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ARE THERE SUBSTANDARD VETERINARY ORAL FORMULATIONS OF AMOXICILLIN/CLAVULANIC ACID IN MALAYSIA, THE UNITED KINGDOM, SERBIA AND THAILAND?

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Introduction:

Substandard quality of antimicrobial formulations has negative consequences on patient care due to lack of clinical efficacy as well as potential implications for the selection of antimicrobial resistance. Amoxicillin/clavulanic acid (AMC) is the most commonly used oral antimicrobial drug in companion animals worldwide.

Objectives:

The objectives of the study were to detect types and frequency of deficits in the quality of veterinary oral formulations of AMC in various countries.

Methods:

Prospective study with purposive sampling. AMC tablets formulations destined for canine use were collected from wholesalers or veterinary practice during 2021 and shipped to a central laboratory. Content assay (validated HPLC method with UV detection, according to United States Pharmacopeia) passed when verified in pre-specified 90-120% range of the labelled dose.

Results:

Twenty-one samples were collected from Malaysia(9), the UK(6), Serbia(4) and Thailand(2), yielding 17 different formulations (9 veterinary). Secondary packaging was present for 13/21 samples. Tablets size ranged from 250 to 675 mg. Amoxicillin trihydrate / Potassium clavulanate ratio was 4:1, except for 3 formulations (2:1). Median number of tablets per sample was 32.

Primary packaging integrity was always verified. All formulations contained each of the analytes. For amoxicillin, 2/21 samples were out of specifications (72.8% and 82.3% of labelled content). For clavulanic acid, 4/21 samples were out of specifications (46.9%, 80.0%, 84.3% and 86.5%). One formulation failed for both analytes.

Conclusions: