

Veterinary use of off-label or unregistered therapeutic products

August 2024

The following AVA guidance is designed to assist veterinarians in meeting their professional responsibilities while delivering safe and effective veterinary care when considering the use of unregistered therapeutic products or off-label product use.

Therapeutic products that have Therapeutic Goods Administration (TGA) registration (for human use) or Australian Pesticides and Veterinary Medicines Authority (APVMA) registration (for veterinary use) will have this compliance information contained on their label and product information.

Off-label use of a registered therapeutic item refers to prescribing or using a medication, medical device, or other therapeutic product in a manner not specified in the official labelling approved by the appropriate regulatory agency. This can include using the product for an indication, a patient population, a dosage, or a method of administration not included in the approved labelling.

Off-label use is common practice and can be based on emerging scientific evidence, clinical judgment, or patient needs. However, it also carries risks since the safety and efficacy of the therapeutic item for off-label use may not be well-documented.

Veterinarians are permitted to use their professional judgment to use or supply most drugs or veterinary medicines off-label. This includes accessing beneficial drugs or therapeutic products registered for human use or with limited veterinary registration.

Individual veterinarians must ensure that they are fully aware of any risks and their professional obligations and responsibilities when considering the use of products in this manner.

When a product does not have APVMA registration, or is being used off-label, the AVA recommends the following:

- **Client communication:** Clearly inform your clients that the product is unregistered or is being used off-label and the reasons for this. Ensure this information is part of your client communications and documented in the patient's medical record. You can use the [client communication information](#) issued by the AVA previously to assist.
- **Professional judgment:** Use your professional judgment to assess the appropriateness of this product for your patients. Consider the potential benefits and risks associated with using an unregistered or off-label product.