Regulation of veterinary antibiotics in Australia

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Abstract

The Australian Pesticides and Veterinary Medicines Authority (APVMA)* registers veterinary antibiotic products before they can be supplied, distributed or sold in Australia. Extensive scientific assessment on all new veterinary antibiotic products is undertaken for the APVMA by experts in other government agencies including the Therapeutic Goods Administration (toxicology), the National Occupational Health and Safety Commission (occupational health and safety), Environment Australia (environmental hazards) and state departments of agriculture or primary industry (efficacy and safety) as well as APVMA assessments on food residues, trade and manufacturing. The National Health and Medical Research Council Expert Advisory Group on Antimicrobial Resistance provides advice to the APVMA on the potential transfer of antibiotic resistance from the use of antibiotics in animals to humans, and the impact transfer may have on public health. Food Standards Australia New Zealand (previously Australia New Zealand Food Authority) set maximum residue levels for human foods. The APVMA monitors registered product use through compliance activities and an adverse experience reporting program, and reviews registered products as necessary. The import, manufacture, supply and use of veterinary antibiotics are regulated by Commonwealth and State governments in Australia. *Commun Dis Intell* 2003;27 Suppl:S6–S8.

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Import

All antibiotics must be imported since no antibiotics are manufactured in Australia. Antibiotics may be imported in bulk or as a final product. Imported antibiotics, considered prohibited imports under Customs legislation, can only pass border controls if accompanied by an import permit, issued by the Therapeutic Goods Administration. Data on imports are collected.

Manufacture

The Australian Pesticides and Veterinary Medicines Authority (APVMA) licenses all manufacturers of products containing antibiotics for animal use, provided manufacturers demonstrate compliance with the Good Manufacturing Practice principles.

Registration

The APVMA registers veterinary antibiotic products before they can be supplied, distributed or sold in Australia. In basic terms the APVMA receives, evaluates and finalises applications to:

- approve active constituents;
- register products;
- approve labels; and
- vary particulars of active constituents, products or labels e.g., to allow use in another animal species.

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Extensive scientific assessment is undertaken for the APVMA by experts in other government agencies including the Therapeutic Goods Administration (toxicology, scheduling, and determining an acceptable daily intake), the National Occupational Health and Safety Commission (occupational health and safety), Environment Australia (environmental hazards) and State departments of agriculture or primary industry (efficacy and safety). In addition, the APVMA assesses residues in food. Maximum residue limits are established and are nominated to the Food Standards Australia New Zealand for inclusion in the Foods Standards Code. The National Health and Medical Research Council Expert Advisory Group on Antimicrobial Resistance provides advice to the APVMA on the potential for transfer of antibiotic resistance from the use of antibiotics in animals to humans, and the impact that such transfer may have on public health. A risk assessment approach for new antibiotics and significant extensions to the use of registered antibiotics is used. The important concepts of this risk assessment approach are:

1. Hazard: Antibiotic resistant microorganisms or plasmids coding for antibiotic resistance within an animal species, arising from the use of an antibiotic in an animal species, have the potential to transfer to humans.
2. Exposure: the degree and frequency of exposure of susceptible humans to antibiotic-resistant microorganisms (or their plasmids) from animal sources;
3. Impact: the impact of infections caused by antibiotic-resistant pathogens of animal origin in susceptible humans;
4. Risk: the probability of infections caused by antibiotic-resistant pathogens of animal origin in susceptible humans AND the impact of such infections.

The focus is on commensals and enteric pathogens (and transferable genetic elements) that may be important to susceptible humans, not on target animal pathogens. Further development of this approach will occur as a result of an initiative to develop an internationally harmonised guideline for data required for such risk assessments.

In order to register a product, the APVMA must be satisfied that the product is in accordance with the recommendations for its use that the APVMA proposes to approve:

- would not be an undue hazard to the safety of people exposed to it during its handling or to people using anything containing its residues; and
- would not be likely to have an effect that is harmful to human beings; and
- would not be likely to have an unintended effect that is harmful to animals, plants, or to the environment; and
- would not unduly prejudice trade or commerce between Australia and places outside Australia;
- would be effective according to criteria determined by the APVMA for the product.

Post-registration

After product registration, the APVMA monitors product use through compliance activities and an adverse experience reporting program, and reviews registered products as necessary. In 2002, the APVMA began reviewing the registration of products containing virginiamycin, tylosin, oleandomycin and kitasamycin, as recommended by the Joint Technical Expert Technical Advisory Committee on Antibiotic Resistance report.

Most veterinary antibiotic products are prescription remedies, restricting supply by veterinarians to farmers and animal owners. While general medical practitioners must prescribe through pharmacists, veterinarians are allowed to supply antibiotics without pharmacist involvement. Selected antibiotics for certain purposes are open sellers when incorporated in stock feed e.g., ionophores for disease prevention.

Further information on APVMA activities can be found at the APVMA website from: http://www.apvma.gov.au.

Use

State and territory governments regulate the use of veterinary antibiotic products after retail sale. State and territory legislation are currently being amended with the intent that similar laws will apply across Australia.

Alternatives to antibiotics

The APVMA considers registration of all veterinary chemical products in Australia. The registration of products undergoes scientific assessment with respect to safety in humans, animals and the environment and to efficacy in target animals. Evaluation of applications for alternatives to antibiotics such as vaccines and probiotics are similar to other veterinary chemical products, and the APVMA needs to be satisfied as to such products' efficacy and safety, irrespective of their potential use as antibiotic alternatives.