

Contents

1 Introduction	3
2 About the Animal Medicines Australia Code	3
2.1 Promoting the Code	4
2.2 Legislative and Regulatory Requirements	4
2.3 Relationship to AMA Governance Documents	4
3 Member Obligations	5
3.1 Act in the best interests of the industry	5
3.2 Comply with legislation and regulations	5
3.3 Comply with, and promote understanding of, the AMA Code of Conduct	5
3.4 Participate in industry stewardship activities	5
3.5 Support industry information gathering	6
4 Make Accurate Product Claims	7
5 Promotion to veterinary professionals	7
5.1 False or misleading claims	7
5.2 Unapproved products and uses	8
5.3 Good taste	8
5.4 Unqualified Superlatives	8
5.5 Comparative Statements	8
5.6 Imitation	8
5.7 Other materials	8
6 Use Ethical Market Research Techniques	9
7 Communication with the public	9
7.1 General inquiries	9
7.2 Promotion to the public	9
8 Code Administration	10
8.1 Compliance with the Code	10
8.2 Non-member generated complaints	10

1 Introduction

Animal Medicines Australia represents Australia's leading developers, registrants, manufacturers and formulators of Animal health products.

Animal Medicines Australia member companies produce approximately 80% of the animal health products sold in Australia. These products are used to prevent, treat and manage illness, injury and disease in production and companion animals.

Animal Medicines Australia and its members are committed to safety, stewardship and quality:

- Safety protecting human health and the environment through a rigorous and sciencebased regulatory process, the adoption and promotion of Good Agricultural Practice and the correct use of products according to label directions;
- **Stewardship** the responsible and ethical management of industry products throughout their life-cycle; and
- **Quality** producing products of the highest quality that meet registration specifications every time.

This industry code has as a primary objective the maintenance of the trust and confidence of, and accountability to, all communities with which they engage, the effectiveness of which is assessed from the perspective of the relevant community.

All members are encouraged to participate fully in industry wide dialogue on contemporary issues to ensure that Animal Medicines Australia is a truly representative organisation.

The Code of Conduct has been developed to ensure all Animal Medicines Australia members meet industry standards. The Code of Conduct sets out a series of obligations. Meeting these obligations is a condition of Animal Medicines Australia membership. The Code of Conduct also details a series of policies and programs that member companies are encouraged to adopt, implement or participate in.

Animal Medicines Australia will consult with relevant stakeholders in developing this Code of Conduct, updating the Code and in ongoing education, monitoring and compliance.

The Animal Medicines Australia Board is responsible for ensuring compliance with the Animal Medicines Australia Constitution, By-Laws and Code of Conduct. Rule 4 of the Constitution details the membership admission process and disciplinary procedures.

2 About the Animal Medicines Australia Code

Established in 2006, the Animal Medicines Australia Code of Conduct (the Code) sets out the standards of conduct for the activities of companies when engaged in the promotion of animal health products in Australia, and as permitted by Australian laws and regulations. The Code provides a mechanism for the industry to establish and maintain an ethical culture through a committed, open and transparent self-regulatory approach. The Code should be viewed as a minimum set of standards required for membership of Animal Medicines Australia and does not in any way prohibit more stringent and comprehensive requirements being applied by individual companies.

The Code complements the legislative requirements of the *Agricultural and Veterinary Medicines Code Act* and corresponding control of use legislation in each Australian State and Territory.

It is the responsibility of members of the veterinary pharmaceutical industry to provide an ongoing, objective and scientifically valid interpretation of data on veterinary pharmaceutical and animal health products to veterinary professionals. The industry also has a responsibility to provide appropriate non-promotional information to users and consumers. The Code provides the standard for the provision of this information.

2.1 Promoting the Code

Animal Medicines Australia is committed to continuous and demonstrable improvement in industry conduct associated with engagement with our many stakeholders, and to achieving enhanced understanding of, and compliance with, the Code. Animal Medicines Australia members must abide by the Code in both spirit and letter.

