The ACVM Act: An Update

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The Minister for the Environment, Marion Hobbs, has announced the intended implementation date for the Hazardous Substances and New Organisms (HSNO) Act to be the 2 July 2001 With this comes the concurrent implementation of the Agricultural Compounds and Veterinary Medicines (ACVM) Act Practitioners must be aware of changes that will come to affect the way they deal with animal remedies

Which Act is Responsible for What?

The purpose of the ACVM Act is "to manage risks associated with the use of agricultural compounds being

1 Risks to trade in primary produce
2 Risks to animal welfare
3 Risks to agricultural security "

The ACVM Act will not have regulatory control on the quality of all animal remedies It does, however, continue, as did the ARB, to assess products that must work to avoid, control or eliminate unnecessary pain or distress in animals treated with these products This will include most products considered as medicines or remedies Note here that this only applies to species or classes of animals stated by the proprietor, outside conditions use will have no quality assessment Products not marketed to alleviate pain and distress, but to achieve an effect (eg oestrus control) are not required to supply efficacy data Failure of these products to achieve efficacy claims will be dealt with under the Fair Trading and Consumer Guarantees Acts Products involving performance and production enhancement will not be required to be accompanied by efficacy data, their performance will be assessed by end users and veterinarians

The HSNO Act will manage risks associated with impacts of hazardous substances on the environment and public health A substance is deemed hazardous if it exceeds the level defined in any of the following properties

- Explosive nature
- Flammability
- Ability to oxidize (flame accelerant)
- Corrosiveness
- Acute or chronic toxicity
- Ecotoxicity
- Can generate a hazardous substance on contact with air or water

A substance may be both an animal remedy and a hazardous substance, in which case it is regulated under both the ACVM and HSNO Acts This may increase the costs of regulation of such products up to 3 fold Concerns here are that the minimum defined levels may be excessively low, causing unnecessary costs and regulation of nonhazardous products Many products used in every day practice may come under the control of the HSNO Act cleaners, disinfectants, meths, x-ray processing chemicals, some vaccines and selenium are but a few examples This Act covers these products from the time they are imported or manufactured through to disposal of residues For people using hazardous goods nothing will change until ERMA transfers the thousands of existing substances to the new Act This transition period may take 3 - 5 years Any new substances will be dealt with as applications are received Once products are transferred they will come under the control of the HSNO Act Areas which will affect veterinary practitioners include

- documentation and certification for all hazardous products
- people handling hazardous goods may have to become approved or certified handlers
- packaging controls
- storage conditions
- disposal

ACVM: The Current Situation

At present, all licensed animal remedies are under the control of the Animal Remedies Act (1967) and will remain so until the products are transitioned to the ACVM and/or HSNO Acts This transition period may take up to three years and in the case of the HSNO act, up to 5 years The ACVM Act controls regulation of all substances used to manage animals It supersedes several Acts, such as the Fertilizer Act, the Stock Foods Act, Pesticides Act, Animal Remedies Act Products are assessed for the risks they pose and the decision is made as to whether they require registration or are exempt from registration and therefore subject to no or reduced fees

Products exempt from registration are considered low risk, eg Non-medicated hoof preparations, non-medicated skin preparations for skin quality, homeopathic preparations without disease specific claims There is a range of controls for these types of products that include exemption with conditions, eg not to be used on the teats of lactating animals, made under the code of good manufacturing standards, packaged as individual animal treatment only, not for use in food producing animals Oral nutritional compounds and fertilizers are in a separate category, and are exempt from registration but are subject to a set of prescribed standards

Products requiring registration include almost all of the products currently licensed under the Animal Remedies Act. The term prescription animal remedy (PAR) has been retained as it is internationally accepted They are broken down into PAR classes 1,2 and 3 and "over the counter" (OTC) veterinary medicines

An additional category has been added entitled "Restricted Sale Animal Remedies" These products can be sold only by an approved merchant or distributor At this point in time there are no products in this category, it remains an "empty box"

Off Label or Outside Condition Use

Under the original ACVM Act, use of a licensed animal remedy in a manner not specified on the label was illegal Due to the concern that this would affect the availability of drugs for use in "minor" species and the effect that current safe practices would be made illegal, MAF has endeavored to make changes such that safe "off label", or outside conditions use could continue. Veterinarians have been made exempt from the regulation that off-label use is illegal This enables veterinarians to use all licensed animal remedies (PARs and OTCs), human medicines, or to compound remedies to treat animals under their direct control PARs cannot be used off-label by non-veterinarians, except under the direct supervision or prescription of a veterinarian Any veterinarian giving advice or prescribing off-label use of a product will be unprotected from the manufacturer or registration authority in the event of adverse outcomes of this discretionary use and/or advice, including residues In cases where farmers have used a product incorrectly, veterinarians must be able to prove that the advice they had given was correct Documentation of all off-label use may become a necessity

