The Agricultural Compounds and Veterinary Medicines Act 1997 and products used in the deer industry

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Abstract

The mechanism for regulating substances and products has been changed with the enactment of the Hazardous Substances and New Organisms and Agricultural Compounds and Veterinary Medicines Acts The latter Act specifically deals with products used to manage animals, including deer This paper describes the regulatory changes introduced in the Agricultural Compounds and Veterinary Medicines Act and the consequential effects they will have on the availability and use of products to be used on deer The paper also highlights some challenges that must be met by regulators, proprietors of products, deer farmers and health care advisors to ensure that safe products are available to the deer industry and that they can be used safely.

Introduction

For a number of years we have waited for the commencement of the Agricultural Compounds and Veterinary Medicines (ACVM) Act It was enacted in 1997, but has not been able to commence because its implementation is complementary and subordinate to the Hazardous Substances and New Organisms Act 1996 Both Acts must commence at the same time because Government has split the responsibility between MAF and the Environmental Risk Management Authority (ERMA) to manage the risks posed by the use of substances Risks to public health and the environment are to be managed by ERMA, while MAF will be responsible for managing risks to trade in primary produce, animal welfare and agricultural security In the first instance, controls will be imposed via an ERMA approval MAF may impose additional conditions on the importation, manufacture, sale or use of trade name products used in an agricultural context or to manage animals in any context.

Recently, Government has announced that the Acts will commence approximately mid-year 2000. MAF is progressing its implementation plans as if the commencement will occur in that timeframe This means that regulatory control of trade name products used in the deer industry will be subject to the provisions (including the transitional provisions alluded to below) of the ACVM Act by the fourth quarter of this year The mechanisms for control differ from those presently used but the outcome remains the same – that safe products are available and that they can be used safely.

There will be a three-year transition period in which products that are licensed as animal remedies will remain licensed and subject to the Animal Remedies Act 1967 until they are registered under the ACVM Act This means that, on the commencement day, there will be no significant change to the regulatory status of ethical drugs (prescription animal remedies) Products that meet the definition of an exempted agricultural compound group will not require registration Proprietors of products that are licensed already will be advised accordingly

Immediately after commencement, it may seem like it is business as usual However, changes will occur over the following three years that will have a progressively more obvious effect on the deer industry and health care providers

Regulatory control under the ACVM Act

The ACVM Act provides more flexibility to adjust the level of regulatory control so that it is only what is necessary and sufficient to manage the risks The following are the most significant changes to be introduced via the ACVM Act

Types of regulatory control

The ACVM Act provides for not only registration (similar to licensing) of products but also the exemption from registration of certain groups of products. For example, oral nutritional compounds, including premixes and feed supplements will be able to be marketed for use in deer without incurring the high cost of registration However, products such as antibiotics, biologicals and other ethical products (prescription animal remedies) will have to be registered The control options provided are

- prohibition,
- registration;
- exemption with conditions, and
- exemption without conditions

The Act also provides for prescribing (in regulations) standards for certain kinds of products For example, rather than require oral nutritional compounds to be registered, there will be minimum standards set As long as manufacturers comply with those standards, there will be no need to bring such products to the attention of the ACVM Group.

Scope of products regulated

The scope of products regulated has been increased to include any product used to manage animals whether or not health or productivity claims are made about the product Since the ACVM Act will repeal the Stock Foods Act 1946, oral nutritional compounds will be regulated under the same Act as ethical and over-the-counter veterinary medicines Fertilisers will also be regulated under the same Act.

Conditions on import, manufacture, sale and use

The Animal Remedies Act 1967 specifically regulated the manufacture and sale of products concentrating on licensing as the main form of regulatory control The Agricultural Compounds and Veterinary Medicines Act 1997 will regulate the importation, manufacture, sale and use of products. Regulatory conditions will be imposed on products either via registration or exemption Each condition will indicate who must comply For example, if there is a condition on the manufacture of the product, then the manufacturer must comply, but if the condition is on the use of the product then the user must comply

Registration of trade name products

The product, not the proprietor, will be registered The registration will be placed on the public register, including the identity of the product and all the conditions imposed on that registration MAF will specify what must be put on the label, but will not approve the final label The label will specify the use recommended by the proprietor, but other uses may be listed in the public register MAF will word the conditions very carefully so that alternative safe uses are made legal, but it will make it clear that people use the product in an alternative manner at their own risk The proprietor will not be liable for damages for uses that they do not recommend

Offences and penalties

The nature of the primary offence under that Act has been changed. It will be an offence not to comply with imposed conditions The statutory penalties on summary conviction for non-compliance have been increased considerably ($30,000 for individuals and $150,000 for corporations, rather than the few hundred dollars under the Animal Remedies Act 1967) At the same time, the powers to take action in regard to non-compliance and to modify the conditions of registration have been made more explicit

What will be the same

After the ACVM Act commences, there will still be products that will be subject to veterinary prescription or restricted to veterinary use or supervision. There will still be special arrangements in regard to products used in develveting deer, but the mechanism to achieve this will be different

Safe and effective products for use on deer will still be needed, but there will still be very little incentive to register products specifically for deer. The dilemma about using or advising the use of products not registered for deer will remain

What will be different

The term 'animal remedy' will be replaced with the term 'veterinary medicine' Rather than refer to the PAR (prescription animal remedy) class of a product the conditions will specify either use by, under the supervision of, or under the prescription of a registered veterinarian The effect will be the same as the PAR classification.

A wider range of products (those meeting the definition of exempted agricultural compound groups) will be able to be marketed for use in deer without incurring registration costs.

The cost of registration under the ACVM Act will not increase significantly However, the overall cost of obtaining all the necessary regulatory approvals is likely to increase markedly if the products are or contain hazardous substances

The nature of the ACVM conditions will be such that 'off-label' use will be provided for, but an obligation will be placed on the user to seek veterinary advice before a product is used in an alternative manner. This does not necessarily mean seeking advice from a particular veterinarian, and MAF is hoping the veterinary profession will develop a mechanism by which veterinary advice on the safety of products can be made readily available

What will be the challenges that must be met

Regulators will be challenged with the task of establishing and administering an efficient regulatory process based on

- sound assessment of the risks posed by trade name products, and
- imposition of conditions that are necessary and sufficient to manage the risks

Given the greater flexibility and increased range of regulatory options, the pharmaceutical industry and proprietors of products will be challenged with the task of adjusting the development and marketing of products to make more products available for use in deer

The ACVM Act coincidentally creates an opportunity for deer producers and their associations to contribute to the development of products and the monitoring of the safety of products being used. Education of producers about the safe and prudent use of products will be a service best provided by the industry's own associations.

The veterinary profession will be challenged with the task of working collectively to produce credible and readily available advice on safe uses of products in specialty industry sectors such as the deer industry, as well as developing codes of conduct for the prudent and responsible use of ethical products.

Overall the greatest challenge will be for all parties to concentrate on and work toward the same intent – to make available safe products that can be used safely.