Animal Medicines Australia members must ensure that all employees and agents acting on their behalf are familiar with their obligations under the Code.

2.2 Legislative and Regulatory Requirements

In addition to the Animal Medicines Australia Code of Conduct there are Australian legislative and regulatory requirements. Adherence to the Code in no way reduces a company's responsibilities to comply with the Competition and Consumer Act, the Agricultural and Veterinary Chemicals Code and Administration Acts, State and Territory control of use acts and other requirements, legislation and Codes.

Competition and Consumer Act 2010

http://www.austlii.edu.au/au/legis/cth/consol act/caca2010265/

Agricultural and Veterinary Chemicals Code Act 1994 https://www.legislation.gov.au/Series/C2004A04723

Privacy Act 1988 (Cth)

http://www.comlaw.gov.au/Series/C2004A03712

2.3 Relationship to AMA Governance Documents

The Animal Medicines Code of Conduct is part of the suite of Animal Medicines Australia's governance documents. Other documents include the Animal Medicines Australia Constitution and By-Laws. Nothing contained within the Code should be construed as inconsistent with the provisions of either the Constitution or By-Laws. In circumstances of any potential inconsistency, the provisions of the Constitution or the By-Laws will prevail.

Members of Animal Medicines Australia will:

- · Comply with all relevant legislation, regulation and statutory instruments,
- Participate in a range of stewardship activities,
- Provide information and data as agreed by the Board,
- Make only accurate statements in product claims and publicity material, and
- Act ethically when conducting market research.

Animal Medicines Australia members are also encouraged to adopt and implement a range of other policies and programs promoted by Animal Medicines Australia.

3 Member Obligations

As a member of Animal Medicines Australia your company must comply with the following obligations:

3.1 Act in the best interests of the industry

Members will always act ethically, with integrity and honesty.

3.2 Comply with legislation and regulations

Members will comply with all relevant Commonwealth, state and territory legislation and regulations including, but not limited to:

- The Agricultural and Veterinary Chemicals Code Act 1994 and associated regulations,
- The Corporations Act 2001;
- The Competition and Consumer Act 2010; and
- The Dangerous Goods Code.

3.3 Comply with, and promote understanding of, the AMA Code of Conduct

Animal Medicines Australia members must ensure that all employees, contractors and others associated with the production of animal medicines in Australia are familiar with their responsibilities under the Code.

Animal Medicines Australia and its members may promote the Code, including how compliance with it supports our priority principles of safety, stewardship and quality.

3.4 Participate in industry stewardship activities

Members will take actions and participate in programs that address potential risks associated with veterinary medicines at all stages of the product life cycle. This will include promoting the responsible, judicious and sustainable use of all veterinary medicines, especially antibiotics.

Safe handling, storage and transport

Prior to final retail sale, members will ensure company products that are hazardous materials or dangerous goods are transported by persons that are appropriately trained and licensed.

Members will ensure that all company personnel handling, selling, recommending, giving advice on, or taking responsibility for the safety of industry products have received appropriate training from a reputable organisation such as Agsafe.

Managing waste

Members will support the Industry Waste Reduction Scheme through participation in the *drumMUSTER* and ChemClear® programs for products that fall within the criteria of these programs. The Industry Waste Reduction Scheme aims to:

- reduce the number of agricultural containers entering the distribution scheme;
- increase the re-use of containers originally intended for single use;
- increase the recycling of containers for material recovery;

- improve occupational health and environmental practices by promoting the adoption of easier to clean and handle packaging, the use of safer emptying and rinsing devices and management of chemical containers in an environmentally appropriate way;
- promoting research and development into new formulations, packaging, recycling and material recovery uses;
- educating distributors and farmers to purchase environmentally friendly returnable containers and in the appropriate disposal of non-returnable containers; and

Protecting sensitive materials

Members will maintain the safety and security of manufacturing facilities to protect and safeguard:

- chemicals of security concern; and
- illicit drug precursors.

