EVALUATION OF ANTIBIOTIC/ANTIBACTERIAL FROM PASSIVE VETERINARY DRUG SAMPLES AT NATIONAL VETERINARY DRUG ASSAY LABORATORY (NVDAL) YEAR 2021 – 2024

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ABSTRAK

Antibiotik atau antibakteri merupakan salah satu jenis obat yang paling banyak didaftarkan untuk digunakan pada hewan di Indonesia. Kualitas antibiotik atau antibakteri berperan penting dalam terjadinya resistansi antimikroba. Antibiotik yang bermutu tinggi dan digunakan secara tepat berkontribusi besar terhadap kesehatan hewan serta dapat menekan laju resistansi. Kajian ini bertujuan untuk mengevaluasi berbagai jenis zat aktif antibiotik atau antibakteri dari sampel pasif yang diterima oleh NVDAL pada periode 2021 – 2024. Pemahaman terhadap tren pendaftaran antibiotik sangat penting karena dapat menjadi masukan berharga bagi perumusan kebijakan terkait pemantauan resistansi antimikroba (AMR), pengawasan penggunaan antimikroba (AMU), serta penerapan *antimicrobial stewardship* (AMS). Berdasarkan hasil evaluasi, golongan fluoroquinolon merupakan antibiotik yang paling sering ditemukan pada sampel sertifikasi dan layanan teknis. Sementara itu, tetrasiklin merupakan golongan yang paling banyak ditemukan pada sampel layanan daerah/regional. Beberapa jenis antibiotik yang digunakan pada hewan juga termasuk dalam kelompok highest priority critically important antimicrobials untuk manusia. Oleh karena itu, diperlukan pengaturan dan pemahaman yang lebih mendalam mengenai penggunaan antibiotik berdasarkan tingkat kepentingan veteriner, mekanisme resistansi, serta potensi terjadinya resistansi silang baik dalam satu golongan maupun antar golongan antibiotik.

Kata kunci: antibiotik/antibakteri, BBPMSOH, sampel pasif, golongan antibiotik

ABSTRACT

Antibiotic or antibacterial, is one of the most widely registered drugs for use in animals in Indonesia. The quality of antibiotics/antibacterial plays a significant role in antimicrobial resistance. High-quality antibiotics and their appropriate use significantly contribute to animal health and suppress resistance. This study aims to evaluate various types of antibiotic/antibacterial active substances from passive samples received by NVDAL in 2021 – 2024 period. Understanding the trends in registered antibiotics is important as it provides valuable input for policymaking related to antimicrobial resistance (AMR) monitoring, antimicrobial use (AMU) surveillance, and antimicrobial stewardship (AMS). Based on the evaluation results, fluoroquinolones were the most commonly found antibiotics in both certification and technical service samples. Meanwhile, tetracyclines were the most common among district/ regional samples. Several types of antibiotics used in animals are also included in the Highest Critically Priority Important Antimicrobial for human group. There is a need to regulate and high understanding the use of antibiotics based on the level of veterinary importance, resistance mechanisms, and the high or low probability of cross-resistance within or between antibiotic classes.

Keywords: antibiotic/antibacterial, NVDAL, passive samples, antibiotic class

The National Veterinary Drug Assay Laboratory (NVDAL) is the only technical unit under the Ministry of Agriculture of the Republic of Indonesia responsible for testing the quality of veterinary medicines that are circulating or will be circulated in Indonesia. NVDAL samples are classified into two types, namely active samples and passive samples. Active samples are collected directly by NVDAL officers from the field for monitoring or study purposes. Passive samples consist of certification samples, district/regional service samples, and technical service samples. Certification samples are submitted by veterinary medicine companies (manufacturers, importers, or distributors) for the purpose of registration and samples taken by NVDAL officers from veterinary medicine producers/distributors after the registration number has been issued. District/regional service samples are submitted by veterinary drug inspectors at the districts, municipalities, or provinces for monitoring the quality of veterinary in their respective areas. Meanwhile, technical service samples are submitted by customers for personal or specific purposes and cannot be used for registration process or monitoring.

Every veterinary medicine to be registered, either for new registration or re-registration, must undergo quality testing at NVDAL. Re-registration is required when the validity period of the veterinary drug registration number reaches 10 years from the distribution permit was issued by the Ministry of Agriculture. Only veterinary medicines that meet quality requirements are permitted to proceed with the registration and/or distribution process. All the process of new-registration and re-registration must be met the regulations in Indonesia such as Law Number 41 of 2014 juncto Law Number 18 of 2009 concerning Animal Husbandry and Animal Health, Government Regulation (PP) Number 26 of 2021 concerning the Implementation of the Agricultural Sector, Government Regulation (PP) Number 5 of 2021 concerning the Implementation of Risk-Based Business Licensing, Regulation of the Minister of Agriculture Number 15 of 2021 concerning Business Activity Standards and Product Standards in the Implementation of Risk-Based Business Licensing in the Agricultural Sector, Minister of Agriculture Regulation Number 16 of 2021 concerning Field Studies and Supervision of Veterinary Drugs, and Regulation of the Minister of Agriculture Number 14/PERMENTAN/PK.350/5/2017 of 2017 concerning Classification of Veterinary Drugs.

Antibiotics and antibacterial are among the most widely registered veterinary medicines in Indonesia. According to the Indonesian Veterinary Medicine Index (IHAC, 2023), there are 711 trade names of antibacterial veterinary medicines registered in the country. Antibiotics and antibacterials play an important role in controlling antimicrobial resistance (AMR). However, inappropriate and imprudent antimicrobial use (AMU) can increase both level and diversity of resistance. Conversely, the correct selection of drugs and proper dosing in AMU can help in controlling and reducing the rate of resistance. Therefore, it is essential to ensure that antibiotics and antibacterials circulating in Indonesia meet established quality requirements. Accurate dosing can only be achieved if the active ingredient and its concentration in the finished pharmaceutical product are consistent with the label claim. In addition, injectable and intramammary preparations must be guaranteed to be sterile and non-toxic. The selection of the type of antibiotics for treating infections in the field should be based on accurate diagnosis, the type of bacteria, and bacterial resistance profile. The *World Organisation for Animal Health* (WOAH) classification of the veterinary

importance of antimicrobials should also be carefully considered. Whenever possible, antibiotics of lower importance should be used before resorting to those classified as highly important, in order to preserve the effectiveness of antibiotics categorized as *veterinary critically important antimicrobial agents.*

The aim of this review is to evaluate the types of antibiotics/antibacterials included as passive samples at NVDAL during the 2021 – 2024 period. Understanding the trends in registered antibiotics is important as it provides valuable input for policymaking related to antimicrobial resistance (AMR) monitoring, antimicrobial use (AMU) surveillance, and antimicrobial stewardship (AMS). The results of this review can help inform future policies regarding the authorization, limitation/restriction or ban of antibiotic use in animals.

Materials and Methods

Evaluation was conducted on passive samples containing antibiotic and antibacterial active substances for the period 2021 – 2024. Evaluation was carried out based on the type and quantity of active substance, as well as antibiotic classes. Some of the active substances discussed in this paper also include several classes of antibiotics that function as anticoccidial or antifungal agents.

Discussion

A. Purpose of Antibiotic/Antibacterial Sample Testing

Based on the data presented in Table 1, the proportion of passive samples icontaining antibiotics or antibacterials during 2021 – 2024 ranged from 22.89 to 27.92% of the total of pharmaceutical and premix samples tested at NVDAL. Samples containing antibiotics or antibacterial were the second most frequently tested category in the Pharmaceutical and Premix Laboratory, following multivitamin-multimineral preparations. By passive sample type, certification samples containing antibiotics or antibacterials accounted for **17.27% to 22.30%** of the total certification samples. In 2024, the number of antibiotic-related certification samples decreased due to the absence of sampling activities conducted by NVDAL at distributor, manufacturer, or importer facilities. For district or regional services monitoring samples, the proportion of samples containing antibiotics ranged from 35.62% – 40.54%. The relatively high number of antibiotic samples in this category reflects the strong awareness of veterinary medicine inspectors in district, municipal, or provincial levels regarding the importance of monitoring antibiotic quality. Meanwhile, the number of antibiotic samples in the technical services category s varied depending on the specific needs or interests of the sample owners.

Based on the purpose, certification samples may be submitted for new registration, re-registration, sampling conducted by NVDAL after a product has obtained its registration number, or for other specific purposes, such as, when a registered drug undergoes a change in its manufacturing site. . As the shown in Figure 1 the majority of antibiotic certification samples from 2021 to 2024 were submitted for new registrations. This shows the high interest of the veterinary medicine industry in selling antibiotic preparations.

B. Active substance in antibiotic / antibacterial samples

B.1 Number of antibiotic or antibacterial active substance in veterinary medicine preparation samples

Based on the number of active substances, the majority of certification, district/ regional service monitoring, and technical

service samples collected during 2021 – 2024 were antibiotic or antibacterial samples containing a single active substance (Table 2). Mixed preparations are formulations consisting of two active substances, which may consist of two antibiotics, or one antibiotic with an anticoccidial or antiparasitic agent. Among these combination of sulfadiazine-trimethoprim were the most frequently received mixed antibiotic samples during 2021 – 2024. There is a wide variety of mixed antibiotic combination found in veterinary drugs. As shown in Table 3, certification sample alone contained 24 different two active substances combinations. Data on variations in mixed antibiotic combinations in passive veterinary medicine samples from 2021 to 2024 are presented in Table 3.

B.2 Class and Type of Active Substance of antibiotics/antibacterial from passive sample 2021 – 2024

B.2.1 Antibiotic class from passive sample 2021 – 2024

The variation in antibiotic and antibacterial classes in the 2021 – 2024 certification sample wasvery high, this can be seen from the presence of 19 different antibiotic or antibacterial classes, as shown in Figure 2. In comparison, ł10 antibiotic classes were identified in the district/regional service monitoring samples (Figure 3), and 12 classes of antibiotics were found in the technical service samples. The class of antibiotics most commonly found in certification and technical service samples was the quinolone/fluoroquinolone group. It shows that fluoroquinolones remain among the most in-demand antibiotics within the veterinary pharmaceutical industry. Meanwhile, the tetracycline group was the most commonly found from district/regional service monitoring samples. This difference suggests that while fluoroquinolones are more frequently registered and distributed through formal or offical channels by manufacturers or distributors, tetracyclines are more commonly available at the field level, such as in poultry supply shops or district veterinary drug warehouses. The relatively low number of fluoroquinolone samples in poultry shops may be due to the fact that these products are generally distributed directly from producers or distributors to end users, such as poultry farms.

Table 1 Comparison of the number of veterinary drugs passive samples containing antibiotic/ antibacterial with pharmaceutical and premix samples in 2021 – 2024

Type of samples	Number of samples per year							
	2021		2022		2023		2024	
	Pharm. & Premix	Antibiotic/ Antibacterial	Pharm. & Premix	Antibiotic/ Antibacterial	Pharm. & Premix	Antibiotic/ Antibacterial	Pharm. & Premix	Antibiotic/ Antibacterial
C	807	180 (22,30%)	588	124 (21,09%)	685	152 (22,19%)	660	114 (17,27%)
DM	292	104 (35,62%)	252	100 (39,68%)	268	123 (45,90%)	222	90 (40,54%)
TS	68	28 (41,18%)	73	23 (31,51%)	93	17 (18,28%)	114	24(21,05%)
Total number of samples	**1167**	**312 (26,74%)**	**913**	**247 (27,05%)**	**1046**	**292 (27,92%)**	**996**	**228 (22,89%)**

Note: C = Certification; DM = District/Regional Service Monitoring; TS = Technical Services samples

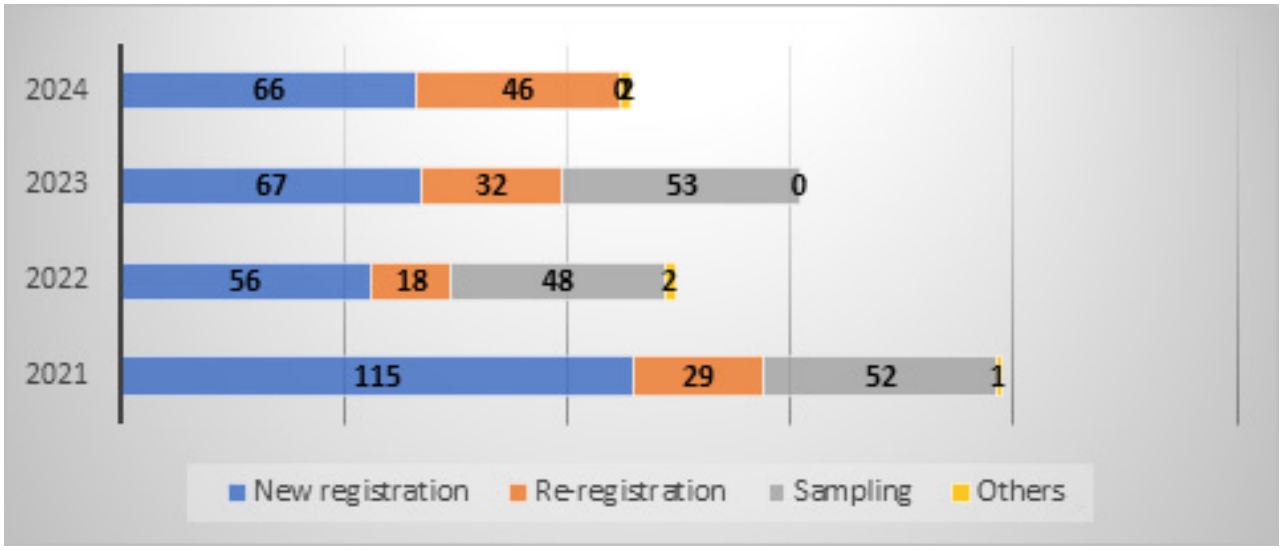

Figure 1 Number of certification samples 2021 – 2024 based on test purposes

Table 2 Number of passive antibiotic or antibacterial samples by number of active substances

Number of active substances	Year											
	2021			2022			2023			2024		
	C	DM	TS	C	DM	TS	C	DM	TS	C	DM	TS
Single antibiotic/antibacterial	153	45	21	98	50	20	129	94	14	87	63	21
Mix antibiotics	38	43	6	19	44	3	15	17	3	18	22	1
Single antibiotic (anticoccidial)**	3	4	-	6	2	-	7	9	-	4	2	-
Antibiotic + anticoccidial	1	8	-	1	3	-	-	3	-	1	2	-
Mix antibiotics (anticoccidial)	1	3	1	-	1	-	-	-	-	2	-	-
Single antibiotic (antifungal)***	1	-	-	-	-	-	1	-	-	1	-	-
Antibiotic + antiparasitic****	-	-	-	-	-	-	-	-	-	2	-	2

