

## NOTICE

*Commonwealth of Australian Gazette no. APVMA 6, 6 June 2006 Agricultural and Veterinary Chemicals Code Act 1994*

### **Proposed changes to generation of stability data under high humidity conditions for veterinary chemical products**

Stability testing is the primary tool used to assess the expiry date and storage conditions for veterinary chemical products. Stability testing includes long-term studies where the product is stored at conditions of room temperature and humidity, as well as accelerated studies, where the product is stored under conditions of high heat and humidity

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) have recently revised the guidelines VICH GL3(R) – Stability: Stability Testing of New Veterinary Drug Substances and Medicinal Products (Revision at Step 9). The revised VICH GL3 specifies relative humidity (RH) conditions for long-term storage at  $30^{\circ}\text{C} \pm 2^{\circ}\text{C}/65\% \text{ RH} \pm 5\% \text{ RH}$ . The current APVMA guidelines specify  $60\% \text{ RH} \pm 5\% \text{ RH}$  at  $30^{\circ}\text{C}$ .

Temperature and relative humidity data available from the Australian Bureau of Meteorology have established that a number of major centres in Australia experience a combination of high humidity and high temperature during the summer months.

High relative humidity can affect the physical and chemical stability of veterinary chemical products. For these reasons the APVMA will adopt the revised VICH storage conditions with effect from 1 July 2006.

Existing stability data generated under the current guidelines or currently being generated will be acceptable to the APVMA. However, all new stability data generated after 1 July 2006 must be carried out under the revised conditions  $30^{\circ}\text{C} \pm 2^{\circ}\text{C}/65\% \text{ RH} \pm 5\% \text{ RH}$ .

The revised APVMA guidelines are available on the APVMA's website at <http://www.apvma.gov.au/guidelines/vetguidelines.shtml#2>

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