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# Veterinary Antimicrobial Products Classifications

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# Veterinary Antimicrobial Products Classifications

Version 1.0

Saudi Food & Drug Authority

Drug Sector

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## **Saudi Food and Drug Authority**

### **Vision and Mission**

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#### **Vision**

To be a leading international science-based regulator to protect and promote public health

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#### **Mission**

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

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## Document Control

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## Table of Contents

➤	Glossary .....	6
1.	INTRODUCTION .....	7
1.1.	Background .....	7
1.2.	Purpose.....	7
1.3.	Scope.....	7
2.	CRITERIA FOR CLASSIFICATION OF VETERINARY ANTIMICROBIAL PRODUCTS:.....	8
3.	VETERINARY ANTIMICROBIAL PRODUCTS CLASSIFICATIONS:.....	10
3.1.	Category .....	10
4.	Antimicrobials shall not be used for the following circumstances: .....	10
4.1.	Use of Antimicrobials for Growth Promotion: .....	10
5.	Appendix:.....	11
	Appendix 1- Prohibited antibiotic substances.....	11
	Appendix 2 - Restricted antibiotic substances .....	12
➤	References .....	13

## ➤ Glossary

<b>AMR</b>	Antimicrobial Resistance
<b>MAH</b>	Marketing Authorization Holder
<b>SFDA</b>	Saudi Food and Drug Authority
<b>OIE</b>	World Organization for Animal Health
<b>WHO</b>	World Health Organization
<b>GCC</b>	Gulf Cooperation Council

## 1. INTRODUCTION

### 1.1. Background

Antimicrobial resistance is a global health threat that leads to the spread of drug-resistant pathogens not responding to the available antimicrobials and increased risk of morbidity and mortality worldwide. <sup>(1)</sup> This threat requires an immediate response to control and minimize the spread of drug-resistant pathogens globally. <sup>(2)</sup> Moreover, AMR has severe medical and economic consequences due to prolonged hospital stays and the need for an intensive care. These AMR consequences are emphasizing the need for an effective tool to prevent and treat drug-resistance infections and improve the effectiveness of the currently available antimicrobials, especially in immunocompromised patients. <sup>(1)</sup> Veterinary antimicrobial classification is an essential tool that helps establish antimicrobial stewardship to reduce antimicrobial resistance and emphasize the appropriate use of antimicrobials. The antimicrobial classification is intended to support antimicrobial monitoring and minimize the risk of AMR. <sup>(2)</sup> Furthermore, the regulation of Veterinary Products in GCC emphasizes the issuing and publishing of lists for veterinary products which are entirely prohibited, and lists of veterinary products that are restricted from being used on specific animal species. <sup>(7)</sup>

### 1.2. Purpose

The veterinary antimicrobials classification aims to guide the stakeholders (Marketing Authorization Applicants and veterinarians) in classifying the veterinary antimicrobial products. This classification is updated periodically to ensure the ultimate safety and efficacy of antimicrobials among animals in Saudi Arabia, promote public health, and provide direct responses to maintain the effectiveness of antimicrobials with high importance.

### 1.3. Scope

This guidance applies to antimicrobial veterinary products intended for animal use as the classifications of veterinary antimicrobial products take place following the complete assessment of products undergoing registration by SFDA. At the time of the submission, the applicant should refer to veterinary antimicrobial product classifications and mention the antimicrobial class in the product's cover letter.

## 2. CRITERIA FOR CLASSIFICATION OF VETERINARY ANTIMICROBIAL PRODUCTS:

- **The importance of antimicrobial for human health:** Large number of people in the community or in certain high-risk populations who are affected by diseases with very limited antimicrobial choices or/and limitation in the availability of alternative antimicrobial drugs to treat infections.
- **The need to use antimicrobials in veterinary medicines.**
- **The antimicrobial's spectrum of activity.**
- **The availability of alternative antimicrobial drugs.**
- **The risk associated with animal use to public health through development of antimicrobial resistance:** the uncontrolled use of veterinary antimicrobial will raise the risk of antimicrobial resistance among animals and humans as well, via direct contact with animals and via consuming animal products such as; meat, milk and eggs.
- **The antimicrobial class is the sole, or one of the limited available therapies to treat serious bacterial infections in human:** An evident that antimicrobials that are the sole or one of few alternatives for the treatment of series bacterial infections in humans occupy an important place in medicine.
- **The route of administration:** The route of administration has a remarkable effect on the ability to transmit AMR, the oral route via feed, premixes, drinking water, or milk replacer is considered the highest risk of transmitting AMR and is followed by injectable drugs and other oral routes such as tablets. Parenteral treatments are considered less risky, and local individual treatments are the lowest risk of AMR transmission. <sup>(1)</sup>
- **The antimicrobial class is used to treat infections in people caused by bacteria transmitted to human from non-human sources (i.e. Animals) or bacteria that may acquire resistance genes from non-human sources:** Antimicrobial agents used to treat disease caused by bacteria that may be transmitted to humans from non-human sources are considered of higher importance because these are most amenable to risk-management strategies related to non-human antimicrobial usage.



