The impact of the Agricultural Compounds and Veterinary Medicines Act on veterinarians

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The Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) and the Hazardous Substances and New Organisms Act 1996 (HSNO Act) must commence at the same time. The Acts were to commence on 1 April 1999, but there will be a further delay. The Minister for the Environment has announced that the HSNO Act (and by association the ACVM Act) will commence by mid-1999, but he has not set a specific date. Consequently, the Animal Remedies Act 1967 will still regulate the importation, manufacture, sale and use of animal remedies until the ACVM Act commences.

Commencement of the ACVM Act will produce significant changes in the regulatory control of products used to manage animals in any way. This includes not only veterinary medicines or remedies in the common usage of those terms but also products that have until now been excluded from regulatory control. The Act is based on the principle that all products used to manage animals should be regulated, but they do not have to be registered unless they pose significant and relevant risks. Products that pose no or only low risk could be exempted either with or without conditions. This paper discusses some of the regulatory changes and their significance to practising veterinarians

Risk management under the ACVM Act

The only risk areas of concern under the ACVM Act in regard to importation, manufacture, sale or use of agricultural compounds or veterinary medicines have been specified in section 4 of the ACVM Act. This section expressly states the purpose of the Act to be to manage:

> *risks associated with the use of agricultural compounds, being-*
> *(I) risks to trade in primary produce, and*
> *(ii) risks to animal welfare; and*
> *(iii) risks to agricultural security.*

While not expressly stated as a risk area, the purpose of the Act is extended to ensure that the use of agricultural compounds or veterinary medicines does not result in breaches of domestic food residue standards. The purpose of the Act also confers on MAF the power to require sufficient consumer information about agricultural compounds or veterinary medicines. The last provision of the purpose of the Act is interpreted to mean that MAF can require a proprietor of a product to provide sufficient information with that product to specify its proper use and any precautions that should be taken when using the product.

Other risks could be caused by the use of veterinary medicines, but these risks are managed under other legislation. For example, assessment of the impact of veterinary medicines on public health (other than exceeding domestic food residue standards) or the environment is not relevant under the ACVM Act. Such risks will be managed under the Hazardous Substances and New Organisms Act 1996.

The ACVM Act does not provide a basis for protecting consumers from faulty or misrepresented veterinary medicines. These risks are managed under the Fair Trading and Consumer Guarantees Acts. Therefore, there will not be any regulatory control under the ACVM Act of the quality of veterinary medicines unless a defect in the quality of the product causes significant risks in any of the areas listed in section 4 of the Act. Nevertheless, there will be regulatory control of the efficacy of trade name products, if inefficacy results in 'unnecessary pain or distress' in the animal(s) treated. This would include the majority of products that veterinarians would consider as medicines or remedies.

Regulatory control of veterinary medicines

As stated above, the ACVM Act brings all substances used to manage animals (companion and production) under regulatory control. This means that, in addition to the pharmaceutical and biological animal remedies controlled under the Animal Remedies Act, the ACVM Act will also control such things as pet foods and stock feeds, premixes, dietary supplements, fertilisers, surgical instruments, human medicines used on animals, cleaning products such as animal shampoos, etc. Many of these products pose no or only low risks in the areas listed above, so the Act has created a mechanism by which groups of products can be exempted from registration. The veterinary medicines that MAF considers can be exempted from registration have been recommended to Government and will be specified in regulations promulgated at commencement of the Act.

The Act replaces licensing with registration as the most stringent form (short of prohibition) of regulatory control of trade name products. All licensed animal remedies will have to be considered under the new Act and given a registration with the appropriate conditions imposed. Until a trade name product is transferred it will remain a licensed animal remedy subject to all the provisions of the Animal Remedies Act, including the provisions for off-label use.

Off-label versus outside-conditions

Unlike the Animal Remedies Act, the ACVM Act makes it an offence to use a trade name product in a manner that is not specified in the registration or exemption conditions. (The term off-label is not used because there may be other uses specified in the conditions that are not included on the label.) Proprietors of a trade name product will be able to choose what uses they want to recommend as long as those uses are within the scope of the conditions imposed. This is to allow alternative or minor uses to be specified without imposing any liability on the proprietors of the products. Anyone using a product in a manner not recommended by the proprietor will have to accept the consequences of any adverse effects.

