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**Biology-Zoology**

# Comparative analysis between the WHO and WOAH classifications for veterinary antimicrobials in Brazil

## Análise comparativa entre as classificações da OMS e da OMSA para os antimicrobianos de uso veterinário no Brasil

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## ABSTRACT

Most antimicrobials used globally in human medicine are also employed in animal treatment, increasing the risk of antimicrobial resistance. In this context, the World Health Organization (WHO) and the World Organisation for Animal Health (WOAH) classified antimicrobials according to their importance in human and veterinary health. This study analyzed the antimicrobial molecules commercially available in Brazil for animal use, comparing their classifications based on WHO and WOAH criteria. Data was collected by consulting the Business Intelligence panel of the Ministry of Agriculture and Livestock (MAPA). A total of 742 registered drugs were identified, comprising 70 distinct antimicrobial molecules, totaling 888 occurrences in different drug formulation combinations. Among these molecules, 55.2% were considered Highly Important Antimicrobials (HIA) by the WHO, while 85.5% were categorized as Critically Important Veterinary Antimicrobial Agents (VCIA) by the WOAH. Divergences in classifications between the organizations were observed, highlighting potential challenges for veterinarians in clinical decision-making.

**Keywords**: Antibiotic therapy; Resistance genes; One Health

## RESUMO

A maioria dos antimicrobianos utilizados globalmente na medicina humana também é empregada no tratamento animal, aumentando o risco de resistência antimicrobiana. Nesse contexto, a Organização Mundial de Saúde (OMS) e a Organização Mundial de Saúde Animal (OMSA) procederam à classificação dos antimicrobianos de importância na saúde humana e veterinária. Este estudo analisou as moléculas de antimicrobianos disponíveis comercialmente no Brasil para uso em animais, comparando suas

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classificações conforme os critérios da OMS e da OMSA. A coleta de dados foi realizada a partir da consulta ao painel *Business Intelligence* do Ministério da Agricultura e Pecuária (MAPA). Foram identificados 742 medicamentos registrados, compostos por 70 moléculas distintas de antimicrobianos, que totalizaram uma frequência de 888 ocorrências em diferentes combinações de formulações medicamentosas. Dentre essas moléculas, 55,2 % foram consideradas como altamente importantes (HIA) pela OMS, enquanto 85,5 % foram categorizadas como agentes veterinários criticamente importantes (VCIA) pela OMSA. Foram observadas divergências nas classificações entre as Organizações, as quais destacam potenciais desafios na tomada de decisão pelos médicos veterinários.

**Palavras-chave:** Antibioticoterapia; Genes de resistência; Saúde Única

## 1 INTRODUCTION

Contemporary medicine underwent a significant revolution in the 20th century with the introduction of antibiotic therapy. This began in 1928, when Alexander Fleming discovered penicillin, marking the start of the "Antibiotic Era" (Fleming, 1945). Since then, a series of innovative compounds has enabled the effective combat of bacteria, leading to advances in the treatment of various infections, surgical procedures, organ transplantation, and increased life expectancy (Ventola, 2015; O'Neill *et al*., 2016). Additionally, they have improved animal Health conditions, contributing to animal welfare and productivity (Hao *et al*., 2014).

However, despite the remarkable progress, the widespread use of antimicrobials has led to the acceleration of the development and spread of bacterial resistance genes, jeopardizing many of the therapies currently available and raising global concerns (Estany-Gestal, Salgado-Barreira, & Vazquez-Lago, 2024). The indiscriminate use of these agents in both human and veterinary medicine leads to environmental contamination due to the disposal of pharmaceutical waste in soil and water, which increases selective pressure on bacteria (Hsieh, Huang, & Lee, 2009).

In the long term, the increase in antibiotic resistance is responsible for developing superbugs. Consequently, there is an increase in morbidity and mortality rates, as well as a rise in the treatment costs of various diseases (Chen, Kumar, & Wu, 2023). In 2019, approximately 5 million human deaths worldwide were associated with antimicrobial

resistance (Murray *et al*., 2022), a number that is expected to rise to 10 million victims by 2050 (Ranjbar & Alam, 2019).

