



# Regulation of Veterinary Medicines under HSNO

**On 1 July 2005, veterinary medicines previously registered under the Animal Remedies Act will be transferred to the Hazardous Substance and New Organisms (HSNO) Act.**

**This means that veterinary medicines will now be regulated by both the HSNO Act and the Agricultural Compounds and Veterinary Medicines (ACVM) Act.**



## What is HSNO?

The Hazardous Substances and New Organisms (HSNO) Act 1996 replaced a number of well-known laws including parts of the Animal Remedies Act, the Dangerous Goods Act, the Pesticides Act and the Toxic Substances Act.

The purpose of HSNO is to *protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms*. HSNO is administered by the Environmental Risk Management Authority (ERMA New Zealand).

Veterinary medicines generally fall under HSNO because they are also hazardous substances. A substance is considered to be hazardous if it triggers certain threshold levels for any one of the following intrinsic **hazardous properties**:

- explosiveness
- flammability
- oxidising capacity
- corrosiveness
- toxicity
- ecotoxicity.

## Veterinary Medicines Affected

Any veterinary medicine that triggers one or more of the hazardous property thresholds is governed by HSNO.

This includes the following types of products:

- Parasiticides
- Other 'large volume' products, such as bloat remedies and antimicrobials
- Small volume finished dose veterinary medicines, including
  - Analgesics, anesthetics, euthanasia agents and sedatives
  - Antidotes and anti-inflammatory agents
  - Antibiotics
  - Endocrine agents and steroids
  - Hormones
  - Vaccines
- Products intended for companion animals, including skin and coat conditioners.



## The Transfer Process

The process of transferring products to HSNO involves classifying the hazardous properties of the active(s) and all components within each product. This assessment drives a **hazard classification** for the product, which in turn triggers a suite of **controls**.

These controls cover the full lifecycle of the product. They may place restrictions or requirements on how the substance may be used, how it must be packaged and transported, the type of information that must be provided with the substance, and requirements for emergency management and disposal.

Over the last 12 months ERMA New Zealand has been consulting with the manufacturers of veterinary medicines, veterinarians and other parties in this industry on the classifications and controls. Decisions following this consultation are detailed in Transfer Reports, which are available from the ERMA New Zealand web site at: [www.ermanz.govt.nz/hs/transfer-vetmeds-indiv.timetable.asp](http://www.ermanz.govt.nz/hs/transfer-vetmeds-indiv.timetable.asp).

In preparing veterinary medicines for transfer, careful attention is paid to existing regulatory requirements to safeguard against manufacturers, retailers, users etc, having to meet unnecessary compliance costs under HSNO. Nevertheless, there will be some changes in the compliance regime. Two issues we know the veterinary industry is particularly concerned about are the Approved Handler control and labelling requirements.

## Approved Handler and Tracking Controls

The Approved Handler and Tracking controls are an important requirement in the management of hazardous substances. Only the most highly hazardous substances trigger these controls. For a person to become an Approved Handler, they must have experience and competence in handling the substance(s) concerned, as well as a knowledge of HSNO. Following transfer, such persons may be deemed to be an Approved Handler for a period of time, after which they must get a full five year Approved Handler test certificate.

Tracking is the recording of what happens to a hazardous substance throughout its lifecycle (i.e. from the point of import or manufacture in New Zealand, through distribution and transport to the point of use and/or disposal). For most substances the lifecycle endpoint is the use of the substance for its intended purpose.

For veterinary medicines, it is generally only those products that are acutely toxic that require Approved Handlers and Tracking. These include, for example, some of the organophosphate parasiticides.

## Deeming Veterinarians as Approved Handlers

Veterinarians are highly trained individuals and have an understanding of the hazardous properties of chemicals they use, whether they are veterinary medicines or not. Therefore, when veterinary medicines are transferred, veterinarians who hold an annual retention certificate from the Veterinary Council of New Zealand will be deemed to be Approved Handlers under HSNO to store and use these products.

Veterinarians will also be deemed to be Approved Handlers for other chemicals they are likely to use in the course of their practice. However, this will not apply where hazardous substances are stored solely for the purposes of resale.

## Location Test Certificates

When veterinary medicines that are flammable or have oxidizing properties are being used or stored above certain minimum quantities, a Location Test Certificate is required. This test certificate is comparable to the old Dangerous Goods Licence that was required under the Dangerous Goods Act.

For more information about obtaining a Location Test Certificate, refer to the *Quick Guide – Location Test Certificates* at [www.ermanz.govt.nz/resources/publications/pdfs/ER-QG-23-1.pdf](http://www.ermanz.govt.nz/resources/publications/pdfs/ER-QG-23-1.pdf).

## Other Hazardous Substances Covered by HSNO

There are many other chemicals that, because of their hazardous properties, are regulated by HSNO. Some of these have already been transferred, whilst others are currently going through the transfer process.

Chemicals and products that have been transferred and which may be used by veterinarians include certain pesticides and common solvents (e.g. methylated spirits), as well as other hazardous substances such as formalin.

Information on the controls applying to transferred substances is available from the ERMA web site and the Hazardous Substances Register.



## Monitoring and Enforcement of HSNO Controls

The main enforcement agency is the Department of Labour, together with other central and local government agencies.

Enforcement agencies monitor compliance with the HSNO Act and regulations and controls set by ERMA New Zealand. They can issue compliance orders and prosecute offenders when controls are not complied with.

Enforcement agencies can also advise on how to comply with the HSNO Act and its regulations.

## Staged Implementation

ERMA New Zealand recognises that it is not practical for industry to change overnight from one regulatory regime to another. Therefore, the transfer of veterinary medicines includes a period of Staged Implementation, to enable a smooth transition to the new system.

Staged Implementation consists of an initial six month period before any of the new HSNO controls apply, followed by, over the subsequent 18 months, progressive implementation of controls for disposal, packaging, identification and emergency management.

Staged Implementation should address many of the manufacturers concerns regarding product labelling, by enabling existing stocks of veterinary medicines to move through the supply chain in the normal manner.

## Key dates for Transfer and Staged Implementation

<b>1 July 2005</b>	Veterinary medicines transferred to HSNO. Six month period starts before the new controls apply. This will allow parties to become familiar with the controls and to come into compliance. Certain controls have a longer period as detailed below.
<b>1 January 2006</b>	Compliance required with all HSNO controls, with the exception of specific regulations for disposal, packaging, identification and emergency management listed below.  Approved Handler test certificates required (either deemed or full five year certificates). Veterinarians who hold an annual retention certificate from the Veterinary Council of New Zealand will be deemed to be Approved Handlers for the storage and use of veterinary medicines (but not for their resale).
<b>30 June 2006</b>	Test certificates for Hazardous Substances Location required.  Compliance required with regulations 21-34 of the Hazardous Substances (Emergency Management) Regulations 2001 (concerns fire extinguishers and emergency management response plans).
<b>30 June 2007</b>	Compliance required with: <ul style="list-style-type: none"><li>• Regulations 6-20 and 42 of the Hazardous Substances (Emergency Management) Regulations 2001 (concerns information and signage)</li><li>• Regulations 11 to 14 of the Hazardous Substances (Disposal) Regulations 2001 (concerns disposal information on product labels)</li><li>• The Hazardous Substances (Packaging) Regulations 2001</li><li>• The Hazardous Substances (Identification) Regulations 2001 (concerns information and documentation requirements for product labels, safety data sheets, signage and advertising).</li></ul>
<b>1 January 2007</b>	Persons handling veterinary medicines that have the Approved Handler control must have a full 5 year Approved Handler test certificate. The exception is veterinarians with an annual retention certificate, as they will be deemed to be Approved Handlers for the storage and use of veterinary medicines.

## Further Information

In the lead-up to and following transfer, additional information will be provided on the application of HSNO controls to veterinary medicines and the actions required by manufacturers, retailers, users and others in the industry to ensure they are in compliance with these controls.

In the meantime, for further information on the transfer of veterinary medicines, visit ERMA New Zealand's website at: [www.ermanz.govt.nz/hs/transfer-veterinary-medicines.asp](http://www.ermanz.govt.nz/hs/transfer-veterinary-medicines.asp) or contact

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