VMDA CODE OF PRACTICE FOR THE PROMOTION OF ANIMAL MEDICINES IN AUSTRALIA

23 April, 2002

While it is possible to legislate and describe processes or standards for the development, testing, manufacture and control of animal medicines, appropriate standards of marketing conduct and product promotion cannot readily be defined by the same means. For this reason, responsible Animal Health Companies and businesses will concur in the acceptance of this Code of Practice and submit to its principles and tenets.

Members of the Veterinary Manufacturers and Distributors Association (VMDA) agree voluntarily to observe the principles and spirit set out in the following Code, designed to guide the manner in which members will advertise and promote animal medicines to both the general public and animal health professionals. Specifically:

- Responsibly inform the target audience, consistent with the registered label claims for the product, its use and safety information as approved by the National Registration Authority (NRA)
- Uphold an appropriate standard in the communication of information
- Ensure that all claims and assertions are accurate, balanced, consistent with NRA-approved labelling and based on sound and objective scientific considerations
- Ensure that such promotion leads to the responsible use of the animal health medicine, yet not openly encourage off-label use

Animal Health Companies which are not members of VMDA are also invited to accept and observe the Code as their own.

The Code emphasises the importance in the public interest of providing fair, accurate and objective information on animal medicines so that rational decisions for prescribing and/or use can be made. Moreover, the Code accepts the principle that such information should be presented in a form and by ways and means which conform not only to minimum legal requirements but also to ethical standards and canons of good taste.

This Code is intended to embody the basic principles and provisions which the Animal Health Industry (VMDA members) believes are appropriate to guide the conduct of its marketing activities, and for the maintenance of standards which are in the interests of the broader Animal Health Industry as a whole. The Code represents an act of self-discipline and participants are encouraged to resolve differences between themselves, but consistent with the principles herein.

At this time, there are no provisions outside of consumer common law which can be used to set minimum standards or resolve issues between competitor Companies. If there is direct compromise of the approved label instruction-claim, NRA ruling can be requested; otherwise, if there is representation which is believed to constitute misleading and/or deceptive conduct, then action can be taken under sections 52 and 53 of the Trade Practices Act.

This Code does not purport to provide such mechanism as adoption of the Code is strictly voluntary, however, there can be little doubt that if all members of the Animal Health Industry strive to conduct their businesses cooperatively, in the spirit of this Code and in a manner not likely to bring the Industry into disrepute, then there should rarely be issue which might prompt Regulator (NRA, DOH) or legal involvement and dictate.

Persons or Companies who consider that promotion of an animal medicine has fallen below the standards described by this Code are invited to write or otherwise contact the Executive Director of the VMDA (Inc), Locked Bag 2000, Peakhurst Delivery Centre, NSW 2210, Telephone 02 9487 1798, Fax 02 9487 1842 and request further confidential consideration of the issue by the VMDA Board.

PROVISIONS OF THE CODE

1 Definitions

1.1 The term ‘promotion’ means those marketing activities, coming under the control of the participating Company, which do or may encourage the prescribing, supply or use of the Company’s products. It includes, for example, the activities of representatives; various aspects of sales promotion such as journal and direct mail advertising including ‘teaser’ campaigns; the use of films and other audio-visual or multimedia material and exhibitions; and the provision of samples, gifts and hospitality. The terms ‘promotional purposes’ and ‘promotional material’ must be construed accordingly.

The conformity of promotion within this Code will be assessed in terms of its probable impact, taking its content as a whole, upon a reasonable person within the class of those to whom the promotion is directed and also taking into account its probable impact on persons within other classes to whom it is likely to be promoted, albeit by less direct means.

1.2 The term ‘animal medicine’ means any unbranded or branded medicinal product intended for use in animals.

1.3 The term ‘business user’ means any person who uses animal medicines during the course of his/her business or occupation, eg. a farmer or farm manager.

1.4 The term ‘lay user’ means all those to whom promotion may be directed, other than members of the veterinary and animal health-pharmaceutical professions or the business user, as defined in Clause 1.3 above.

1.5 The term ‘participant’ refers to VMDA member Companies, and to those non-member Companies who have agreed to abide by this Code.

2 Application of the Code

2.1 The Code applies in its entirety in relation to promotion directed towards the veterinary and animal health-pharmaceutical professions, distributors of animal medicines, the business and lay user.

2.2 The requirements of Clauses 7.2 and 7.4 do not apply to advertisements containing only information of a commercial nature, such as announcements of changes in prices or packaging, or to adverse reaction warnings or recalls of defective products etc, always provided that no claims for the product are made.

2.3 The requirements of Clause 7.2 (except for the provisions of sub-clause vii thereof) do not apply to teaser campaigns.

Methods of Promotion

Methods of promotion must never be such as to bring discredit upon, or reduce confidence in, the Industry.

Promotional programs must not specifically denigrate another member's product in such a way that the Industry as a whole can be discredited.

Nature and Availability of Information

3.1 Upon reasonable request, participants shall promptly provide members of the veterinary and animal health-pharmaceutical professions, registered merchants and the business user, with accurate and relevant information about the animal medicines which they market.

3.2 Information about animal medicines should reflect current knowledge or responsible opinion.

3.3 Information about animal medicines must be accurate, balanced and must not mislead, either directly or by implication, so that critical unbiased judgements and decisions can be made.

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

3.4 When promotional material refers to published studies, clear references must be given as to where they can be found.

3.5 All information included in promotional material must be capable of substantiation and substantiation must be provided without delay in response to inquiries.

Such substantiation need not be provided however in relation to the validity of indications approved by the Australian National Registration Authority for Agricultural and Veterinary Chemicals (NRA).

3.6 All information should be presented so as to maintain the respect and confidence of the veterinary and animal health-pharmaceutical professions, registered merchants, the business user and the public, and to promote the correct use of animal medicines.

3.7 Handouts, flip-charts etc. not for general circulation purposes but for face-to-face presentations must be no less authentic and capable of substantiation than advertising and other general publications.

Claims and Comparisons

3.8 Claims for the usefulness of an animal medicine should be based on an up-to-date evaluation of all the evidence and should reflect this evidence accurately and clearly.

3.9 Exaggerated claims should not be made and all-embracing claims and superlatives should be avoided. Claims should not imply that an animal medicine, or an active ingredient, has some special merit, quality or property unless this can be substantiated and is consistent with approved label claim-indication.

3.10 The word ‘safe’ must not be used without qualification and it must not be stated categorically that a product has no side-effects or toxic hazards.

3.11 The word ‘new’ should not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been generally promoted, for more than twelve months in Australia.

3.12 Comparisons of products must be factual, fair and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis, or in any other way.

3.13 Brand names of products of other Companies must not be used unless the prior consent of that Company has been obtained, or unless the brand name is fully and correctly qualified with ® or ä , as appropriate.

3.14 Care should be exercised to avoid ascribing claims or views to scientific authors in such a way as to suggest, wrongly, that these represent up-to-date opinions.

3.15 No reference may be made to any individual or official body, or to unpublished material, without the consent of the individual, body or any author concerned.

Disparaging References

3.16 The products or services of other Companies should not be disparaged either directly or by implication.

3.17 The clinical and scientific opinions of members of the veterinary and allied professions should not be disparaged either directly or by implication.

Printed Promotional Material

3.18 The Poisons Act restricts the promotion and or display of some animal medicines according to their Schedule; Schedule 4 animal medicines may only be promoted to registered veterinarians.

3.19 Except for journal advertisements and posters subject to Clause 7.4, the following information should be given, clearly and concisely, on printed promotional material, and on journal advertisements which include particulars of dosage:

(i) The brand name of the product.
(ii) A quantitative list of the active ingredients, using the approved or other non-proprietary names.
(iii) One or more indications for use, consistent with the approved package leaflet.
(iv) Side-effects, precautions, contra-indications and withdrawal periods of the product in the recommended dosage, relevant to the advertised indication(s), and the species of animal to which reference is made.
(v) A form of words which indicates clearly that further information is available on request to the Company or is to be found in the package leaflet relating to the product.
(vi) The legal category-Poison Schedule/class of the product.
(vii) The Company name and address, or other contract details as appropriate.

3.20 If a full and complete copy of the package leaflet accompanies the promotional material, then the requirements of Clause 7.2(i)-(vii) will be deemed to be satisfied, provided that the promotional material displays boldly and prominently a statement to the effect that it is accompanied by the package leaflet.

3.21 The requirements of Clause 7.2 do not apply in the case of a journal advertisement, or poster, intended as a reminder advertisement (this will generally mean an advertisement that does not include particulars of dosage and/or statements of claim). Such advertisement or poster must always contain the following information:

(i) The brand name of the product.
(ii) The approved or other non-proprietary names of the active ingredients.
(iii) A form of words which indicates clearly that further information is available on request.
(iv) The Company name and address.

3.22 The requirements of Clause 7.2 or Clause 7.4 do not apply if an article designed as a promotional aid bears no more, in relation to the product, than the brand name, generic name and Company name and logo.

3.23 Promotional material, such as mailings and journal advertisements, must not be designed to disguise its real nature.

3.24 Promotional material should conform, both in text and illustration, to canons of good taste.

3.25 Veterinarians' names or photographs must not be used in promotional material in any way that is contrary to the Australian Veterinary Association's Code of Professional Conduct.

3.26 Promotional material should not imitate the devices, copy, slogans or general layout adopted by other manufacturers in a way that is likely to mislead or confuse.

3.27 Where appropriate, for example, in technical and other informative material, the date of printing or of the last review, should be stated.

3.28 Extremes of format or size of printed material should be avoided.

3.29 Postcards, other exposed mailings, envelopes or wrappers, should not carry matter which could be considered unsuitable for public view.

3.30 The requirements of Clause 7.2 do not apply in the case of journal advertisements or product leaflets which appear to be aimed at the lay owner of companion animals. Such information should comply with Clause 7.4 (i)-(iv).

References to Official Bodies

Unless specific requirements, statutory or otherwise, have been imposed, manufacturers should not include in any announcement or promotional material a reference to the National Registration Authority for Agricultural and Veterinary Chemicals or similar official bodies.

Distribution of Printed Promotional Material

3.31 Promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.

3.32 Restraint should be exercised on the frequency of distribution and on the volume of promotional material distributed.

3.33 Mailing lists must be kept up to date. A request for a name to be removed from one of these lists must be complied with promptly and no name may be restored except at the individual's request or with his/her permission.

Reprints, Abstracts and Quotations (such use is, of course, subject to the law of copyright)

3.34 Quotations must accurately reflect the meaning of the author and the significance of the study.

3.35 Reprints of articles must not be included in mailings without permission of the author or original publisher.

Audio-Visual Material

11.1 Audio-visual material, except for radio and television advertising, must comply with all relevant requirements of the Code, with the exception of Clause 7.2.

11.2 When audio-visual material is used to promote a product, copies of the relevant approved package leaflet or a document incorporating the information required by Clause 7.2, must be made available to all persons present or to whom the material is sent or delivered. Alternatively, the material should bear a form of words indicating that further information is available from the Company and giving the name and address of the Company.

4 Material Reproduced on Television Apparatus, Visual Display Units or Similar

12.1 Promotional material which is made available by systems which enable the material to be accessed and reproduced on to television apparatus, visual display units or similar, must comply with all relevant requirements of the Code, with the exception of Clause 7.2. Such material includes viewdata systems, memory disks and the like, but not video-tapes which come within the scope of Clause 11, or radio and television broadcasting which comes within the scope of Clause 13.

12.2 The obligatory information required by Clause 7.2 must be available through the system conveying the promotional material and instructions for accessing that information must be displayed with the promotional material.

Radio and Television Promotion

13.1 Information about animal medicines broadcast on radio or television must be accurate, balanced and must not mislead, either directly or by implication.

13.2 All such information should be presented so as to maintain the respect and confidence of the professional, business and lay viewer or listener, and to promote the correct use of animal medicines.

Sales Representatives

4.1 Participants shall ensure that all their representatives undergo thorough training and possess sufficient animal health and technical knowledge to present information on the Company's products in an accurate and responsible manner.

4.2 Representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties.

4.3 Representatives must not employ any subterfuge to gain an interview.

4.4 Representatives must ensure that the frequency, timing and duration of calls, together with the manner in which they are made, are such as not to cause inconvenience.

4.5 Representatives must take adequate precautions to ensure the safe-keeping of animal medicines in their possession. Any requirements imposed by the Poisons Act must also be observed.

4.6 They must transmit to their companies forthwith, any information which they receive in relation to the use or properties of the products which they promote, which appears to reflect upon the safetyor efficacy of those products. In particular, having regard to the Companies' commitment to pharmacovigilance, they must transmit reports of side effects and/or adverse reaction.

Samples

4.7 Samples of products restricted by law to supply on prescription, and of any other products that it would be unsafe to use except under veterinary supervision, may be made available only to veterinarians and must not be sent to them except in response to their instructions.

4.8 Where samples of products restricted by law, to supply on prescription, are distributed by a representative, the sample must be handed directly to the veterinarian or given to a person authorised to receive the sample on his behalf, per requirements under the Poisons Act. A similar practice must be adopted for products which it would be unsafe to use except under veterinary supervision.

4.9 An accurate accounting system must be established for samples of products, restricted by law to supply on prescription, which are made available to representatives for distribution.

4.10 Samples sent by post must be packed so as to be reasonably secure against the package being opened by young children.

Market Research

4.11 Methods used for market research must never be such as to bring discredit upon, or reduce confidence in, the animal health industry. The following provisions apply whether the research is carried out directly by the participant or by an organisation acting on his behalf.

4.12 Interviews or access to respondents must not be gained by subterfuge.

4.13 Any incentives given should be kept to a minimum and be commensurate with the work involved.

4.14 Questions intended to solicit disparaging references to competing products or companies must be avoided.

4.15 Market research must not be used as a form of disguised sales promotion.

Relations with the General Public and the Communication Media

4.16 Information about scientific progress or discovery in the field of animal medicines must be presented in a balanced way.

4.17 Promotion directed to the lay user must never be such as to bring discredit upon, or reduce confidence in, the animal health industry or the veterinary profession.

Sponsorship, Gifts, Hospitality

Shall not be such as to bring discredit upon, or reduce confidence in, the Industry.

19 Administration

These guidelines are intended to assist both complainants and subject Companies to ensure that a fair and full review is conducted of a complaint lodged. If these general criteria are not met, the complaint may be returned to the complainant for more information, or the review may be conducted in the absence of a complete response.

For **externally generated complaints**, the complainant is encouraged to contact the subject Company prior to lodging a complaint with VMDA, as a satisfactory explanation or solution may be immediately available.

As a next step, the complainant can simply report what is perceived as a problem, provided the nature of the practice being complained about is fully stated, with a simple explanation of reason(s) for the objection.

If the complaint is based on scientific issues, supporting literature and explanation is highly desirable to ensure a balanced review, with copy of that literature to be provided by the complainant for use in the review process. It is not sufficient to simply object or claim that the issue is not supported.

For **internally generated complaints**, all effort should first be made between the Companies to achieve an amicable solution; complaints must not be used as a competitive tool. Subsequently, persons or Companies are invited to write or otherwise contact the Executive Director of the VMDA, who will minimally request (for the purpose and investigation and review):

- A summary page containing,
    1. Subject Company and product(s)
    2. Description of complaint, itemising specific claims at issue and rationale for the alleged breach (possibly as an attachment)
    3. Section(s) of this Code alleged to have been breached or other detailed explanation of the reason for the complaint
    4. Details of attempts to resolve the matter with the subject Company.
- For scientifically-based complaints, supporting data cross-referenced to the claims at issue or the issue under challenge.
- For marketing-based complaints, the alleged consequences (damage to complainant or the Industry) with supporting data, if available.
- Copy of the approved product information for the complainant's product, if specifically mentioned in a comparative context.
- Written endorsement by the CEO or other senior Executive of the complainant Company.

Note – while dialogue with the subject Company is not absolutely essential, the complaint may not be accepted for evaluation until such attempt is made or explanation is provided for why such attempt was not made. The Executive Directory of VMDA will have discretionary right to request or accept comment on this issue.

20 Response

When a complaint is accepted for evaluation, the subject Company will be presented with a summary or otherwise of the facts at issue and asked for response.

In their response, the subject Company may well include:

- Details of attempts to resolve the matter direct with the Complainant.
- A summary of the response to the/each alleged breach (possibly as an attachment).
- Their substantiation of the specific claims at issue with supporting data.
- Original samples of materials at issue, where appropriate.
- Written endorsement by the CEO or other senior Executive of the subject Company.

The Executive Director of VMDA, together with the Executive, will then consider and make recommendation-conclusion in respect of the issue(s) presented. The complainant, the subject of the complaint, and all relevant parties will be advised.