



Why Veterinary Medicines Should Be Exempt from HSNO

February 2010

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A joint paper by Agcarm, Animal Remedy and Plant Protectant Association, Federated Farmers of New Zealand, and the New Zealand Veterinary Association

This document presents a case for exempting veterinary medicines from the HSNO regime. It explains the rationale for this request, the issues that have led to the proposal, and some options for the exemption. It was written to accompany submissions to a government discussion document about updating HSNO to the latest version of the Globally Harmonised System, and which asked if there were any possible exemptions to HSNO. The government discussion document can be viewed at: www.ermanz.govt.nz/hs/abouths/ghscriteria.html

1. Quick Summary

Main reasons for an exemption are:

- An exemption would be in line with the Government's commitment to review regulations and "remove requirements that are unnecessary, ineffective and excessively costly" both to industry and users;
- There is policy inconsistency between the treatment of human medicines and veterinary medicines – human medicines are exempt from HSNO, veterinary medicines are not;
- Veterinarians use human as well as veterinary medicines in animals;
- The ACVM Act has been amended and now covers the management of risks to public health. This should be sufficient oversight for the negligible risks that most veterinary medicines pose to humans and the environment;
- The cost of the HSNO assessment process and application of controls is not justified when the risks of adverse effects are negligible;
- HSNO controls on veterinary medicines apply mainly to their toxic and ecotoxic properties. The ACVM Group already assesses toxic effects on animals so it would be a logical extension for ACVM Group to assess toxic risks to people as well;
- The actual and recognised adverse effects to people from veterinary medicines are **not** managed by HSNO controls (eg, antibiotic resistance, accidental injection with vaccine containing live infectious organisms, risks from needle-stick with oil-based vaccines, potential for interference with tuberculosis testing after self-injection with Johne's disease vaccine);
- The only veterinary medicines posing risks to the environment are those used in a bulk, dispersive manner (principally ecto-parasiticides for production animals);

- A one-step registration process for veterinary medicines would manage risks effectively and save unnecessary costs;
- The animal health market in New Zealand is small and costs to registrants of the dual regulatory process are hindering introduction of innovative products and technology which would benefit New Zealand agriculture and keep veterinary medicine abreast of international trends.
- An exemption would reduce the amount of superfluous information on labels;
- ERMA would have more resources to concentrate on important areas where hazardous substances pose higher risks to humans and the environment, eg light industrial/workshops.

2. Introduction

The New Zealand Veterinary Association, Agcarm, the Animal Remedy and Plant Protectant Association (ARPPA) and Federated Farmers of New Zealand are requesting that many veterinary medicines be exempted from the HSNO Framework.

For the purposes of this document, the term 'veterinary medicines' is used. A veterinary medicine is a product intended for the use in or on an animal. It includes:

- Restricted Veterinary Medicines. These were formerly known as Prescription Animal Remedies and are medicines prescribed after a consultation with a vet. They might include vaccines or treatments for specific conditions;
- Over the counter products. These are regulated products that do not require a vet consultation. They include parasiticides for the treatment of worms and ticks.
- Exempt products: These are animal health products, for example homeopathic preparations, which are deemed to be exempt from the ACVM Act. However they are not exempted from the HSNO regime.

The reasons for seeking an exemption for all three types of veterinary medicines from HSNO are:

- policy inconsistency between the treatment of finished dose human medicines and veterinary medicines;
- the absence of adverse effects from veterinary medicines and the unnecessary cost incurred by assessment and application of HSNO controls;
- the inadequacy of HSNO controls for managing some recognised risks to humans from veterinary medicines;

- the deleterious effect of regulatory compliance on the current and future supply of veterinary medicines into the New Zealand market.

Our understanding is that it was not anticipated that the HSNO Act would apply to most veterinary medicines. Our concerns have been made known to Government for several years. At the New Zealand Veterinary Association conference in 2001, Minister for the Environment Marian Hobbs gave the assurance that finished dose form medicines would be exempt from HSNO. Industry also made submissions seeking an exemption in 2005.

Another important point is that the HSNO regulations are based on the United Nations' Globally Harmonised System. But the GHS was not written to cover veterinary medicines.

The introduction to the GHS states: "at the point of intentional human intake or ingestion, or intentional application to animals, products such as human or veterinary pharmaceuticals are generally not subject to hazard labelling under existing systems. Such requirements would not normally be applied to these products as a result of the GHS".

The GHS framework was always intended as a system for labelling of hazardous chemicals, including pesticides. Other substances such as human and animal medicines and food are typically not under the GHS umbrella.

3. The Animal Health Market

Internationally the animal health market is small with total sales ex-registrant estimated at about US\$20 billion per annum (less than the size of a mid-ranked human pharmaceutical company). The market has been growing but only slowly. Ongoing efficiencies have been achieved through takeover and amalgamation of companies with more effective use of research, manufacturing, marketing and distribution channels. Continued roll-out of innovative new products is to a large extent an offshoot of research undertaken in the much larger human medicines area.

