DRAFT STATUTORY INSTRUMENT ON
REGULATING USAGE OF
ANTIMICROBIAL DRUGS IN
VETERINARY SPECIES: KEY
FEATURES AND FUTURE PLANS

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Taj Pamodzi
Dr Daniel Ndambasia – Registration Officer, Veterinary Medicines, ZAMRA
WHAT IS THE ZAMBIA MEDICINES REGULATORY AUTHORITY (ZAMRA)?

- STATUTORY NATIONAL MEDICINES REGULATORY BODY FOR ZAMBIA

- ESTABLISHED UNDER AN ACT OF PARLIAMENT, THE MEDICINES AND ALLIED SUBSTANCES ACT NO. 3 OF 2013 OF THE LAWS OF ZAMBIA

- IT SERVES TO REGULATE AND CONTROL THE MANUFACTURE, IMPORTATION, STORAGE DISTRIBUTION, SUPPLY, SALE AND USE OF MEDICINES AND ALLIED SUBSTANCES.

- THE MAIN OBJECTIVE IS TO ENSURE THAT ALL MEDICINES AND ALLIED SUBSTANCES BEING MADE AVAILABLE TO THE ZAMBIAN PEOPLE CONSISTENTLY MEET THE SET STANDARDS OF QUALITY, SAFETY AND EFFICACY

- “REGULATING MEDICINES FOR PUBLIC HEALTH PROTECTION”
PROVISIONS OF THE ACT

SECTION 42, SUBSECTION (9) OF THE MEDICINES AND ALLIED SUBSTANCES ACT, 2013;

“THE MINISTER MAY, FOR THE PURPOSE OF PREVENTING THE IMPROPER USE OF PRESCRIPTION ONLY MEDICINES, ON THE RECOMMENDATION OF THE AUTHORITY, BY STATUTORY INSTRUMENT___”
a) PROVIDE FOR THE CONTROL OF THE IMPORTATION, EXPORTATION, SALE, POSSESSION, DISTRIBUTION, USE AND LABELLING OF PRESCRIPTION ONLY MEDICINES;

b) EXCLUDE ANY PRESCRIPTION ONLY MEDICINE OR PREPARATION OF SUCH MEDICINE FROM THE OPERATION OF THIS PART;

c) PROHIBIT, REGULATE OR RESTRICT THE MANUFACTURE OF PRESCRIPTION, ONLY MEDICINE; AND

d) REGULATE THE USE BY ANY MEDICAL DOCTOR, DENTAL SURGEON OR VETERINARY SURGEON OF PREPARATIONS CONTAINING A PRESCRIPTION ONLY MEDICINE AND THE DISPENSING OF THE PREPARATIONS.
RATIONALE

• THE AUTHORITY CATEGORIZES ALL ANTI-INFECTIVES AS POM-V
• ACKNOWLEDGEMENT OF THE THREAT OF THE DEVELOPMENT OF AMR
• ACCESS OF ANTIMICROBIAL DRUGS SHOULD BE THROUGH AN AUTHORIZED PRESCRIBER
  • AGROVET SHOP GUIDELINES
• PRODUCT REGISTRATION REQUIREMENTS
  • PRODUCT COMPOSITION; CIAS TO HUMAN HEALTH
  • LABELLING REQUIREMENTS
  • INDICATIONS; THERAPEUTIC, PROPHYLACTIC, GROWTH PROMOTION
  • CATEGORY OF DISTRIBUTION
  • SMPC; CONTRAINDICATIONS, WITHDRAWAL PERIODS ETC
CURRENT REGISTERED ANTIMICROBIAL DRUGS

REGISTERED VETERINARY MEDICINES AS AT MAY 2019

- Antimicrobial Drugs: 28%
- Other Veterinary drugs and allied substance: 72%
USAGE OF VETERINARY ANTIMICROBIAL DRUGS – CONCEPT OF SI

• AROSE AS A CONCERN REGARDING THE USAGE OF ANTIMICROBIAL DRUGS
• AS PRESENTED TO TECHNICAL COMMITTEE ON VETERINARY MEDICINES AT ITS MEETING IN MARCH 2019
• TRENDS LOCAL, AND REGIONAL
• CONCERNS, LOCAL STUDIES
• Antimicrobial drugs not to be registered, distributed or marketed for purposes of use as a growth promoter in any animal species which is kept for or whose products are meant for human consumption.
ADMINISTRATION

• ANTIMICROBIAL DRUGS NOT TO BE ADMINISTERED FOR THE PURPOSES OF GROWTH PROMOTION TO ANY ANIMAL SPECIES WHICH IS KEPT FOR OR WHOSE PRODUCTS ARE MEANT FOR HUMAN CONSUMPTION. THIS SHALL INCLUDE, ADMINISTRATION OF AN ANTIMICROBIAL DRUG THROUGH FEED, DRINKING WATER OR ANY OTHER MEANS ON A ROUTINE BASIS ASIDE FROM A THERAPEUTIC PURPOSE.
COMPOSITION

• ANTIMICROBIAL DRUGS NOT TO BE COMPOUNDED WITH ANY VITAMIN, HERBAL PREPARATION OR ANY OTHER PREPARATION AS A FINISHED PRODUCT WHICH MAY PREDISPOSE IT TO BE USED ON A ROUTINE BASIS FOR THE PURPOSES OF PROPHYLAXIS OR GROWTH PROMOTION.
USAGE IN FEED

• ANTIMICROBIAL DRUGS NOT TO BE COMPOUNDED WITH ANY FEED, OR FEED PREMIX FOR USE AS A FEED ADDITIVE IN FEED INTENDED FOR USE IN ANY ANIMAL SPECIES WHICH IS KEPT FOR OR WHOSE PRODUCTS ARE MEANT FOR HUMAN CONSUMPTION.
ESTABLISHMENT OF CRITICALLY IMPORTANT CLASSES OF ANTIBIOTICS

• CRITICALLY IMPORTANT ANTIMICROBIAL DRUGS USED IN VETERINARY MEDICINE OF SIGNIFICANCE IN HUMAN MEDICINE.

• THE FOLLOWING CATEGORIES OF ANTIMICROBIAL DRUGS ARE NOT TO BE USED IN ANY ANIMAL SPECIES WHICH IS KEPT FOR OR WHOSE PRODUCTS ARE MEANT FOR HUMAN CONSUMPTION.*
• FLUOROQUINOLONES
• CEPHALOSPORINS 3\textsuperscript{rd} AND 4\textsuperscript{th} GENERATIONS
• PHENICOLS
• POLYMYXINS

*LIST IS NOT EXHAUSTIVE AND MAY BE SUBJECT TO REVISION BY THE MINISTER UPON RECOMMENDATION BY THE AUTHORITY.
WAY FORWARD

• ALL INCLUSIVENESS IN DEVELOPING LEGISLATION THAT SAFEGUARDS THE PUBLIC

• ENSURE COMPLIANCE TO BEST PRACTICES BY PRESCRIBERS

• COLLABORATION WITH STAKEHOLDERS TO CONTINUOUSLY SENSITIZE THE PUBLIC ON JUDICIOUS USE OF ANTIMICROBIAL DRUGS

• KEEP ABREAST WITH TRENDS AT INTERNATIONAL, REGIONAL AND LOCAL LEVEL WITH REGARDS AMR AND AMU
AFTER THOUGHT???

- ROUTINE USE AND SUB THERAPEUTIC
- SUB THERAPEUTIC DOSES AND MRL
- VIABLE ALTERNATIVES, BIOSECURITY, VACCINATION
- CREATE AN ENVIRONMENT WHERE WE DO NOT NEED THE USE IN THE FIRST PLACE
The thoughtless person playing with penicillin treatment is morally responsible for the death of the man who succumbs to infection with the penicillin-resistant organism.