Responding to antimicrobial resistance

Members will support efforts to respond to antimicrobial resistance. This will include supporting Australia's *National Antimicrobial Resistance Strategy* or other initiatives to minimise the development and spread of antimicrobial resistance and ensure the continued availability of effective antimicrobials to protect human and animal health.

Members will support industry initiatives to minimise and reduce the development of antimicrobial resistance, such as the *Commitment and Actions on Antibiotic Resistance*. The commitment recognises that antibiotics are key to treating infections in humans and animals, and that there are no alternatives to treating life threatening bacterial infections. AMA members will:

- protect animal health in a unified, One Health approach;
- use antibiotics judiciously and responsibly;
- promote disease prevention and increased access to products and expertise
- invest in development of products for prevention and treatment; and
- increase knowledge transparency and communication.

Members may not register or promote the use of antimicrobials that are relevant to human medicine exclusively for growth promotion.

Members will promote responsible and judicious use of antimicrobials through promotion of relevant national prescribing guidelines for animals.

3.5 Support industry information gathering

Members will support industry information collection and gathering activities, including by:

- Providing information and data for the purposes of calculating membership fees
- Participating in industry market research activities including the Australia Animal Health Audit reports, including:
 - Animal Health Audit report,
 - Distribution report, and
 - Doses report.

Providing information to the AMA secretariat in April each year for the Annual Head
Count Survey.

4 Make Accurate Product Claims

Members will ensure that all product claims are consistent with the product registration, approved label or use and safety information approved by the Australian Pesticides and Veterinary Medicines Authority (APVMA).

Members will only describe a product as safe when appropriate qualifications are applied.

Members will support the responsible use of veterinary medicines by:

- Supporting industry communication and outreach initiatives and promote responsible use messages;
- Ensuring users (including veterinarians, farmers and pet owners) have access to the information necessary to use products responsibly, and
- Provide information services for users seeking additional information about a product.

5 Promotion to veterinary professionals

It is the responsibility of AMA members to ensure that the content of all promotional and medical claims is balanced, accurate and correct. This responsibility relates not only to the product being promoted, but to any information given, or claims made about other products, disease states or conditions.

With regard to balance, members will ensure that adequate safety information is included in relation to efficacy or other promotional claims.

Care must be taken to ensure that all promotional material does not denigrate a competitor's product in such a way that the industry may be discredited.

Activities of company representatives will comply with the Code at all times.

5.1 False or misleading claims

All information, claims and graphical representations provided to veterinary professionals or members of the public will be current, accurate, balanced and must not mislead either directly, by implication, or by omission.

All claims must be referenced. A clear style of typeface must be used with adequate space between lines.

If qualifying statements are used with a promotional claim, they should be linked to the relevant claim with a readily identifiable symbol such as an asterisk or a similar device. Qualifying statements must appear directly below or adjacent to the claim.

It is unreasonable to cite the results of an excessively favourable (or excessively unfavourable to a comparator product) study in a manner that misleadingly suggests that those results are typical. Use of information or conclusions from a study that is clearly inadequate in design, scope or conduct to furnish support for such information and conclusions is not acceptable.

Data previously valid but made obsolete or false by the evaluation of new data must not be cited.

Reprints and abstracts of scientific reports will not omit relevant parts or be quoted out-of-context in such a way to imply a meaning other than that intended by the author.

5.2 Unapproved products and uses

A product or use that has not been approved or permitted by the Australian Pesticides or Veterinary Medicines Authority (APVMA) may not be promoted in advertising materials. Members may assist veterinarians with scientific information that supports their responsible prescribing practices. This may include supplying information on uses that do not appear on labels.

5.3 Good taste

All promotional and educational material (including graphics and other visual representations) will conform to generally accepted standards of good taste and recognise the professional standing of recipients. Materials must not contain anything that would be likely to cause serious or widespread offence, taking into consideration prevailing community standards.