Notes: * consist of 2 antibiotics, **antibiotics that also anticoccidial, ***nystatin, ****antibiotic + antiparasitic ivermectin, C= certification samples, DM = District/regional services monitoring samples, TS = technical service samples

Table 3 Variations in mixed antibiotic combinations in passive veterinary medicine samples from 2021 – 2024

Type of Samples	Active substance of mix antibiotics
Certification	amoxicillin – clavulanic acid ampicillin – cloxacillin ampicillin - neomycin calcium fosfomycine - tylosin

Type of Samples	Active substance of mix antibiotics
Certification	cephalexin - kanamycine ciprofloxacin - tylosin doxycycline – erythromycin doxycycline – neomycin enrofloxacin – tylosin enrofloxacin - trimethoprim erythromycin – neomycin erythromycin - tetracycline lincomycin-spectinomycin norfloxacin - tylosin oxytetracycline – amprolium* oxytetracycline – neomycin sulfachloropyridazine - trimethoprim sulfadiazine-trimethoprim sulfadiazine - sulfamerazine sulfadimidine-sulfamerazine sulfadiazine - tetracycline sulfamethoxazole-trimethoprim sulfaquinoxaline – amprolium* sulfaquinoxaline – diaveridine*
District/ Regional Service Monitoring	Ciprofloxacin – tylosin doxycycline – erythromycin enrofloxacin – tylosin erythromycin – tetracycline erythromycin – oxytetracycline erythromycin - sulfadimethoxine lincomycin-spectinomycin norfloxacin - tylosin Oxytetracycline – amprolium* Oxytetracycline - neomycin sulfadiazine-trimethoprim sulfadiazine – tetracycline sulfadiazine - sulfamerazine sulfadoxine – trimethoprim sulfaquinoxaline – diaveridin* sulfaquinoxaline – pyrimethamine*
Technical Services	Chloramphenicol – ivermectin** doxycycline – erythromycin Fosfomycin - tylosin sulfadiazine-trimethoprim