The spread of antimicrobial residues is a complex issue, as it is intrinsically related to three major spheres: humans, animals, and the environment (Boqvist, Söderqvist, & Vågsholm, 2018). Thus, the concept of "One Health," proposed in the 1990s, advocates for "an integrated and unifying approach that aims to sustainably balance and optimize the health of people, animals, and ecosystems," and it should be adopted to combat antimicrobial resistance (WOAH, 2022a).

Since most antimicrobials used globally in humans are also intended for animal use (Van Boeckel *et al*., 2017), international organizations have been mobilizing to promote global actions aimed at mitigating the development of antimicrobial resistance and preserving the effectiveness of existing medications. In this context, the World Health Organization (WHO) and the World Organisation for Animal Health (WOAH) classified antimicrobials of clinical (human) importance and antimicrobials of veterinary importance, respectively. The categorization aims to guide decision-making regarding antimicrobial treatment, ensuring responsible use in both areas while considering the potential risk of antimicrobial resistance development and spread (WOAH, 2021; WHO, 2024).

Due to global concerns about One Health and the contribution of veterinary medicine to the spread of antimicrobial resistance, this study aimed to analyze the different antimicrobial molecules used in veterinary medicine in Brazil and compare them according to classifications established by the WHO and WOAH.

## 2 METHODS

The list of antimicrobials indicated for treating bacterial infections in animals was obtained through a consultation with the Business Intelligence panel of the Ministry of Agriculture and Livestock (MAPA) in March 2024. The "Pharmaceutical Products" section was accessed on the homepage of the website. The search was conducted with the registration status as "ACTIVE," the product class as "ANTIMICROBIALS," and the species indicated as "BEES, BIRDS, CATTLE, DOGS, GOATS, RABBITS, HORSES, CATS,

SHEEP, and PIGS." All commercial products were analyzed and classified according to the antimicrobial molecule, class, subclass, and level of importance based on the WOAH classification. In addition, it was verified whether the classes are also authorized for use in humans, based on their level of importance, according to the criteria established by the World Health Organization (WHO).

WOAH (WHO, 2024) defined the classification of the importance level based on the fulfillment of two criteria. The first criterion is related to the response rate to a questionnaire sent to experts regarding the importance of a particular antimicrobial agent. The criterion was considered met when more than 50% of the respondents identified the antimicrobial as necessary. The second criterion was established based on the treatment of animal diseases and the viability of alternative antimicrobial agents. It was considered met when the active ingredients (molecules) within the class were identified as essential for treating specific infections, and there were no sufficient therapeutic alternatives. Antimicrobials that met both criteria were categorized as Critically Important Veterinary Antimicrobial Agents (VCIA), and those that met one of the two criteria were categorized as Highly Important Veterinary Antimicrobial Agents (VHIA). Antimicrobials that did not meet either criteria were classified as Important Veterinary Antimicrobial Agents (VIA).

On the other hand, the WHO categorized antimicrobials based on their importance for human medicine and the risk of antimicrobial resistance, considering the implications that the use of antimicrobials in animals may have on human Health, according to the established criteria and prioritization factors (WOAH, 2021). Thus, antimicrobials were classified by WHO as authorized for use only in humans, which include Critically Important and High Priority Antimicrobials (HPCIA) and Critically Important Antimicrobials (CIA), authorized for both human and animal use, which encompass the classifications Highly Important Antimicrobials (HIA) and Important Antimicrobials (IA); and authorized for animal use only.

The antimicrobial data obtained from the MAPA system, along with their respective classifications according to WHO and WOAH, were tabulated in Excel. The

frequency distribution was then analyzed using SPSS software to understand better the molecules available for use in veterinary medicine in the country.

## 3 RESULTS AND DISCUSSION

### 3.1 Antimicrobial molecules marketed in Brazil

The MAPA Business Intelligence (BI) panel survey identified 742 registered antimicrobial medications intended for use in various animal species. Among the medications, 70 molecules with antibiotic activity were identified and distributed across 16 classes.