5.4 Unqualified Superlatives

Unqualified superlatives will not be used. Claims must not imply that a product or an active ingredient is unique or has some special merit, unless its relevance to a clinical outcome can be substantiated with evidence of adequate quality.

The words 'safe' or 'unique' must not be used without qualification. Although in some circumstances 'unique' may be used to describe some clearly defined special feature of a product, in many instances it may be taken as implying a general superiority. In such instances, this is unacceptable unless the claim can be supported in every respect.

5.5 Comparative Statements

The intention of this provision is to prohibit unfair and unjustified comparisons with the products or activities of a competitor.

Care must be taken to ensure that any comparison properly reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way. Comparisons of products must be factual, fair, capable of substantiation, referenced to its source. 'Hanging' comparatives – those that merely claim that a product is better, stronger, safer etc. must not be used.

Comparative claims must be substantiated with respect to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, any claims must be clearly identified as pertaining to that parameter.

5.6 Imitation

Promotional information and materials should not imitate the devices, copy, slogans or general layout adopted by other companies in a way that is likely to mislead or confuse.

5.7 Other materials

Ensure that hand-outs, flip-charts, presentation slides or other material not for general circulation purposes but for face-to-face presentation are no less authentic and capable of substantiation than advertising and other general publications.

6 Use Ethical Market Research Techniques

Members should ensure that methods used for market research do not discredit or reduce confidence in the industry. Interviews must not be gained by subterfuge.

Members, when selecting individuals or organisations to undertake any market research activities, should ensure that the contracted organisation or individual complies with the Australian Market and Social Research Society *Code of Professional Behaviour* (available at www.amsrs.com.au, or an equivalent standard of professional conduct.

The sole purpose of these activities must be to collect data and not a means to promote to and/or reward healthcare professionals. Market research may be undertaken about an unapproved product or unapproved use; however, market research must not be used to promote an unapproved product or unapproved use.

Market research studies will be clearly identified as such when the initial approach is made to participants. It must be clear to a participant that the market research is being conducted by or on behalf of an animal medicine company, but the name of the company need not be disclosed.

Any payment (whether cash or voucher in lieu of cash) will be kept to a minimum and should not exceed a level commensurate with the time involved.

Promotion should not be represented as market research or research of any type.

Market research should not be able to be confused with a competition and should be a genuine initiative to collect relevant and useful information to enhance the quality use of medicines.

7 Communication with the public

This section of the Code of Conduct establishes the ways in which AMA members appropriately interact with members of the public to enhance the quality use of veterinary medicines in support of better animal health outcomes.

Any activities, communications, publications or other materials provided to members of the public must not bring discredit on, or reduce confidence in the veterinary medicines and animal health industry.

Consistent with section 5 of this Code, all information, claims and graphical representations provided to members of the public must be current, accurate, balanced and must not mislead either directly, by implication, or by omission. All statistics or analyses provided to the public by companies must be referenced to their source.

7.1 General inquiries

Inquiries to AMA members regarding the use of products must be handled by appropriately qualified personnel. Requests from individual members of the public for information or advice on the diagnosis of animal disease must always be refused and the inquirer recommended to consult a veterinarian.

7.2 Promotion to the public

The promotion of prescription-only products or veterinarian-only products to the public would breach the Agricultural and Veterinary Chemicals Code Act and this Code which stipulates that prescription products must not be promoted to the public.

8 Code Administration

The Constitution of Animal Medicines Australia, under Rule 4.5(a) provides that each member agrees to be bound by both the Constitution and this Code of Conduct.

8.1 Compliance with the Code

All members are expected to comply with the provisions of the Code. Primary responsibility for resolving a dispute involving an alleged breach of this Code by a member lies with the members subject to that dispute.

In accordance with the provisions of the Constitution, non-compliance by a member may result in the member:

- Being expelled from membership of the Company;
- Suspended from membership for a specified period; or
- Subject to other sanctions.

8.2 Non-member generated complaints

Complainants are encouraged to contact the relevant member as a satisfactory explanation or solution may be immediately available.