Note: * anticoccidial; **antiparasite

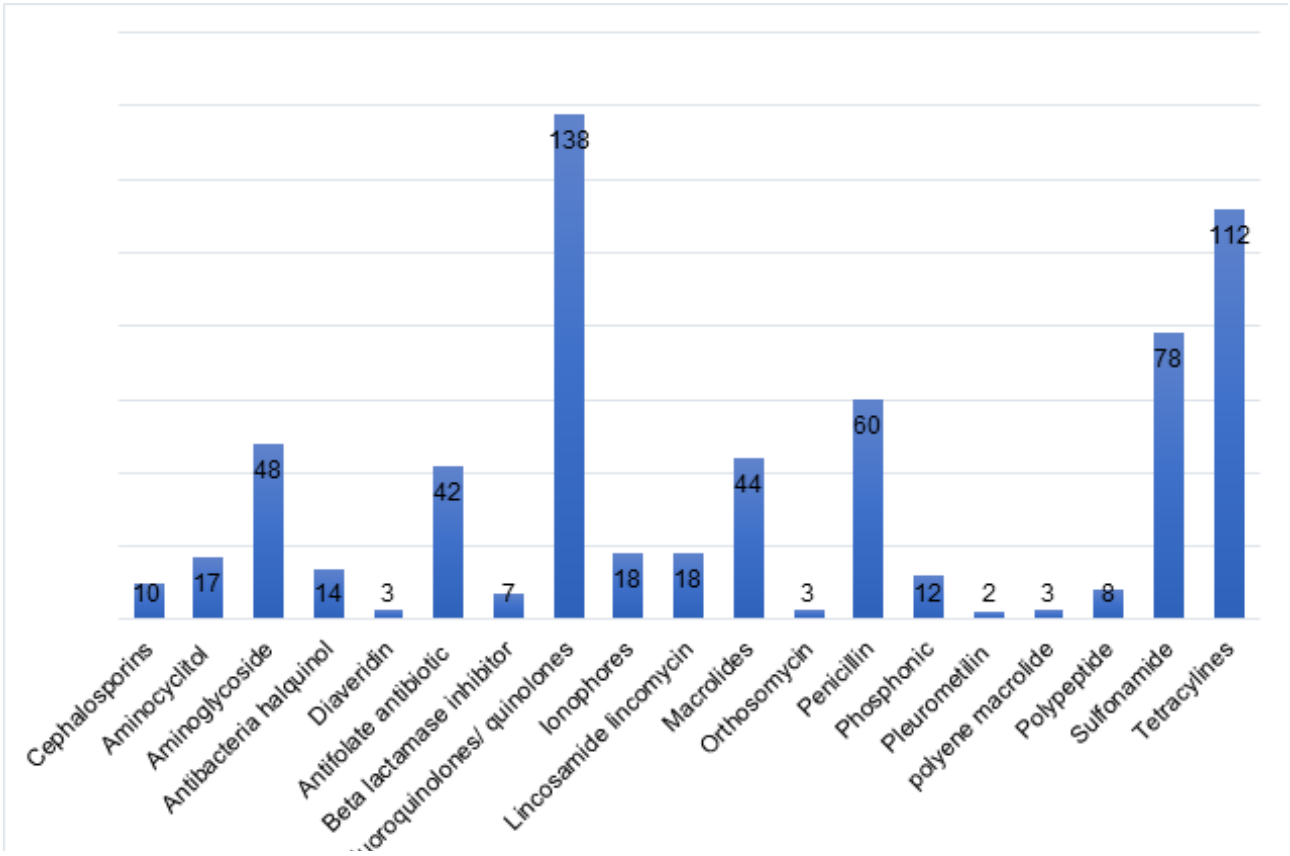

Figure 2 Number of certification samples based on antibiotic / antibacterial class 2021 – 2024

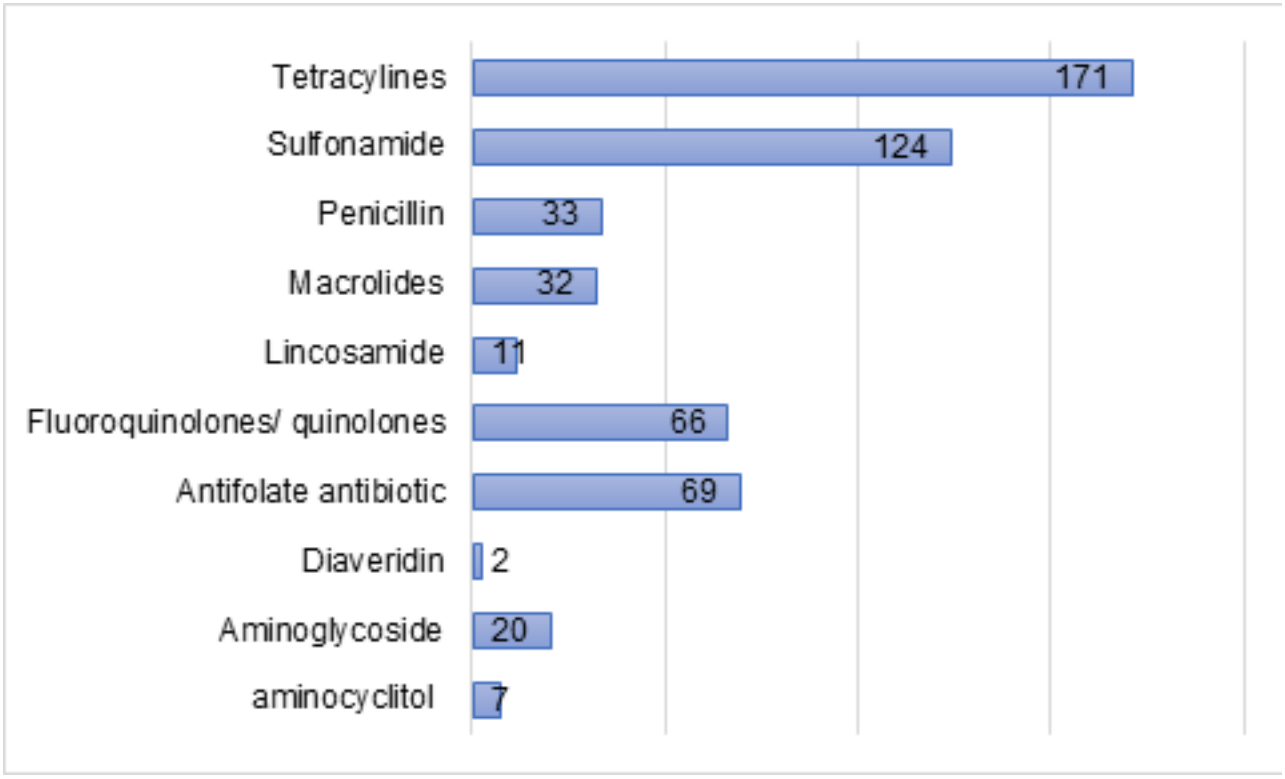

Figure 3 Number of district/ regional services monitoring samples based on antibiotic/ antibacterial class 2021 – 2024

