Using veterinary medicines safely and effectively - hazards of off-label use.

**Notice type:** Advisory

**Date:** 01/09/2015

Using veterinary medicines safely and effectively.

**Prescription Required:**
Yes

**Target Audience:**
Veterinarians, marketing authorisation holders, pharmacists, Licensed Merchants, general public.

**Problem Or Issue:**
Unfortunately each year, the Health Products Regulatory Authority (HPRA) receives a number of notifications of adverse reactions to veterinary medicinal products following the off-label (non-authorised) use of veterinary medicinal products. Such usage can give rise to adverse effects in animals, and occasionally, in humans.

Off-label use includes the use of a veterinary medicine:

• at a dosage different to that recommended, or

• for an indication that it not mentioned on the product labelling or literature, or

• in a species other than the approved target species, or

• in a manner not specified in the product literature, or

• in combination with, or concurrently with another veterinary medicine for which such use has not been recommended.

**Background Information Or Related Documents:**
In accordance with national legislation, the off-label use of products is allowed only under exceptional conditions and is restricted to use under the responsibility of veterinary practitioners. Off-label use of veterinary medicines may give rise to:

• serious interactions with other medicines being administered together or at the same time,

• adverse effects in the animals undergoing treatment,

• adverse effects in the person administering the product,

• violation of maximum residue limits due to the persistence of drug residues in animals,

• diminished efficacy and the potential for resistance to develop.

Full information on the correct method of use (along with other relevant information) for each marketing authorisation is available from the website of the HPRA where the ‘Summary of Product Characteristics’ (SPC) for each product  granted a marketing authorisation by the HPRA is published.  This information is also generally available from the package leaflet and/or labelling for each veterinary medicinal product.

**Actions To Be Taken:**
Unauthorised (off-label) use of a veterinary product may potentially result in the occurrence of adverse events in a treated animal, or in the user.

Prescribers are reminded to acquaint themselves with the conditions of use of veterinary medicines and to take note of any warnings of potential interactions or specific precautions to be taken. Off-label use of veterinary medicines carries risks and prescribers need to weigh up the risks and give appropriate advice to users in order to mitigate the risks involved.

Users are advised that unless otherwise directed by your veterinary practitioner in exceptional circumstances, veterinary medicinal products should only be used in accordance with the terms of the marketing authorisation of the product.

Note that the marketing authorisations of veterinary medicinal products may be updated from time to time with important new safety information, arising from the on-going monitoring of the safety aspects of products once marketed.

Consequently, it is important that prescribers and users of veterinary medicinal products always consult the most up-to-date information available for each product which is available on the website of the HPRA.

In order to minimise the occurrence of adverse events in users of prescribed veterinary medicinal products, the HPRA wishes to stress the importance of the following three key measures:

1. Prescribers should ensure that they are familiar with the most up-to-date information on the correct use of the product which is available from the SPC published on the HPRA website for veterinary medicinal products granted a national marketing authorisation by the HPRA, or from the European Medicines Agency (EMA) website for products granted a centralised marketing authorisation.

2. Prescribers should ensure that the user of the product has been adequately informed of the correct method(s) of use of the product at the time of prescribing/dispensing.

3.  Users of the product should have access to appropriate information on the correct use of the product (product labelling and package leaflet), clearly understand how a particular veterinary medicinal product is to be safely used (before use) and know where to get additional information and/or clarification if necessary (prescribing veterinarian).

In addition to the above, following receipt by the HPRA of reports of a significant adverse event in the user of a prescribed veterinary medicinal product following ‘off-label’ use, the HPRA intends to communicate to the Marketing Authorisation Holder of that product a recommendation that the MAH advises the user that the product should only be used in accordance with the terms of the marketing authorisation and to refer the user to this advisory notice.

**Further Information:**
Further information on the correct use of all veterinary medicinal products granted marketing authorisations by the HPRA is available from the website of the HPRA.