When analyzing the compositions of the medications, it was found that these molecules appear a total of 888 times (Table 1), reflecting their presence in multiple commercial formulations, which may consist of a single molecule or a combination of them. This data highlights the wide availability of antimicrobials in the national market and emphasizes the recurrence of certain active ingredients in combined formulations.

The three most frequent classes of antimicrobials in the formulations were penicillins (18.8%), sulfonamides (17%), and quinolones (13.3%), representing the most common active ingredients in the Brazilian market. Penicillins account for 39.2% of the antimicrobials available for goats, 35.7% for horses, and 30.9% for cattle. Sulfonamides were the main class for birds (35.8%), pigs (30.0%), and sheep (18.5%), while quinolones had the highest usage frequency in dogs (25.8%) and cats (23.6%).

A 2014 survey of 3,004 European veterinarians found that penicillin was the most commonly used class of antimicrobials in veterinary medicine (Briyne, Atkinson, Borriello & Pokludová, 2014). The annual WOAH report on antimicrobial agents for animal use revealed that penicillin was the most frequently used class of antimicrobials in the treatment of animals in 55 countries (WOAH, 2022b), which corroborates our research findings.

Table 1 – Classes of Antimicrobials Available in the National Market for Different Animal Species in 2024

| Classes of antimicrobials | n | % |
|---|---|---|
| Penicillin | 167 | 18,8 |
| Sulfonamides | 151 | 17,0 |
| Quinolones | 118 | 13,3 |
| Tetracyclines | 101 | 11,4 |
| Aminoglycosides + 2-Deoxystreptamine | 85 | 9,6 |
| Cephalosporin | 63 | 7,1 |
| Aminoglycosides | 62 | 7,0 |
| Macrolides | 44 | 5,0 |
| Amphenicols | 36 | 4,1 |
| Pleuromutilins | 22 | 2,5 |
| Polypeptides | 18 | 2,0 |
| Lincosamides | 15 | 1,7 |
| Phosphonic acid derivatives | 2 | 0,2 |
| Treatment of mycobacteria | 2 | 0,2 |
| Ansamycins | 1 | 0,1 |
| Ionophores | 1 | 0,1 |
| Total | 888 | 100,0 |

Source: Adapted from MAPA BI Panels (2024)

Legend: *n: number of observations; %: percentage of observations

Furthermore, the results of the present study show that, despite the wide availability of antimicrobial molecules for animals in the national market, totaling 70 different molecules, commercial products mainly focus on using only 10 molecules,

which together account for more than 50% of the total medications available in Brazil. Considering all animal species, the most used molecules in the 742 available medications were enrofloxacin in 83 (9.3%) products; trimethoprim in 58 (6.5%); oxytetracycline in 53 (6.0%); procaine benzylpenicillin in 45 (5.1%); neomycin in 41 (4.6%); gentamicin in 40 (4.5%); florfenicol in 34 (3.8%); doxycycline in 32 (3.6%); ceftiofur in 30 (3.4%); and dihydrostreptomycin in 29 (3.3%) commercial products.

### 3.2 Classification of antimicrobial molecules according to OIE

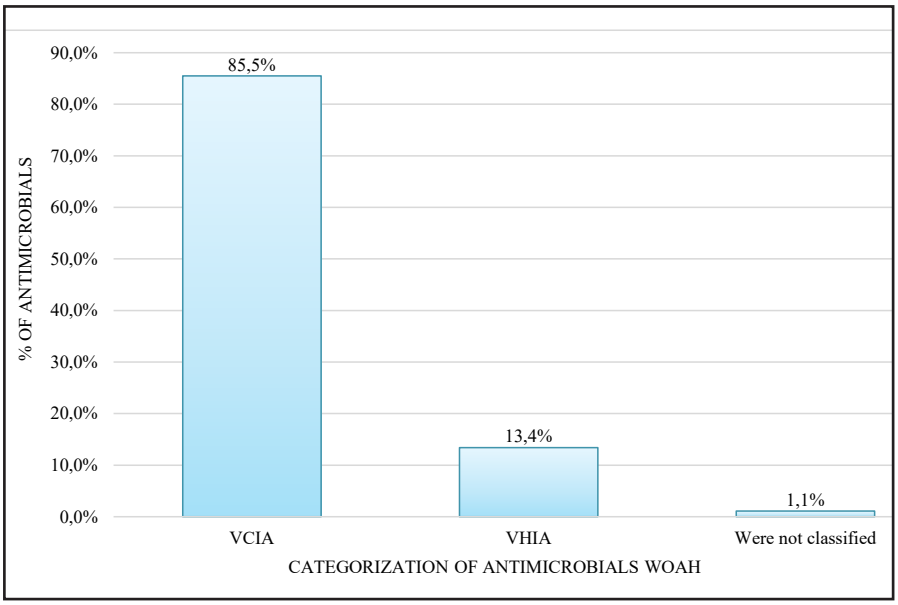
The frequency of occurrence of molecules in commercially available antimicrobial formulations in Brazil, along with their respective classification according to the criteria established by OIE, is presented in Graph 1.

Three molecules did not fit into any of the WOAH classifications: azithromycin (n = 6), isoniazid (n = 2), and pradofloxacin (n = 2). None of the commercially available molecules were classified as VIA, demonstrating that a high percentage of the active ingredients in medications in Brazil are considered critical, making it essential that they remain available to ensure animal Health (Gehring, Mochel, & Schmerold, 2023).

WOAH classified all 10 molecules with the highest frequency of occurrence in commercially available formulations as VCIA (WOAH, 2021). Therefore, veterinarians must prescribe antimicrobials with a high level of scrutiny, using bacterial identification tests and antimicrobial susceptibility testing rather than relying on the empirical selection of these drugs (Gehring *et al*., 2023).

In 2020, Souza and colleagues assessed antimicrobial resistance in 235 bacterial strains isolated from infections in companion animals in Paraná. The study identified 64.26% of the agents as multidrug-resistant and 15.32% as extensively drug-resistant. Additionally, ten bacteria showed isolated susceptibility to certain drugs while being resistant to all other tested classes (Souza *et al*., 2020).

Graph 1 – Classification according to WOAH and frequency of occurrence of the molecules of the Antimicrobials in Commercially Available Medications in Brazil in 2024




Source: The authors (2024)
Legend: VCIA: Critically Important Veterinary Antimicrobial Agent. VHIA: Highly Important Veterinary Antimicrobial Agent

In food-producing animals, the situation is also concerning. A study investigated the antimicrobial resistance profile of non-Aureus *Staphylococcus* in 190 mastitis isolates from buffaloes, goats, and sheep in the Northeast region of Brazil. The results showed that 30.8% of the isolates from buffalo milk samples, 25.8% from goats, and 25% from sheep exhibited multidrug resistance to beta-lactams (de Souza Santos *et al*., 2020). In pig farming, an analysis of 160 bacterial strains isolated from 51 farms in Brazil found that 98.75% of the isolates were resistant to at least one antimicrobial agent. In contrast, 31.25% of the strains were multidrug-resistant (Serpa *et al*., 2020). These data demonstrate the emergence of antimicrobial resistance, a particularly alarming scenario, given its interaction with One Health, which affects animal, human, and environmental health (Boqvist *et al*., 2018).

Azithromycin is a widely used antimicrobial in humans and animals, and it is used in treating infections in the genitourinary, respiratory, oral, and skin systems (Serpa *et al*., 2020). In Brazil, this molecule is present in six commercially available

veterinary drugs, most of which are indicated for use in dogs and cats (five drugs). At the same time, one is also indicated for horses. Its use is recommended for treating various diseases; however, there are already reports of resistant strains in humans and animals (Retsema, 1999; Pereira *et al*., 2009; Oliveira *et al*., 2016; Vaz *et al*., 2021). The WOAH's absence of classification of azithromycin as an important veterinary agent may encourage its inappropriate use, accelerating the resistance process. This fact also poses a risk to human Health, as azithromycin is widely used, including for the treatment of sexually transmitted infections caused by chlamydiae, which are distinct and difficult-to-treat bacteria (Van Cutsem, 2023).

