



Antimicrobial Resistance Direction Statement for Animals and Plants, and Work Programme

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1 Antimicrobial Resistance Direction Statement for Animals and Plants, and Work Programme

1.1 PURPOSE

The Ministry for Primary Industries (MPI) seeks your views on this proposed direction statement and work programme for dealing with antimicrobial resistance.

1.2 SUBMISSIONS

MPI welcomes written submissions on the proposals contained in this document. All submissions must be received by MPI no later than **5 pm, 8 April 2016**.

We will consider all relevant material made in submissions, so you are welcome to provide information supporting your comments. Please make sure you include the following information in your submission:

- the title of this consultation document;
- your name and title;
- your organisation's name, if applicable, and whether your submission represents the whole organisation or a section of it; and
- your contact details (phone number, address, and email).

Submissions should be sent directly to: ACVM.consultation@mpi.govt.nz

While we prefer to receive electronic submissions, you may also post your submission to:

Antimicrobial Resistance Direction Statement

ACVM Programmes and Appraisals

Ministry for Primary Industries

PO Box 2526, Wellington, New Zealand

1.3 SUBMISSIONS ARE PUBLIC INFORMATION

Your submission is public information. Submissions may be the subject of requests for information under the Official Information Act 1982 (OIA). The OIA specifies that information is to be made available to requesters unless there are sufficient grounds for withholding it, as set out in the OIA. Submitters may wish to indicate grounds for withholding specific information contained in their submission, such as if the information is commercially sensitive or if they wish personal information to be withheld. MPI will take such indications into account when determining whether or not to release the information.

Any decision to withhold information requested under the OIA is reviewable by the Ombudsman. For more information please visit:

<http://www.ombudsman.parliament.nz/resources-and-publications/guides/official-information-legislation-guides>

2 Antimicrobial Resistance Direction Statement for Animals and Plants

2.1 INTRODUCTION

Antimicrobial agents are important tools in the management of infections in humans, animals and plants. Without them, human health, agricultural production and animal health outcomes (including companion animals), would be significantly compromised.

Antimicrobial resistance¹ (AMR) in humans is generating world-wide concern and there are a number of global initiatives currently underway to understand the epidemiology of human AMR. In parallel, there are global concerns that as AMR increases in animals and plants antimicrobials will become less effective for both therapeutic and prophylactic use. Use of antimicrobials in animals and plants may also contribute to AMR in humans.

The Ministry for Primary Industries considers this an important issue and has developed this Direction Statement to outline its vision, goals and objectives for primary sectors and other stakeholders. This will underpin and set the direction for its work programme in this area.

2.2 GLOBAL CONCERN

The global concern about antimicrobial resistance has led to the development of a “One Health” approach on management of antimicrobial resistance. Internationally, a number of organisations, such as the World Health Organization (WHO), the Codex Alimentarius Commission (CAC), and the World Organisation for Animal Health (OIE), have incorporated this approach. WHO has developed a draft global action plan and the CAC, via an *ad hoc* Task Force, has developed guidance on risk assessment for antimicrobials used in human and veterinary medicine. OIE has developed guidelines on use of antimicrobials in animals. Also, the Food and Agriculture Organization (FAO) has significantly increased its focus on antimicrobial resistance over the last few years. In association with these activities, a number of countries have developed national strategies on AMR.

The intent of all these activities is to minimise and/or slow resistance to antimicrobials. Actions in countries overseas have included banning the use of certain antimicrobials that are important for human use, restrictions on prophylactic use in production animals in some countries, and global efforts to increase surveillance and monitoring. Other endeavours include promoting research to understand better mechanisms of resistance and interlinkages between animals and humans, industry and public awareness activities, and developing new antimicrobials to enter the market with novel modes of action.

¹ Antimicrobial resistance means microbes are resistant to one or more antimicrobial agents. In this context, “antimicrobial” is a general term for drugs, chemicals, or other substances that either kill or slow the growth of microbes. Substances that are considered antimicrobials include surface disinfectants, antibiotics, parasiticides, anti-fungal and anti-viral agents.

2.3 NEW ZEALAND

Compared with other countries, New Zealand currently does not have scientific evidence of AMR in animals and plant as a significant concern. This is likely due to strong regulatory controls on use of antimicrobial agents, relatively low-intensity animal husbandry systems, and continuing investment by Government and industry in antimicrobial resistance initiatives. However, it is important that both Government and industry continue to take a pro-active approach to minimise the development of antimicrobial resistance in animals and plants.