- **The following international classifications were considered:**

- The World Health Organization's ([WHO](#)) [Critically Important Antimicrobials for Human Medicine, 5th Revision \(2023\)](#) is classifying antimicrobials according to their importance in human medicine (e.g. spectrum of activity, potential to develop resistance, and sole, or one of limited available therapies, to treat serious bacterial infections in human). <sup>(8)</sup>
- The World Organization for Animal Health's (OIE) [List of Antimicrobial Agents of Veterinary Importance \(2021\)](#) is classified based on non-human antimicrobial usage for food producing animals (e.g. treatment of serious animal disease and availability of alternative antimicrobial agents). <sup>(6)</sup>

Note: Some pathogens of interest to WHO are less critical in Saudi Arabia. These may reflect the importance of antibacterial agents, resulting in the relatively low reliance on these agents in Saudi Arabia.

### 3. VETERINARY ANTIMICROBIAL PRODUCTS CLASSIFICATIONS:

#### 3.1. Category

- **Prohibited:** Refers to antimicrobials that are not authorized for animal use. These antimicrobials are considered of high importance in human medicine to treat serious bacterial infections and limited or no availability of alternative antimicrobials for effective treatment in case of emergence of resistance to these agents. They are not authorized in veterinary medicine but authorized in human medicine by SFDA. ([Appendix 1](#))
- **Restricted:** Antimicrobial products under this class are restricted to specific target species, indications, or routes of administration. Antimicrobial drugs are of high importance to human health. Mitigation strategies to tackle antimicrobial resistance; such as Veterinary antimicrobial classification guideline, need to be implemented to minimize the risk to public health resulting from veterinary use. The restricted antimicrobials under this class should be used whenever possible based on the results of antibiotic susceptibility testing (i.e. Blood culture, urine culture...Etc.). ([Appendix 2](#))
- **Accessible:** Refers to all antimicrobials authorized for animal use and not listed in restricted and prohibited veterinary antimicrobials lists. Antimicrobials under this class have alternatives in human medicine but few in veterinary medicine. Agents belonging to this category are considered low risk to public health. Unnecessary use and unnecessarily long treatment periods should be avoided; moreover, group treatment should be restricted to situations where individual treatment is not feasible.

#### 4. Antimicrobials shall not be used for the following circumstances:

##### 4.1. Use of Antimicrobials for Growth Promotion:

Antimicrobials should not be used for growth promotion purposes especially in food producing animals such as; chickens to increase egg production in large scales. Using antimicrobials should be restricted for treatment purposes only.

## 5. Appendix:

### Appendix 1- Prohibited antibiotic substances

Prohibited	
Antibiotic class, subclasses	Antibiotic(S)
<b>Polymexins</b>	Colistin
<b>Amdinopenicillins</b>	Mecillinam, Pivmecillinam
<b>Carbapenems</b>	Meropenem, Doripenem
<b>Cephalosporins</b>	Fifth Generation Cephalosporins Anti-MRSA Cephalosporins I.E., Ceftaroline And Ceftobiprole
<b>Glycopeptides</b>	Vancomycin
<b>Glycylcyclines</b>	Tigecycline
<b>Ketolides</b>	Telithromycin
<b>Lipopeptides</b>	Daptomycin
<b>Monobactams</b>	Aztreonam
<b>Oxazolidinones</b>	Linezolid
<b>β-Lactamase Inhibitor Combinations</b>	Piperacillin-Tazobactam, Ticarcillin With Clavulanic Acid
<b>Phosphonic Acid Derivates</b>	Fosfomycin
<b>Pseudomonic Acids</b>	Mupirocin
<b>Rifamycins</b>	Rifampicin, Rifaxamin, Rifabutin
<b>Riminofenazines</b>	Clofazimine
<b>Streptogramins</b>	Pristinamycin, Virginiamycin
<b>Sulfones</b>	Dapsone
<b>Antimycobacterials</b> <i>(Drugs used solely to treat tuberculosis or other mycobacterial diseases)</i>	Isoniazid, Ethambutol, Pyrazinamide, Ethionamide, Cycloserine, P-Aminosalicylic Acid, Prothionamide, Capreomycin
<b>Note: Substances newly authorized in human medicine are to be determined.</b>	

## Appendix 2 - Restricted antibiotic substances

Restricted	
Antibiotic class, subclasses	Content of restriction
<b>Gentamicin</b>	Not allowed for: <ul style="list-style-type: none"> <li>• Oral route in food producing and non-food producing animals</li> <li>• Topical and Injection in food producing animals</li> </ul>
<b>Chloramphenicol</b>	Not allowed to be used in veterinary medicine in any dosage form except dosage forms intended for external use
<b>All the Third-generation fluoroquinolones e.g.:</b> <ul style="list-style-type: none"> <li>• <b>Enrofloxacin</b></li> <li>• <b>Ciprofloxacin</b></li> <li>• <b>Levofloxacin</b></li> </ul>	Not allowed for: <ul style="list-style-type: none"> <li>• Use in poultry (Chickens)</li> <li>• Oral route in large animal (To be used via injection only)</li> </ul>
<b>Note: Substances newly authorized in human medicine are to be determined.</b>	

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