IRISH MEDICINES BOARD

ADDENDUM TO IMB POLICY ON THE SUPPLY OF ANTIPARASITIC PRODUCTS FOR COMPANION ANIMALS

July 2013

On 22 May 2013, the Board of the IMB, having received the opinion of its Advisory Committee for Veterinary Medicines following the latter's consideration of the matter in early 2013, accepted that an application for a topical adulticidal flea product containing fipronil and which did **not** have an indication for flea allergic dermatitis (FAD), could be supplied by Licensed Merchants (LM supply category), but **not** under the category 'Companion Animal Medicines' (CAM supply category).

This means that in future, applications for spot-on adulticidal flea treatments, which do not have an FAD claim, may be considered for sale/supply either under POM(E) or LM categories according to benefit/risk assessment carried out by the IMB, taking into account the wish of the applicant.

The Board accepted the opinion of the ACVM that the following criteria would apply to the allocation of products to the LM category:

a. No particular skill is needed to use or administer the veterinary medicinal product;
b. The products contain only active substances have been subject to prescription-control in an essentially similar formulation for at least five years and with an exemplary pharmacovigilance record during that time;
c. Point-of-sale information by the supplier on the administration, use and disposal of the product is required or recommended, but the technical details are easily understood;
d. Point-of-sale information on the management / prevention of the disease is available and the technical details are easily understood;
e. The summary of product characteristics of the veterinary medicinal product is clear and written in a manner that is understandable by a lay person;
f. There is minimal risk to the animal or animals treated, to the person administering the product or to the environment;
g. The veterinary medicinal product is not subject to special storage conditions.

Following further consideration of the matter in response to queries from applicants, the IMB wishes to clarify that the change to the policy relates to spot-on formulations of fipronil. However, other products which have well recognised efficacy and an exemplary safety profile (over more than five years) may also be considered, provided appropriate justification is provided.