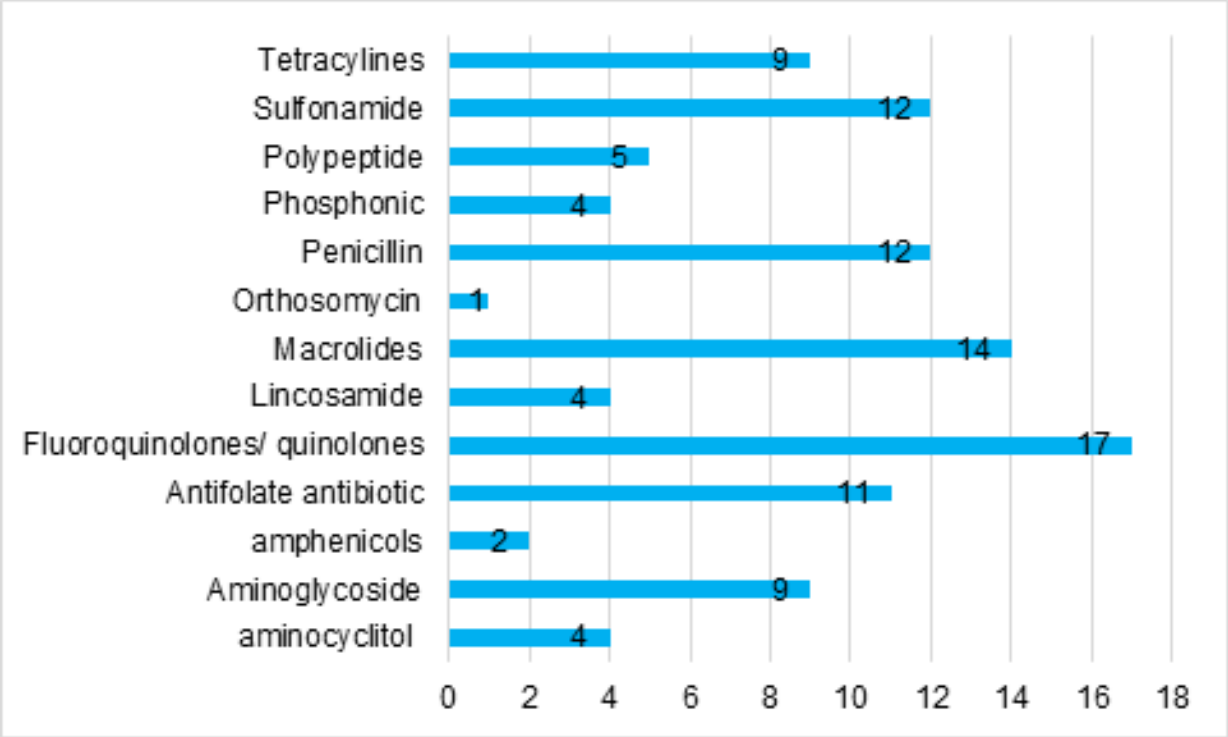

Figure 4 Number of technical service samples based on antibiotic / antibacterial class 2021 – 2024

B.2.3 Type of Active Substance of antibiotics/antibacterial from passive sample 2021 –2024

Table 4 Number of samples based on active substance of antibiotics/antibacterial from passive sample 2021 – 2024

Class antibiotics	Antibiotics	Number of samples per year												Total samples 2021 –2014
		2021			2022			2023			2024			
		C	DM	TS	C	DM	TS	C	DM	TS	C	DM	TS	
1st generation cephalosporines 3rd generation cephalosporins	Cefadroxil	0	0	0	0	0	0	0	0	0	1	0	0	1
	Cephalexin	0	0	0	0	0	0	0	0	0	2	0	0	2
	Ceftiofur	3	0	0	0	0	0	3	0	0	1	0	0	7
	Σ	3	0	0	0	0	0	3	0	0	4	0	0	10
Aminocyclitol	Spectinomycin	4	3	1	5	1	3	5	1	0	3	2	0	28
Aminoglycoside	Gentamicin	5	0	0	1	2	0	8	1	0	2	0	0	19
	Neomycin	7	4	0	7	5	3	7	1	2	5	2	0	43
	Streptomycin	2	0	0	1	2	3	1	2	1	0	1	0	13
	Kanamycin	0	0	0	0	0	0	1	0	0	1	0	0	2
	Σ	14	4	0	9	9	6	17	4	3	8	3	0	77
Amphenicols	Chloramphenicol	0	0	0	0	0	0	0	0	0	0	0	2	2
Antibacterial	Halquinol	1	0	0	1	0	0	3	0	0	9	0	0	14
Antibacterial agent and dihydrofolate reductase (DHFR) inhibitor	Diaveridine	1	2	0	0	0	0	0	0	0	2	0	0	5