Agriculture's contribution to New Zealand's GDP has grown in the last 15 years and now stands at over 17% (including downstream processing). The single biggest contributor to agricultural production is livestock production. Veterinary medicines are for both the livestock and companion animal industries. The former has been a stand out economic performer for New Zealand in terms of productivity gains in recent years. Ongoing productivity gains are dependent on continued application of science including innovative new medicines.

Many veterinary medicines are low profit service lines, with total sales of less than \$100,000 per annum. In a tiny market, fixed costs such as those associated with registration (development of data packages for assessment, trial work,

labelling etc) represent a greater proportion of cost of sales than in jurisdictions with larger sales. The dual regulatory regime in New Zealand represents an impediment to both the continued registration, and introduction, of new products to the market.

4. The Registration Requirements For Veterinary Medicines

Veterinary medicines are managed under the Agricultural Compounds and Veterinary Medicines Act, which registers trade name products. These products are assessed and assigned conditions of registration, which include classification as either Restricted Veterinary Medicine (RVM), Over the Counter (OTC), or Exempt.

RVMs are required to be prescribed by a veterinarian after a veterinary consultation and cannot be sold to the public without veterinary authorisation. They are further classified to give increasing restriction and control on who may use the product and under what conditions. The RVM classification provides a system for managing veterinary medicines that parallels the system for prescription human medicines.

The ACVM manages specific risks: risks to trade in primary produce, to animal welfare and to agricultural security, and risks to public health. It must also ensure there is no breach of domestic food residue standards.

Veterinary medicines also require clearance under the various laws and regulations commonly known as HSNO (Hazardous Substances and New Organisms).

5. Inconsistency in treatment of human and vet medicines under HSNO Act

a. *Prescription medicines under HSNO*

With the exception of new organisms, human prescription medicines licenses under the Medicines Act are exempt from the provisions of the HSNO Act.

b. *Many prescription and veterinary medicines are the same drugs*

A number of veterinary medicines are identical to human medicines; they are made in the same manufacturing plant, have the same or similar formulation, and in some cases are in the same container but carry different labels. Many other veterinary medicines, while not identical to human medicines, are equivalent active compounds.

The different treatment on the basis of whether a label indicates human or veterinary use is a clear inconsistency.

The prescription conditions, and other controls set under the ACVM Act, already manage much of the risk to humans from veterinary medicines. For example the risk of antibiotic resistance to humans is managed by the RVM system and a system of stratified and increasingly stringent controls. In addition those veterinary medicines that are subject to habituation, addiction and abuse are already subject to further controls under the Misuse of Drugs Act and its regulations.

In registering veterinary medicines, the ACVM Group assesses risks to animals and public health. These cover off many of the risks to people, which easily (and logically) could be dealt with at the same time.

c. *Use of human medicines in animals*

The inconsistency in management of human and veterinary medicines is further reinforced by the fact that human medicines are increasingly being used in animals. Veterinarians are permitted to use products licensed under the Medicines Act on animals when there is no restricted veterinary medicine that meets the treatment or welfare needs of the animal, and provided the risks under the ACVM Act are managed.

On a global scale, New Zealand is a very small market for veterinary medicines (less than 1% of the world market), and the regulatory hurdles – ACVM Act and HSNO Act – are a deterrent to registrants with products that have a small or limited market niche. Where potential registration and other fixed costs are spread over a small number of unit sales, price becomes a deterrent to entry or continued registration, particularly when veterinarians can access equivalent human products.

The increasing sophistication of veterinary practice that requires access to human medicines that have not been developed and registered for veterinary use, mean that veterinarians use a large number of human medicines in animals.

A Massey University survey indicated that over 60% of the drugs used in their companion animal (cats and dogs) practice, and 30% of those used in the equine practice were human medicines. The dual cost of registration under the ACVM and HSNO Acts is expected to contribute to increasing numbers of prescription medicines being used in animals.

6. Appropriateness of HSNO controls to veterinary medicines

a. *What are the adverse effects from veterinary medicines?*

The number of recorded cases of adverse effects to people or the environment from veterinary medicines is extremely small. This would indicate that the risks are very small. Therefore it is difficult to see the justification for imposing the cost of a HSNO assessment process. It would be preferable that any risks that do exist are managed under the ACVM Act.

b. HSNO controls and management of risks from veterinary medicines

(i) Risks to People

Most of the major risks to humans from veterinary medicines are not risks that are managed under the HSNO Act. These include the dangers from:

- infectious substances;
- suicide;
- development of antibiotic resistance;
- injection-site lesions from accidental self-injection with oil-based adjuvant vaccine;
- potential interference with tests for human disease from accidental human injection with a veterinary vaccine;
- potential interference with human reproduction from accidental human injection with a vaccine containing a hormone as an antigen;
- the potential for abuse of addictive or performance enhancing drugs;
- the potential for use of anaesthetics and sedatives for committing.

