously), were also used off label to manage cardiac and renal-related conditions. Furthermore, propofol, an intravenous anesthetic approved for human use, was used for induction and maintenance of anesthesia in dogs (Table 2).

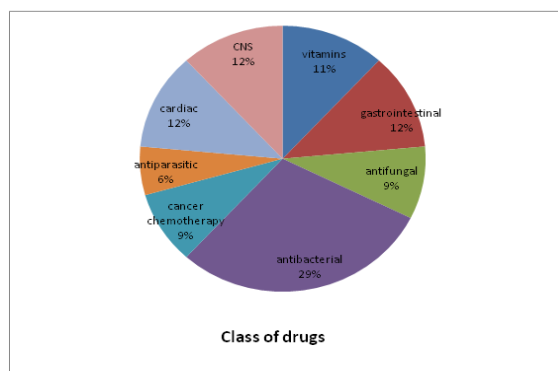


Fig.2 Distribution of human approved drugs prescribed off label to dogs

Another less frequently used but clinically relevant category of off-label drugs in dogs included chemotherapeutic agents, such as vincristine, which was used for the treatment of canine transmissible venereal tumor (CTVT). Additionally, allopurinol, a drug approved in human medicine primarily for managing gout and hyperuricemia, was used off-label as part of the antiparasitic protocol for canine leishmaniasis.

In cats, nonsteroidal anti-inflammatory drugs (NSAIDs) such as meloxicam were commonly administered off-label, especially via the subcutaneous route, for postoperative or chronic pain management (Table 3). Glukokortikosteroides were also used in cats, but with less intensity compared to antibacterial drugs.

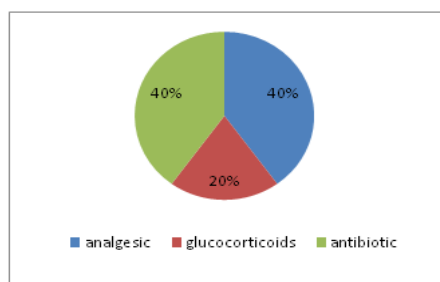


Fig 3. Distribution of human approved drugs prescribed off label to cats

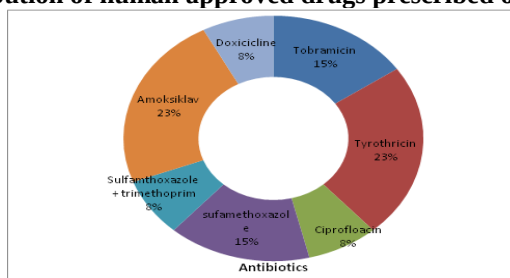


Fig 4. Distribution of off label prescribed antibiotics in dogs

Table 1. Distribution, route and indication of off label prescribed antibiotics in dog

Class of antibiotics	%	Route of administration	Indication
Tobramicin	15%	oculus uterque OU	ceratitis
Tyrothricin	23%	auris utraque AU	Otitis
Ciprofloacin	8%	oculus uterque OU	Ceratitis
sufamethoxazole	15 %	Per os	cystitis
Sulfamthoxazole+ trimethoprim	8%	Per os	cystitis
Amoksiklav	23 %	Per os	gastrocolitis
Doxicicline	8 %	Per os	E. canis

Table 2. Distribution of off label prescribed drugs according to pharmacologic class in dogs and route of administration.

Class of drugs		%	Route of administration
Vitamins	Vitamin C	25 %	Per os
	Vitamin A	25 %	
	Neurobion	50 %	
Gastrointestinal	Hepatoprotective – silymarine	50 %	Per os
	Procinetics – metoclopramide	50 %	I.V
Antifungal	Kanesten	33%	Local
	Ketoconazole	33%	
	Fluconazole	33%	
Antiparasitic	Allopurinol	100%	Per os
Cancer Chemotherapy	Vincristine	100%	i.V
Cardiac	Diuretics furosemide	50%	s.c
	ACE inhibitors Enalapril	50%	Per os
CNS	Diazepam	25%	I.V
	Propofol	50%	I.V
	Fenobarbitol	25%	Peros

Table 3. Distribution of off label prescribed drugs according to pharmacologic class in cats

Class		%	Route of administration
Analgesic	<i>Meloxicam</i>	40	i.m
Glucocorticoids	Dexametasone	20	Topical
Antibiotic	Amoxicilin	30	Per os
	Sulfamthoxazole+ trimethoprim	10	

4. Discussion

The reasons all over the world why veterinarian frequently use “off-label” drugs from human medicine may be different: low price in, a human-approved drug may be significantly cheaper than a similar veterinary-approved product, making it a more affordable option for pet owners; the number of medications developed and approved specifically for animal use is far smaller than those available for humans; limited veterinary drugs, no medicines available for treatment of specific condition, many animal diseases do not have a corresponding approved animal drug, more suitable drug formulathe available animal drug may not come in a suitable strength or form for a particular patient. (Filipovic 2008, Holso et al. 2005, Escher et al. 2011, Rollin et al. 2002).

The most common reason for off label use of human drugs by Macedonian veterinaries is leak of availability of certain drugs i.e. drugs are registered for human use and are not registered for veterinary use in Macedonian market. A certain number of therapeutic agents required in small animal practice, particularly those used for infectious, cancer treatment, and analgesic indications, are registered for human use and are not available for the veterinarians. Beyond this regulatory limitation another reason for off label use of human drugs in veterinary medicine is economic reason or low price. Human formulations are frequently more affordable, more widely stocked in pharmacies, and available in multiple generic forms, making them a practical option for both veterinarians and pet owners.