Class antibiotics	Antibiotics	Number of samples per year												Total samples 2021 –2014
		2021			2022			2023			2024			
		C	DM	TS	C	DM	TS	C	DM	TS	C	DM	TS	
Antifolate antibiotic	Trimethoprim	18	20	4	6	21	3	8	12	2	10	16	2	122
Beta lactamase inhibitor	Clavulanic acid	3	0	0	1	0	0	0	0	0	3	0	0	7
Fluoroquinolones/ quinolones	Enrofloxacin	30	12	5	22	12	1	19	18	2	14	9	4	148
	Flumequin	3	0	1	1	0	0	2	2	0	4	0	3	16
	Norfloxacin	5	3	0	4	0	0	2	0	0	1	0	0	15
	Ciprofloxacin	10	5	0	5	3	0	4	1	0	8	0	0	36
	Levofloxacin	0	1	0	0	0	0	3	0	1	1	0	0	6
	Marbofloxacin	3	0	0	0	0	0	3	0	0	2	0	0	8
	Σ	48	21	6	32	15	1	30	21	3	28	9	7	221
	Maduramicin	2	0	0	1	0	0	0	0	0	0	0	0	3
	Monensin	0	0	0	1	0	0	2	0	0	3	0	0	6
	Narasin	0	0	0	1	0	0	1	0	0	0	0	0	2
	Salinomycin	1	0	0	2	0	0	2	0	0	1	0	0	6
	Semduramicin	0	0	0	1	0	0	0	0	0	0	0	0	1
	Σ	3	0	0	6	0	0	5	0	0	4	0	0	18
Lincosamide	Lincomycin	2	3	1	6	1	2	7	1	0	3	6	1	33
Macrolides	Erythromycine	12	15	2	9	10	0	3	5	2	3	2	3	66
	Tilmicosin	2	0	0	2	0	0	5	0	1	2	0	1	13
	Tylvalosin	2	0	3	1	0	0	0	0	1	0	0	1	8
	Spiramycin	0	0	0	0	0	0	1	0	0	0	0	0	1
	Tildipyrosine	0	0	0	0	0	0	1	0	0	0	0	0	1
	Kitasamycin	1	0	0	0	0	0	0	0	0	0	0	0	1
	Σ	17	15	5	12	10	0	10	5	4	5	2	5	90
Orthosomycin	Avilamycin	1	0	0	0	0	0	1	0	0	1	0	1	4
Penicillin	Amoxicillin	14	4	1	9	7	6	15	9	1	12	5	4	83
	Ampicillin	1	1	0	1	3	0	1	1	0	3	2	0	13
	Cloxacillin	2	0	0	0	0	0	0	0	0	1	0	0	3
	Penicillin	1	0	0	0	1	0	0	0	0	0	0	0	2
	Σ	18	5	1	10	11	6	16	10	1	16	7	4	101
Phosphonic	Fosfomycin	2	0	3	5	0	1	3	0	0	2	0	0	16
Pleurometilin	Tiamulin	2	0	0	0	0	0	0	0	0	0	0	0	2
polyene macrolide/ antifungal	Nystatin	1	0	0	0	0	0	1	0	0	1	0	0	3
Polypeptide	Bacitracin	0	0	1	1	0	0	3	0	0	0	0	0	5
	Enramycine	2	0	0	1	0	0	1	0	4	0	0	0	8
	Σ	2	0	1	2	0	0	4	0	4	0	0	0	13

Class antibiotics	Antibiotics	Number of samples per year												Total samples 2021 –2014
		2021			2022			2023			2024			
		C	DM	TS	C	DM	TS	C	DM	TS	C	DM	TS	
Sulfonamide	Sulfadiazine	17	16	4	7	24	3	9	11	2	9	16	0	118
	Sulfaquinoxaline	1	7	0	1	3	0	9	11	2	9	16	0	59
	Sulfamerazine	1	0	0	1	6	0	1	0	0	1	0	0	10
	Sulfamonomethoxine	1	0	1	3	0	0	0	1	0	0	0	0	6
	Sulfadimidine	1	0	0	0	0	0	1	0	0	0	0	0	2
	Sulfamethoxazole	2	0	0	0	0	0	1	0	0	0	0	0	3
	Sulfachloropyridazine	1	0	0	0	0	0	0	0	0	1	0	0	2
	Sulfadoxine	0	5	0	0	5	0	0	1	0	0	1	0	12
	Sulfadimethoxine	1	0	0	0	0	0	0	0	0	0	0	0	1
	Sulfadimethylpirimidine	0	1	0	0	0	0	0	0	0	0	0	0	1
	Σ	25	29	5	12	38	3	21	24	4	20	33	0	214
Tetracylines	Chlortetracycline	2	0	1	1	0	0	0	0	0	0	0	0	4
	Doxycycline	15	15	2	9	10	0	6	26	1	12	15	2	113
	Oxytetracycline	26	19	2	14	15	1	19	10	0	5	20	0	131
	Tetracycline	3	5	0	0	7	0	0	19	0	0	10	0	44
	Σ	46	39	5	24	32	1	25	55	1	17	45	2	292