All of these are real risks that veterinarians deal with daily. They are currently managed by way of the registration of veterinary medicines; by the Restricted Veterinary Medicine classification, which restricts access to the products; and by the link between the ACVM, veterinarians, medicines and the Misuse of Drugs Act.

Some veterinary medicines that carry some of the risks listed above do not trigger any hazard controls under HSNO Act.

The HSNO process identifies a large number of hazard properties for a variety of veterinary medicines; in particular Class 6 (toxicity) and Class 9 (ecotoxicity). The risks to people from Class 6 (toxic) hazards, which

a large number of veterinary medicines trigger under HSNO, are largely theoretical because they require actual exposure to the product, hence would require a person to ingest, inhale, or self-inject a veterinary medicine that is labelled as 'FOR ANIMAL TREATMENT ONLY'.

Many veterinary and human pharmaceuticals are harmful to people because of their inherent pharmacological properties. They are used in animals specifically for their biological effect; this is not a side-effect of a product designed for some other purpose. For this reason regulatory systems have evolved to ensure they are used appropriately, safely and effectively. Their handling and use is regulated by requiring licensing (or registration) under statute such as the Medicines Act, the Animal Remedies Act and its successor the ACVM Act, as well as scheduling under the Misuse of Drugs Act. The registration process imposes controls on how and by whom the drugs can be used and how they are distributed, with controls varying to the degree of harm that could result to humans (or animals) by inappropriate use. As many veterinary and human medicines are essentially the same substances, it makes sense for them to be managed under similar or parallel regulatory systems.

Compared with the control mechanisms that have evolved to manage the risks to humans from prescription medicines, the HSNO controls appear blunt and inappropriate for many veterinary medicines. They do not take account of the existing controls, the manner in which drugs are used or the complexity of pharmacological actions.

The HSNO default controls (or exemptions from controls) do not apply well to many pharmaceuticals, for which controls need to be tailored more closely to particular uses and situations. Real risk management is achieved by restricting access and use of these products to individuals who understand the biological processes and are trained and equipped to manage their safety.

(ii) Risks to the environment

The main veterinary medicine that poses any potential risk to the environment are those used in a dispersive manner (principally ecto-parasiticides for production animals), for which continued HSNO controls may be deemed appropriate. If ecto-parasiticides were a sticking point to obtaining an exemption for veterinary medicines, the industry would agree to their exclusion from an exemption.

7. Interface With Other Legislation

Veterinary medicines that are also hazardous substances are currently required to undergo assessment and approval under the HSNO Act and registration under the ACVM Act. The application and registration processes and the consequent labelling required under this dual regulatory regime imposes considerable costs on the registrant companies, who are supplying products into a relatively small market. Most veterinary medicines are imported, there is very little manufacturing in this country.

As noted previously, the ACVM Group assesses all veterinary medicines for registration, including the risk of toxicity to animals. As toxicity to animals and people in most cases will be the same or very similar, it would be logical for the one group to undertake both.

If a product is also a prescription medicine under the Medicines Act it requires the consent of the Director-General of Health before registration as a veterinary medicine. This provides a mechanism whereby particular risks to humans from veterinary medicines (for example, antibiotic resistance) are currently managed.

8. Exemption Options

There are a range of exemption options. Rather than present the perfect option, we have chosen to cascade possible options.

The following possible options are in order of significance, with options one the widest exemption, option seven the narrowest:

1. All veterinary medicines.
2. All veterinary medicines – excluding ecto-parasitidices for large animals.
3. All veterinary medicines – excluding parasiticides for large animals.
4. All veterinary medicines – excluding products which are classified as Dangerous Goods and in packages exceeding 200ml/200grams.
5. All Restricted Veterinary Medicines.
6. Unitised doses (ie, packed separately) of Restricted Veterinary Medicines.
7. Unitised doses of Restricted Veterinary Medicines for companion animals.

All the above options exclude single ingredients used in the manufacture of veterinary medicines, which would remain under HSNO.

Other cascade options should be considered. The main point here is that difficulties with exempting some animal health products **should not be used** as a reason for dismissing exemptions on other animal products. For example, if it

was deemed that paracitocides for large animals could not be excluded from HSNO because they are used in a dispersive manner and pose risks to the operator and the environment, there is still sound reasoning for exempting veterinary medicines which, for example, are not classified as Dangerous Goods and which are in containers not exceeding 200ml/200g.

The exact boundaries of an exemption could be worked through relatively easily. A one-day workshop of stakeholders and regulators could easily develop the draft boundaries for an exemption which would be acceptable to all parties.

9. Conclusion

Agcarm, Federated Farmers, the NZ Veterinary Association, and the Animal Remedy & Plant Protectant Association recommend that:

“Veterinary medicines should be exempted from the HSNO regime”

Agcarm, New Zealand Veterinary Association, Animal Remedies and Plant Protection Association, and Federated Farmers of New Zealand.

For further comment on this paper contact:

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