Antibacterial drugs represent the most frequently used class of ‘off label’ drugs in small animal practice in our country, and these data are similar to results from other countries in Europe (Tomanic et al. 2022, RoliTarillion et al.2025, Odensvik et al. 2001, Tarillion et

al.2025). This trend suggests that veterinarians in small animal practice across the region face similar therapeutic limitations.

Oral application of antibacterial drug amoxicillin–clavulanic acid (Amoksiklav[®]) was the most commonly prescribed off label drugs in our research in both dogs and cats, reflecting its broad-spectrum activity, safety profile, and low prices.

Topical antibacterial preparations were the veterinarian’s choice for local treatment of bacterial infections. Topical-ocular and auricular application of antibacterial drugs (tobramycin, tyrotricin, ciprofloxacin) were frequently used. Most likely due to the limited availability of veterinary-specific topical agents for eye and ear infections.

Sulfonamides were choice of off label treatment of cystitis in dogs. Doxycycline continued to serve as the standard off-label treatment for *Ehrlichia canis* infections, reaffirming its well-documented efficacy and longstanding use in managing vector-borne diseases in dogs. Veterinarians in small animal practice, in order to provide appropriate therapy based on evidence-based medicine, are replacing the gap and lack of appropriate drugs from veterinary pharmaceutical market with off-label use of drugs from human medicine.

Tomanicet et al.(2021) reported that oral antimicrobials were the most commonly off label prescribed drugs for dogs in Serbia which is in agreement with our study. Our data shows that digestive issues are the most common condition for therapeutic use of off label antimicrobial drugs, which is in agreement with others studies (Gomez-Poveda and Moreno 2018, Tomanicet et al. 2021, Rantala et al, 2004) where digestive disorders were the most common condition for off label use of antimicrobial drugs in dogs. In our study, in cats, analgesic were the most common medications for off label use, and the main reason was the lack of *registered analgesic suitable for veterinary use in these species*.

In this use of human drugs in veterinary medicine, veterinarians should always determine the correlation between clinical necessity and potential risk, and always should be guided by foundational principle in medicine “*primum non nocere*”. While human drugs may offer effective therapeutic alternatives, their pharmacokinetics, absorption, distribution metabolism, elimination and toxicity profiles are often different in certain animal species. Dogs and cats demonstrate significant interspecies variation in drug absorption, hepatic metabolism, and renal elimination (Court 2013, Davis 2013). Differences such as feline deficiencies in glucuronidation or breed-specific sensitivities in dogs (e.g., MDR1 mutations) heighten the risk of adverse reactions when human formulations are used without evidence-based dosing guidelines. Several studies have documented significant variation in prescribed doses, incomplete documentation, and unjustified use for off-label drugs, suggesting that veterinarians in clinical practice rely on their own individual experience rather than standardized protocols (Rantala et al.2004, Escher et al. 2011, Grave et al. 1992).

The widespread use of human antimicrobials in small animal medicine raises additional concerns related to antimicrobial resistance. Companion animals live in close contact with humans, facilitating potential bidirectional transfer of resistant bacteria. Off-label prescribing, particularly when involving critically important antimicrobials, may increase the risk for antimicrobial resistance if the therapy is not supported by culture and susceptibility testing, appropriate dosing, and treatment duration. While some studies have shown that veterinarians often rely on their own experience, others studies highlight increased awareness of antimicrobial resistance and conscientious use of antibiotics in small animal practice (Karagiannidou et al. 2020, Hardefeldt et al. 2022, Radford et al. 2015).A study in Norway has shown that 50% of antibacterial drugs used in dogs were off label from human medicines, while in Sweden this percentage was 20%. (Odensvik et al. 2001). These differences may be as a result of different regulations, differences in procedure for

registration of drugs in each country, different animal populations and different therapy choices for companion animals ((Odensvik et al. 2001, Hölsö et al. 2005, Tanaka et al. 2017). Guidance for specific indications in cats and dogs could contribute to greater legal certainty in small animal practice with regard to the justification of off-label use (Tarillion et al. 2025).

Consequently, there is a potential risk of transmission of resistant genes from companion animals to humans (Pomba et al. 2017, Schwarz et al. 2017), giving more reasons for veterinarians to be more careful with antibacterial drugs used in companion animals. Responsible off-label use of antibiotics is critical for minimizing the development of antimicrobial resistance, a significant public health concern. Use of antimicrobials should be addressed in the context of One Health Concept of the World Health Organisation (WHO). One Health involves the public health, veterinary, public health and environmental sectors. (WHO 2017). Ethically, veterinarians must balance their obligation to treat animals effectively with the responsibility to avoid harm.

5. CONCLUSION

In conclusion, the findings of this study indicate that in small animal veterinary practice in North Macedonia, the off-label use of human medicinal products, particularly antibacterial drugs, remains a widespread and routine clinical practice. This situation reflects the limited availability and limited registration of veterinary-licensed, as well as the need for veterinarians to use drugs intended for human use in order to manage a broad range of medical conditions in dogs and cats.

Clearer professional guidelines and better regulation are needed to provide veterinarians with clear and standardized protocols, thereby justifying the use of human drugs.

To ensure safer and more rational use of off label drugs in veterinary medicine more studies are needed. Future research should focus on collecting more evidence-based data, evaluating treatment outcomes, and identifying potential risks associated with off-label use of human drugs in small animal practice. These efforts should be complemented by the development of national recommendations and clinical guidelines that support veterinarians in making informed and responsible therapeutic choices.

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