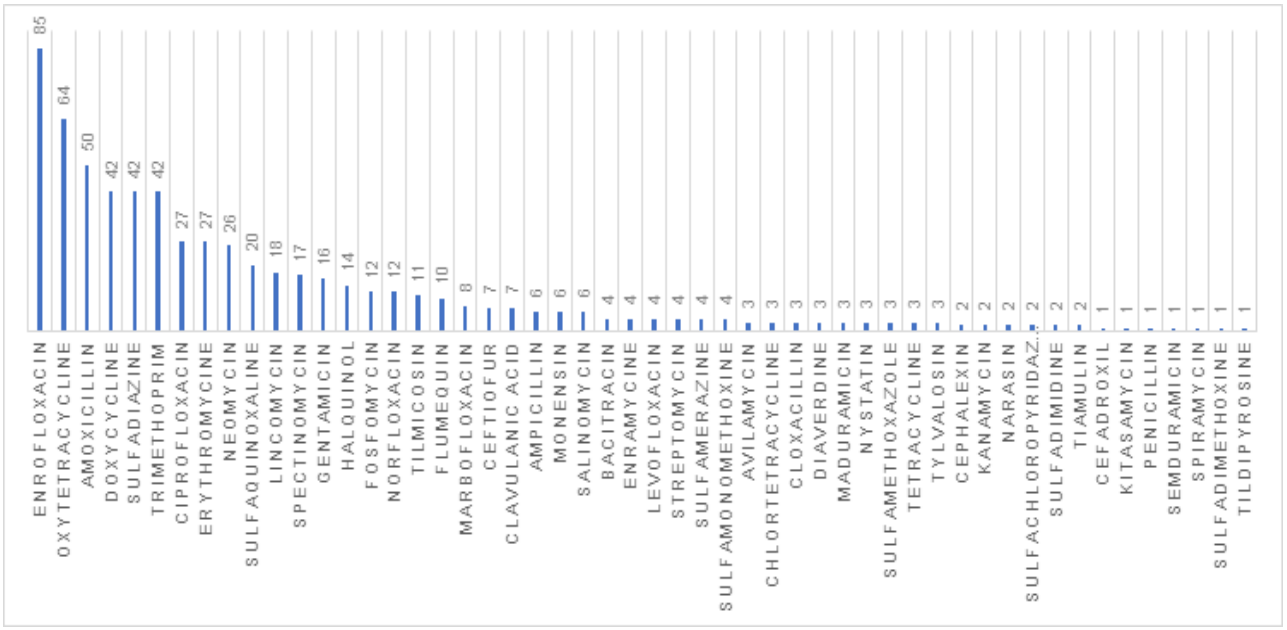

Figure 5 Number of certificate samples based on active substance of antibiotics/antibacterial

Based on the data presented in Table 4 and Figure 5, enrofloxacin was the most frequently found active substance in certification or registration samples. In August 2024, the Ministry of Agriculture held a meeting with veterinary medicine stakeholders and agreed to implement a ban on the use of five fluoroquinolones in animals, effective January 1, 2026. The five fluoroquinolones included in the ban are ciprofloxacin, levofloxacin, norfloxacin, oxolinic acid, and nalidixic acid. These fluoroquinolones are also used in human medicine, and one or more these compounds are officially registered in Indonesia to use in animal (IAHC, 2023). Meanwhile, fluoroquinolones use in human, Indonesia only approved ciprofloxacin and levofloxacin (MoH, 2023). Interestingly, the evaluation of certification samples in 2024, revealed that some companies still submitted products containing ciprofloxacin and levofloxacin for new registration or re-registration. This finding is important because the fluoroquinolone group is categorized by the World Health Organization (WHO, 2019) as the highest priority critically important antimicrobials for human medicine.

Therefore, it is important to use these drugs carefully in animals. In addition to their critical importance for human medicine, the level of cross-resistance within this group is very high. It is thus recommended that fluoroquinolones be used only as a last-resort option for treating infections in animals. Besides fluoroquinolones, macrolides, also third and fourth-generation of cephalosporins are also classified by the World Health Organization (WHO, 2019) as Highest Priority Critically Important Antimicrobials (HP-CIAs) for humans. Among the five macrolides listed in Table 4 and Figure 5, there are two drugs, erythromycin and spiramycin, ~~,~~ are also used in humans~~,~~ (MoH, 2023). Meanwhile, the third-generation of cephalosporin, ceftiofur, is used exclusively in animals, and is not used in humans (WOAH, 2023). However, there are ongoing concerns about cross-resistance between ceftiofur and other third- and fourth-generation cephalosporin group that are widely used in humans (Ishii *et al*. 2021).

Conclusion

The fluoroquinolones/quinolones class was the one most frequently included in the registration framework. Several types of antibiotics samples in 2021 – 2024 period categorized as highest priority critically important antimicrobials for humans which are also used in animals, eitheras single active substances or in combination with other antibiotic active substances. There is a clear need to strengthen the regulation regulate the use of antibiotic use based on the level of veterinary importance, resistance mechanisms, and the likelihood of cross-resistance within or between antibiotic classes. The findings of this evaluation highlight current trends in antibiotic registration and underscore the importance of evidence-based policies to ensure prudent and responsible use of antibiotics in animals.

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