While individual New Zealand Government agencies and industry sectors have work programmes to address antimicrobial resistance from their individual areas of responsibility (such as the Ministry of Health for human health), there is a need for greater formal direction in this area and better coordination across Government agencies and industry.

2.4 VISION

New Zealand has a pro-active and scientifically based regulatory system to minimise the risk of AMR in animals and plants.

2.5 GOAL

Effective antimicrobials are available for responsible use in animals and plants, and any antimicrobial resistance has minimal impact on animal, plant or human health.

2.6 SCOPE

Antimicrobials: those agents used in managing animal and plant health that have the potential for AMR to negatively impact on animal, plant or human health.

2.7 OBJECTIVES

- Establish and maintain a scientifically robust platform for regulatory decisions regarding AMR for animals and plants that is in line with best international practice.
- Maintain and continue to enhance New Zealand's regulatory system for antimicrobials used for animals and plants, which is in line with best international practice and is tailored to New Zealand's agricultural and public health needs.
- Remain abreast of international developments and approaches toward AMR, particularly as they impact the New Zealand context.
- Ensure antimicrobials are used in a prudent and responsible manner and facilitate other intervention tools to reduce the use of antimicrobials.
- Liaise with other government agencies, industry and other stakeholders to ensure AMR work programmes remain aligned and complementary, as much as practical.
- Facilitate awareness and understanding of AMR and communicate effectively with all stakeholders.

3 Antimicrobial Resistance Draft Work Programme

3.1 INTRODUCTION

This proposal reflects an initial range of activities that MPI is considering as part of the AMR work programme. The list of activities is not finalised. As a result of consultation, items may be removed or added. In addition, other initiatives may come into MPI's consideration during the course of the work programme.

MPI recognises that a number of these work programme tasks crossover into the human health arena (and the 'one health' approach being adopted by some countries). This means MPI and the Ministry of Health (MoH) are working together to ensure the whole of any AMR problem is addressed. MPI and MoH have already agreed a mechanism to coordinate the AMR work programme.

As part of the work programme MPI will establish internal governance arrangements. This internal arrangement is not part of this consultation.

3.2 CATEGORIES OF ACTIVITIES

The activities in this draft work programme are divided into two categories:

- activities that are considered a higher priority and more likely to occur in the short term; and
- activities that are not considered as pressing.

Activities have been grouped under a broad area within each category. The order in which they are presented does not reflect any particular priority or hierarchy.

3.3 HIGHER PRIORITY ACTIVITIES

3.3.1 Science

- Develop an integrated surveillance and monitoring programme (including pre-slaughter/harvest) for AMR in foodborne bacteria (disease causing and others) from animals, plants and food.
- Establish an agreed standard for laboratory testing methods for antibacterial susceptibility.
- Establish a national system for veterinary laboratories to report to MPI on AMR findings from samples.
- Develop a surveillance programme of the sales and consumption of antimicrobials in animals and plants.
- Determine the contribution of the food chain to the overall burden of human AMR.
- Analyse the New Zealand context in relation to the generic understanding of the epidemiology of AMR (OIE, FAO) in order to validate this model and identify vulnerabilities and opportunities.

3.3.2 Regulatory

- Review the controls (conditions of registration) and labelling of antimicrobial-based trade name products to ensure they are fit for purpose.
- Establish a regular programme of system audits on the regulatory oversight of antimicrobial-based veterinary medicines.
- Develop guidance documents on prudent use principles (including examples).

3.3.3 Other

- Establish an AMR information sharing network covering:
 - industry (sectors and manufacturers);
 - regulatory bodies, such as MoH, Veterinary Council of New Zealand (VCNZ) and MPI; and
 - end user groups, such as Federated Farmers, New Zealand Veterinary Association (NZVA) and Horticulture NZ.
- Review the AMR Steering Group composition and terms of reference to ensure suitability in the context of the new work programme.
- Initiate discussions with stakeholders on the need for, potential design of, and funding options for the AMR work programme.

3.4 LOWER PRIORITY ACTIVITIES

3.4.1 Science

- Review international literature on the association of transfer of AMR from companion animals to humans.

3.4.2 Regulatory

- Work with our overseas regulatory partners and with international organisations such as VICH, OECD and OIE to harmonise international data submission requirements and risk assessment.

3.4.3 Other

- Establish closer ties with other nations to promote quality, safety, and efficacy of antimicrobials and strengthen their veterinary medicine supply chains.