



Animal Health Alliance
SOLUTIONS FOR THE FUTURE

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Christine McDonald
Secretary
The Senate
Standing Committee on Finance and Public Administration
References Committee
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**Inquiry into the progress in the implementation of the recommendations of the 1999 Joint Expert
Technical Advisory Committee on Antibiotic Resistance (JETACAR)
– Animal Health Alliance (Australia) Ltd Submission**

The Animal Health Alliance (Australia) Ltd (the Alliance) is the voice of the animal health industry in Australia. It represents registrants, manufacturers and formulators of animal health products. The association's member companies represent in excess of 85 per cent of all animal health product sales in Australia (ex factory gate). The Alliance manages both national and state issues with the objective of ensuring its members can operate within a viable regulatory environment. The Alliance also contributes to sustainable industry risk reduction practices that provide business opportunities to members and add value to the broader Australian community.

Members of the Alliance:

- share community concerns that ensuring the health and wellbeing of animals is essential;
- are committed to supporting the production of high quality and safe food from animal sources;
- recognise the importance of preventing antimicrobial resistance in both animal and human populations;
- support and promote the responsible use of antimicrobials in both food and companion animals.

The Alliance welcomes the opportunity to supply this submission to the Senate inquiry into progress in the implementation of the recommendations of 1999 JETACAR report.

The Alliance notes the terms of reference for the inquiry to be:

Progress in the implementation of the recommendations of the 1999 Joint Expert Technical Advisory Committee on Antibiotic Resistance, including:

- a) examination of steps taken, their timelines and effectiveness;
- b) where and why failures have occurred;
- c) implications of antimicrobial resistance on public health and the environment;
- d) implications for ensuring transparency, accountability and effectiveness in future management of antimicrobial resistance; and
- e) any other related matter.

The Alliance member companies are key stakeholders, in the research, development, registration and manufacture import/export, supply and disposal of veterinary antimicrobials in Australia. We have been actively involved in the JETACAR process since its inception in the late 1990's when our industry association was known as Avcare.

Since the release of the JETACAR report in 1999 and the implementation of a series of the report recommendations, the Alliance has been actively engaged with government to ensure the ongoing viability of veterinary antimicrobial use from a risk/benefit perspective, taking into consideration the need for animal welfare, production of high quality and safe food balanced with the need to protect public health.

The Alliance and its member companies have actively engaged with government and federal regulators – particularly Australian Pesticides and Veterinary Medicines Authority (APVMA) – in the regulatory activities initiated out of the JETACAR report recommendations. The Alliance has always supported risk based regulatory decisions made on the latest scientific information.

In relation to the specific JETACAR report recommendations that relate and impact on veterinary antimicrobial use in Australia, the Alliance has worked co-operatively with APVMA and its agencies to deliver a number of recommended improvements and will continue to support the APVMA in areas where further work is required. For example:

RECOMMENDATION 1

That the use of antibiotic growth promotants in food-producing animals should not be used unless they:

- are of demonstrable efficacy in livestock production under Australian farming conditions;
- are rarely or never used as systemic therapeutic agents in humans and animals, or are not considered critical therapy for human use; and
- are not likely to impair the efficacy of any other prescribed therapeutic antibiotic or antibiotics for animal or human infections through the development of resistant strains of organisms.

RECOMMENDATION 2

That the APVMA review the use of (three) antibiotic growth promotants currently registered in Australia that do not appear to fulfil the criteria above in terms of their impact on human and animal health. The review would use a risk analysis approach and include a cost-benefit analysis. JETACAR also recommended that the APVMA review the prophylactic use of two of these antibiotics in animals and the possible public health impact of this use.

In relation to these first 2 recommendations, the Alliance member companies have actively and co-operatively engaged with APVMA in defining the risk parameters here and as a flow on from this participated in assisting the APVMA complete reviews of the antimicrobials avoparcin and virginiamycin. The Alliance and its member companies are still engaged in the ongoing APVMA review of the macrolide class of antimicrobials namely kitasamycin, oleandomycin and tylosin.

RECOMMENDATION 3 and 11

To improve the audit trail for antibiotics from the importer to the end-user, and to establish a comprehensive monitoring and audit system for antibiotic usage covering all areas of antimicrobial use.

The Alliance has worked with APVMA to draft and refine a 'Code of Practice' on Collection of Animal Antimicrobial Supply Data for submission to the National Registration Authority for Agricultural and Veterinary Chemicals (formerly known as NRA, now called APVMA). As a follow up to this Code being developed the Alliance member companies have voluntarily offered 'Supply Data' to the APVMA on relevant veterinary antimicrobial products when requested. The voluntary supply of data by Alliance member companies to APVMA have resulted in the public release in 2005 of the APVMA report entitled "Quality of Antimicrobial Products Sold for Veterinary Use in Australia 1999/2000 – 2001/2002". The most recent APVMA report covering 2005 – 2010 is being finalised at present.

RECOMMENDATION 4

That the APVMA would evaluate all new applications for registration of antibiotics for use in animals, major extensions of use, and any reviews of currently registered antibiotics, in accordance with Part 10 Special Data Requirements. This data Part includes a risk analysis associated with antimicrobial resistance.

The Alliance has worked actively with APVMA to update and maintain Part 10 Special Data Requirements. This Part 10 is a mandatory component of any product application relating to veterinary antimicrobials that are submitted to the APVMA for regulatory consideration.

RECOMMENDATION 6

That all antibiotics for use in humans and animals (including fish) be classified as S4 (prescription only).

The Alliance and its member companies have worked with APVMA and its agencies over the years since the JETACAR report was released to ensure a review of the scheduling of veterinary antimicrobials has been undertaken from a risk/ benefit perspective.

RECOMMENDATION 10

That a comprehensive surveillance system be established incorporating passive and active components measuring incidences and prevalence of antibiotic-resistant bacteria and resistance genes, covering all areas of antibiotic use.....The overall surveillance system should include medical (including nosocomial), food – producing animal and veterinary areas, with particular emphasis on the establishment of food-chain (included imported food) and environmental connections, and including molecular studies of resistance genes.....

The Alliance would support a whole of government, multi-sector initiative of surveillance and monitoring based on a risk/ benefit approach. The Alliance is prepared to consider in such an initiative, to offer company global expertise and knowledge to ensure success of such a program. Alliance member companies have or are at present undertaking surveillance and/or sensitivity surveys and similarly support professional bodies that undertake similar initiatives.

RECOMMENDATION 15

That prudent use codes of practice for antibiotics be developed and regularly updated by medical and veterinary peak bodies, including learned societies, professional organisations, producer organisations, pharmaceutical companies and State/Territory medical and veterinary registration boards, and promulgated to their members. These codes of practice should be based on the principles articulated in this report.

The Alliance and its members companies continue to support contemporary prudent use, codes of practice guidelines for our industry not just within Australia but within the international animal health industry. Both domestic (particularly those produced by the Australian Veterinary Association) and international (especially those produced by the International Federation of Animal Health) codes of practice are tangible examples of this ongoing commitment.

I look forward to the opportunity to discuss these issues in more detail with the Committee.

Yours sincerely

Dr Peter Holdsworth AM FAICD
Chief Executive Officer

Animal Health Alliance (Australia) Ltd