Isoniazid, a molecule not listed in the WOAH classification, may have been excluded because the WHO recognizes it as exclusively for human use. Since 1952, this molecule has been used as a first-line treatment for human tuberculosis, the second leading cause of death worldwide from a single infectious agent after COVID-19 (Marques, de Barros, & Lima, 2021), which justifies its restriction for veterinary use.

In Brazil, the treatment of bovine tuberculosis is prohibited by law, and the control and eradication of the disease in cattle are carried out through the euthanasia of positive animals (WHO, 2023). However, although isoniazid is not used in treating bovine tuberculosis, this molecule is commercially available in Brazil as one of two medications used to treat other respiratory diseases in cattle. This finding may serve as a warning for the spread of resistance genes to the Mycobacterium genus, which can be shared between humans and cattle (Brasil, 2017; Vázquez-Chacón *et al*., 2021).

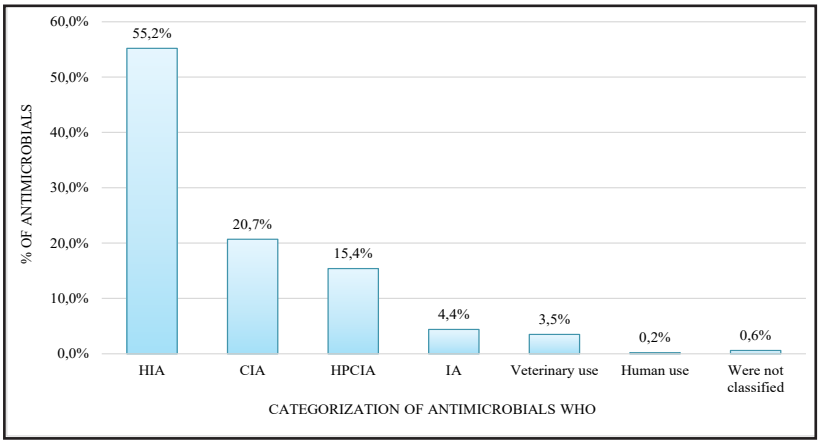
Pradofloxacin, not listed by the WOAH, is the newest third-generation veterinary fluoroquinolone, approved for use in dogs and cats (Borham *et al*., 2022) and, recently, also in food-producing animals (Sykes & Blondeau, 2014). This molecule showed superior activity against certain bacteria, with a lower likelihood of resistance development compared to azithromycin or enrofloxacin (Blondeau & Fitch, 2024). Although pradofloxacin is used in the treatment of bacterial diseases in dogs and cats, an in vitro study demonstrated that this molecule could be a valuable ally to other antimicrobial agents for treating bovine

respiratory diseases (Biswas, Maggi, Papich, Keil, & Breitschwerdt, 2010). Therefore, it is necessary to update the WOAH classification to include this active ingredient in its list of antimicrobials authorized and marketed in veterinary medicine, ensuring a more comprehensive and up-to-date approach to the responsible use of these drugs.

## 3.3 Classification of antimicrobial molecules according to the WHO

The frequency of occurrence of molecules in commercially available antimicrobial formulations in Brazil, along with their respective classification according to WHO criteria, is presented in Graph 2.

Graph 2 – Classification according to the WHO and frequency of occurrence of antimicrobial molecules in commercially available drugs in Brazil in 2024




Source: The authors (2024)
Legend: HIA: Highly Important Antimicrobial; CIA: Critically Important Antimicrobial; HPCIA: Critically Important and High Priority Antimicrobial; IA: Important Antimicrobial

Monensin was the only molecule classified as exclusively for veterinary use by the WHO, and when compared to the WOAH classification, it received the highest criticality level. The WHO classified Isoniazid as exclusive for human use and is not listed by the WOAH. In addition, the molecules sulfacetamide and sulfadoxine were not mentioned in the WHO list and, therefore, were not classified in terms of their level of importance. While the WOAH did not classify sulfacetamide, sulfadoxine received the highest level of criticality (WOAH, 2021; WHO, 2024).

According to the WOAH, the 10 most used molecules in veterinary medicine were classified as VCIA (Veterinary Critically Important Antimicrobials). However, in the classification according to WHO criteria, discrepancies were observed in the level of criticality at which the same molecules were classified. According to the WHO, procaine benzylpenicillin, oxytetracycline, doxycycline, florfenicol, and trimethoprim were classified as HIA, while dihydrostreptomycin, neomycin, and gentamicin were classified as CIA. Only the molecules ceftiofur and enrofloxacin, both classified as having a lower level of criticality, received the highest importance classification under HPCIA.

Among the antimicrobials classified as HPCIA, many are considered critically important to human and animal Health. They should be used only in essential cases, when there are no therapeutic alternatives, such as fluoroquinolones and third- and fourth-generation cephalosporins (PAHO & MAPA, 2022). When analyzing the molecules that make up the commercially available antimicrobial drugs for veterinary use in Brazil, third-generation cephalosporins (cefoperazone and ceftiofur) and fourth-generation cephalosporins (cefoquimone) were identified.

Although they are widely used only in veterinary medicine, ceftiofur and cefquinome were classified by the WHO as HPCIA due to the risk they pose to One Health, as they belong to the beta-lactam class and thus have mechanisms of action similar to ceftriaxone, a drug used to treat severe bacterial infections in humans. Thus, their use may increase the selection pressure and the spread of resistance genes, including those responsible for producing extended-spectrum beta-lactamases (Sato *et al*., 2014; Taylor et al., 2021).

A 2019 study in the State of São Paulo showed that veterinary professionals made third—and fourth-generation cephalosporins their first choice for treating mastitis. It also found that personal experience and the shorter withdrawal period were the most critical criteria in therapy selection. This contradicts global recommendations for the judicious use of these compounds and represents a crucial point regarding the risks of antimicrobial resistance (Nobre, 2019).

The present study also observed that the molecules cefoperazone, colistin, fosfomycin, and polymyxin B have the highest risk classification by the WHO, categorized as HPCIA. At the same time, the WOAH classified these molecules as intermediate risk, labeling them as VHIA.

Colistin was reclassified by the WHO in 2024 as a higher priority due to its increased use for treating severe infections in humans worldwide and the reported spread of bacteria resistant to this molecule through food. In human medicine, colistin is considered the last resort for treating multidrug-resistant Gram-negative Enterobacteriaceae. Even with the restricted indication for use, isolates from humans and animals with resistance genes have been identified, and these can be transmitted along the food chain (WHO, 2024).

In Brazil, MAPA has prohibited the use of colistin as a zootechnical additive to improve animal performance in feed since 2016, through Normative Instruction No. 45, dated November 22, 2016 (Brazil, 2016). Subsequently, Normative Instruction No. 01, dated January 13, 2020, expanded this restriction, prohibiting other performance-enhancing additives, such as tylosin, lincomycin, and tiamulin (Brazil, 2020).

Despite recommendations for the use of colistin in animals to be highly restricted, its use as a growth promoter in food-producing animals in some countries still represents a significant risk factor for the spread of antimicrobial resistance, which can compromise its effectiveness as a therapeutic resource in humans (EMA, 2022). According to the WOAH annual report, there was a concerning 2% increase in the use of antimicrobials in animals globally between 2019 and 2021, following several consecutive years of significant decline. These data indicate an increase in the use of antimicrobials in the animal sector, which is linked to the use of these drugs as growth promoters, including colistin, which has a higher priority (WOAH, 2024a).

### 3.4 Challenges in the classification of antimicrobials and impacts on One Health

The WOAH's classification was conducted in June 2021, while the WHO's was published in February 2024. The different methodologies adopted by the institutions and the periods during which the classifications were conducted may explain the discrepancies observed. Although both classifications are interconnected and share the goal of guiding the appropriate use of antimicrobials, different perceptions of clinical value and associated risks inevitably lead to variations in classifying these compounds (Gehring *et al*., 2023).

During the conduct of this study in May 2024, the WOAH published a technical working document, highlighting, as a future goal, updating the list of antimicrobial classifications of veterinary importance (WOAH, 2024b). This process will involve reviewing the criteria to align with the new classification list from the WHO, released in February 2024. However, until this update is implemented, the lack of alignment between the classifications may confuse veterinarians' decision-making related to antimicrobial treatment.

Responsible and judicious veterinary prescribing is essential to prevent the development and spread of resistance. This includes the proper selection of antimicrobials based on factors such as the target species, route of administration, antimicrobial culture and susceptibility testing, and the environment in which the animal is housed (Ballash, Parker, Mollenkopf, & Wittum, 2024). Therefore, classifying antimicrobials according to their level of criticality, coupled with a cautious clinical approach, is an essential tool to help professionals make more informed decisions, thereby reducing the risk of emerging resistant bacterial strains.

Although it is evident that the use of antimicrobials in veterinary medicine plays a significant role in antimicrobial resistance, predicting its risks and direct impacts is not an easy task, which can hinder the development of specific actions within the One Health framework (McEwen & Collignon, 2018). In Brazil, Normative Instruction No. 26,

dated July 9, 2009, establishes criteria for the registration, manufacturing, control, and use of veterinary antimicrobials, covering aspects such as efficacy, safety, and residues, among others (Brazil, 2009) however, the commercialization of these medications to the final consumer is still not subject to regulation. Thus, the acquisition of antimicrobials for animal use is carried out without proper supervision, and the competent authority has no control over prescriptions or sales volumes (Rached & Grotto, 2023).

The easy sale of these products to the final consumer compromises veterinary care. Using these medications without professional recommendation can harm animal Health, given that pet owners often lack the necessary knowledge. Additionally, self-medication can compromise care and diagnosis because it may mask clinical signs or worsen the clinical condition. Moreover, improper use can promote the development of antimicrobial resistance (Costa Junior, 2018).

In this context, One Health faces a concerning scenario, as the availability of these products for purchase without the requirement for a veterinary prescription, coupled with the lack of reliable data on the commercialization of antimicrobials in animals, hinders the development of strategies to combat antimicrobial resistance. Therefore, there is a need to develop a comprehensive surveillance system for the use of antimicrobials in animals and the spread of resistance genes in the country, to facilitate the implementation of truly effective interventions. This may aid in establishing criteria for future antimicrobial classifications.

On the other hand, there has been progress in Brazil regarding the traceability of antimicrobials intended for animal use through the country's participation in the "Working Together to Combat Antimicrobial Resistance" project, funded by the European Union and led by the regional office of the Pan American Health Organization (PAHO), in collaboration with the United Nations Food and Agriculture Organization (FAO) and WOAH. Brazil's participation aims to drive the implementation of the National Action Plan for the Prevention and Control of Antimicrobial Resistance within the One Health framework (PAN-BR), the National Action Plan for the Prevention and Control of

Antimicrobial Resistance in Agriculture (PAN-BR AGRO), and, finally, the National Program for the Prevention and Control of Antimicrobial Resistance in Agriculture (AgroPrevine). These plans aim to strengthen public policies to address antimicrobial resistance in the country, promoting coordinated and practical actions (PAHO & MAPA, 2022).

## 4 CONCLUSION

The analysis of antimicrobials marketed in Brazil reveals a concerning scenario regarding antimicrobial resistance, considering the widespread availability of these medications for veterinary use. The WHO and OMSA have made efforts to establish guidelines for the responsible use of antimicrobials; however, the divergences between their approaches create barriers to evidence-based therapeutic decision-making by veterinarians, particularly regarding molecules classified as high-priority.

In the Brazilian scenario, OMSA considers a high proportion of veterinary antimicrobials critically important, while the WHO assigns a lower level of criticality to a significant portion of these molecules. The lack of uniformity, coupled with the scarcity of specific data on the consumption and use of antimicrobials in animals in the country, hampers the development of effective strategies to contain antimicrobial resistance. Thus, it becomes imperative to develop national monitoring systems, harmonize international classifications, and implement robust regulatory policies guided by the principles of One Health to mitigate associated risks and preserve the long-term effectiveness of antimicrobials.

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