MAF is intending to include a generic condition on most registered veterinary medicines to allow registered veterinarians to use the products in a manner not specified in the use conditions. MAF is also intending to exempt all human medicines and veterinary compounded preparations from registration. Veterinarians will have the authority to use most products in a manner and on any species as they see fit. However, this authority (it is not a right) will be under the conditions that:

- the veterinarian is acting in accordance with a code of practice approved under section 28 of the Agricultural Compounds and Veterinary Medicines Act 1997; and
- the products are used only on animals under the direct care (direct authority or prescription) of the registered veterinarian.

The consequence of using a product outside the registration or exemption conditions is that the veterinarian takes the full responsibility and accepts the full liability for the action. This is a very significant consequence, and MAF advises all veterinarians to carefully study the NZVA code of practice, *Discretionary Use of Human and Veterinary Medicines by Registered Veterinarians*. That code, which is likely to be approved by MAF under section 28, makes it clear that the veterinarian must:

- make a technically sound decision about the discretionary use that ensure that risks are adequately managed and the discretionary use is justified;
- instruct the client about the proper use and the precautions that must be taken;
- warn the client of potential adverse effects or consequences; and
- record the particulars about the discretionary use.
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Section 4 of the New Zealand Veterinary Council *Code of Professional Conduct* will also be revised to explicitly state a veterinarian's obligations in regard to the use of any treatments on animals and to give effect to the MAF approved NZVA Code. Veterinarians are advised to study the NZVC Code as well.

Levels of veterinary involvement in the use and sale of veterinary medicines

The present prescription animal remedy classification system will be converted into conditions of registration on the level of professional involvement in the use and sale of veterinary medicines. The term prescription animal remedy will be preserved because of its general acceptance both in New Zealand and internationally. PARs will be veterinary medicines that are remedies subject to veterinary involvement and distinct from over-the-counter remedies or veterinary medicines that are not remedies at all such as pet foods, shampoos, etc.

There will be a new class of sale called restricted sale animal remedy (RSAR), which will be a product that can be sold only by an approved merchant/distributor. This class will include products that should be sold only with competent advice over-and-above the advice provided on the label. MAF will introduce a system for approving merchants/distributors who may include veterinary assistants/nurses/receptionists, pharmacists and assistants, and stock and station agents. It is expected that there will be considerable public discussion about the use of this class. The class will be applied only when the restricted sale can be justified to manage specific risks. At this stage, it is not clear whether or not any products will receive this classification.

Advice on the quality of products

As stated above there will be no regulatory control on the quality of veterinary medicines unless the quality fault causes significant risks in any of the specified areas. Consequently, veterinarians will not be able to depend on registration as an assurance that the product is a good product. All that can be inferred from the registration is that the product when used in accordance with the conditions of registration is not likely to cause any of the agreed risk thresholds to be exceeded. Veterinarians will have to become more discerning about the products they use or recommend. They will have to use their professional judgement when choosing from the range of products that are available, under the clear understanding that registration does not imply even a minimum level of assurance about the efficacy of the products.

Conclusion

The ACVM Act will change the regulatory environment in which veterinarians practise. Regulatory control will ensure that products are safe, but it will not ensure that products are effective. Veterinarians will have the authority to use most products in a discretionary manner, but they will have to take on the full responsibility and liability for their actions. Individual practitioners with their present level of knowledge about the quality and effects of the products they use or recommend may be hard pressed to meet their obligations under the ACVM Act. The profession as a whole may have to create mechanisms to support the information needs of its members. The Veterinary Professional Insurance Society has already identified the issues associated with off-label use under the Animal Remedies Act. Under the ACVM Act these issues will also include statutory offences if the conditions of registration or exemption are not complied with. Veterinarians are advised to take the time to understand their statutory obligations and to promote cooperation in developing support systems that will help them all meet those obligations.