Any off-label use of an animal remedy or human drug is also governed by NZVA policy (B1 1 of member's manual) This is a document which all practitioners must be familiar with The guidelines for situations where off label use may be considered include

"(a) where no approved preparation is available for the condition,

(b) where directions for use of an approved preparation have been superseded by recent scientific information which is not yet reflected in label directions and no other equally suitable preparation is available for the condition,

(c) where an approved preparation has been shown to be ineffective,

(d) where an unlicensed* preparation is known to be of superior performance eg In terms of safety, efficacy, and or convenience of dose form "[1]

*note· under ACVM Act, all products used on animals for human consumption must be licensed

Over the counter medicines may not be used off-label by non-veterinarians unless they seek *"veterinary advice"* beforehand It is important to note here that they do not have to speak directly to a veterinarian, only have referred to advice given by a veterinarian, i e they do not have to have a veterinary consultation This may be through farming publications, discussion groups, newsletters etc. In all cases of off-label or outside condition use, there are no assurances made by the drug company regarding effectiveness or meat residues Again, veterinarians are liable for any advice given regarding outside condition use of such product

Unlicensed Products

Use of any unlicensed product is not permitted Any animal treated with an unlicensed product is ineligible for slaughter

With Holding Periods (WHP) and Animal Status Declaration

Stock owners now sign an animal status declaration upon presenting their stock for slaughter There is a section relating to animal treatments that is designed to assure that stock has not been treated with an animal remedy, or if they have, that they have observed the correct withholding period for the drugs used This becomes tricky in situations such as deer where many products are used outside label conditions and no official WHP is stipulated The animal remedy used must be approved for use in farmed animals (if not approved for use in farmed animals, these animals are then not eligible for human consumption) and not prohibited for use in the animals being slaughtered. The withholding time must be observed if stated for the species in question. If no withholding time is stated, or advised by a veterinarian, then the default withholding time becomes that of the longest WHP for another farmed species stated on the label Here again is another area where veterinarians must be very careful of advice given as they will be liable for any breach of the ACVM Act resulting from such advice

In instances where a stock owner is unaware of the treatment history of a class of stock, a mandatory 60 day WHP applies until the 1 September 2001, when it will become a 180 day WHP

Miscellaneous

Generic products may be registered by citing data from a drug already registered, thereby saving costs of producing safety, efficacy and WHP data for minor species This may only happen after a data protection period of 5 years is observed Prior to this time data may only be made available by permission of the original registrant

Retail and Veterinary Retail names Only one name per registration is permitted If a drug company chooses to market a product under another name it must make a second application It may do so relatively inexpensively as cross-referencing may be done thus decreasing registration costs of the second product, thus there will be no deterrent to having two separate names for the same products.

Human medicines used off label by veterinarians are exempt from registration under the ACVM act This allows for 2 identical products to be available, one with the cost of registration under the ACVM act the other not. The cost of registration will push up the cost of the registered drug and veterinarians will use the human drug instead This decreases the use of the registered drug and again reduces the incentive for drug companies to go to the expense of registering products for minor species

Conclusion

The ACVM and HSNO Acts will be instated 2 July 2001 There will be a teething period as products are gradually transferred to this legislation In the eyes of drug manufacturers, the deer industry is a

relatively small market As cost of registration increases, it becomes less likely that drug companies will go to the trouble and expense of getting products registered for use in deer. It becomes the veterinarian's responsibility to advise producers on the use and WHP for drugs used in deer As there are few products licensed for use in deer, it is important that practicing veterinarians are familiar with these Acts and also the NZVA policy on off label or discretionary use of animal remedies and human drugs In the environment of increasing litigation the veterinarian must be aware of the legal ramifications and liabilities that off label use entails

References

1 NZVA Members Manual NZVA Policy – 19/11/94 Off Label Use of Animal Remedies and Human Drugs, B 1 1

2 ACVM website www maf govt nz ACVM

3 ERMA website www ermanz govt.nz

4 HSNO website www hsno govt nz

5 Chris Boland, ACVM, personal communication

6. Peter Dawson, ERMA NZ personal communication