

Notice to distributors and customers: Addition of GHS statements to veterinary chemical product labels

In keeping with the commitment of Animal Medicines Australia and its members to product safety and stewardship, we are providing you with information regarding some upcoming label changes on a range of veterinary chemical products. These changes are being made to comply with provisions of state and territory work health and safety laws by which certain aspects of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) are being incorporated into Australian domestic law.

What is GHS and why does it apply in Australia?

The GHS was created by the United Nations to create a single worldwide methodology for chemical classification, labelling and Safety Data Sheets (SDS). The system is designed to provide users with practical, reliable and easy to understand information on chemical hazards, so that they can take the appropriate preventive and protective measures for their health and safety.

Australia committed to the 2017 introduction of GHS in 2012, including (but not limited to) all agvet chemicals used in workplaces. GHS labelling provisions are scheduled to commence on 1 January 2017 in New South Wales, Queensland, South Australia, Tasmania and the Northern Territory. GHS labelling will not apply to consumer products. In September 2016, Safe Work Australia Members agreed to exempt from GHS labelling all Schedule 8 (controlled drugs) and any Schedule 4 (restricted) veterinary medicines supplied in a form and packaging consistent with direct administration to animals (ie. not including in feed). It is expected that this decision will soon be reflected in the various state and territory *Work Health and Safety Regulations*.

What's changing / what's not changing

In many cases, existing labels and safety data sheets already meet GHS requirements. In some cases, information that is already included on safety data sheets will now also be included on product labels. In some cases, additional information will be added to the labels only, or to both the labels and the safety data sheets.

The introduction of GHS labelling provisions does not cause any change to the composition, dose rates or manufacturing processes for products. Precautionary advice for handling, use and storage may change for some products, even though the risk of exposure through normal use patterns is unchanged.

How is GHS different from APVMA risk assessments and existing use precautions?

Understanding the different systems is essential to ensuring that users continue to take appropriate safety precautions. The APVMA instructions and the GHS information come from a different conceptual basis, therefore it is important that users do not use GHS information as a replacement for APVMA instructions.

A GHS Hazard Statement relates to categorisation for potential harm from a specific chemical, irrespective of the assessed level of risk associated with how it is used, or the specific product in which it is used – and it requires that Hazard Statement to be added to the product if it isn't already present in APVMA text, as well as additional information about preventive and protective measures that should be applied (Preventative Statements) to avoid the hazard associated with that specific chemical. Simply put, a GHS Hazard Statement identifies the hazard associated with some chemicals contained in the product, not necessarily the product itself.

When a product is registered in Australia, the APVMA assesses the evidence for potential harm from the chemicals included in a product as well as its method of preparation and administration (e.g. drench, injection, implant, feed additive). The APVMA will also review data generated with the specific formulation. Such data may identify that certain hazards triggered by the GHS classification system in fact do not occur for a particular product. The APVMA then requires registrants to include recommendations for minimising exposure risks from the product on product leaflets inside the packaging, or on labels – such as the need for ventilation, or the use of personal protection equipment, or correct disposal methods – without requiring each specific chemical hazard to be listed on product packaging.

Notice to distributors and customers: Addition of GHS statements to veterinary chemical product labels

For example, a component of a formulation may trigger classification for skin irritation even though specific studies reviewed by APVMA showed the product in fact did not cause irritation to the skin. APVMA would not require such a product to be labelled for skin irritation because the product is not irritant to the skin nor would it require specific personal protective equipment (PPE) to be worn to avoid skin irritation. The GHS, by contrast, would require the product to be labelled as a skin irritant, and would also require the product to contain precautionary statements for the hazard.

More information

Each AMA member company has worked through the details as they pertain to their specific products and may provide supplementary information to this advice. If you have any questions for AMA members, please contact your relevant company contact. You might also find the following online resources helpful:

Comcare

comcare.gov.au/static/lectora/ghs/index.html

Safework Australia

seminars.swa.gov.au/are-you-ghs-ready

safeworkaustralia.gov.au/sites/swa/about/publications/pages/labelling-agvet-chemicals

Agsafe

agsafe.com.au

Animal Medicines Australia represents the leaders in the Australian animal health industry:

