IRISH MEDICINES BOARD

Notice Information: - Advisory
20 December 2012

Part 1. Product Information

a)	Title:	Further update on Fluke treatments for use in Dairy Animals producing milk for human consumption.
b)	Product Name/Type:	Update on Fluke treatments for use in Dairy Animals producing milk for human consumption.
c)	Reference:	Update on Fluke treatments for use in Dairy Animals producing milk for human consumption.

Part 2. Target Audience

a)	Target Audience:	Farming Public, Pharmacists, Licensed Merchants & Veterinary Practitioners

Part 3. Background Information

a) Background Information:

Currently two active substances with activity against liver fluke (albendazole and oxyclosanide) are permitted for use in lactating dairy cows. Oxyclosanide and certain veterinary medicines containing albendazole can also be used in pregnant dairy animals during the dry period. This is the case also in respect of a single formulation of triclabendazole (a 24% strength) which has recently been authorised by the IMB for use in dry cows. Please consult the IMB website (www.imb.ie) to view the Summary of Product Characteristics (SPC) for up-to-date information on the conditions of use of individual veterinary medicines and information on their use in dairy animals.

Regarding flukicides containing other active substances, the European Commission has recently published the outcome of a review of the withdrawal periods of veterinary medicines containing clorsulon, closantel, nitroxynil, triclabendazole and rafoxanide as the sole active substance in dairy animals during the dry period. The Decision, which is dated 23/11/2012 and which was published on 11 December 2012, is available from the Commission website at http://ec.europa.eu/health/documents/community-register/html/vo23541.htm The Decision follows a review of the substances concerned by the European Medicines Agency. The Decision is binding on Member States and affects the conditions under which veterinary medicines containing the substances concerned can be used in dry stock throughout the EU.

The net effect of the Commission's Decision in respect of flukicide medicines containing clorsulon, closantel, nitroxynil, triclabendazole or rafoxanide is a change to the existing instructions insofar as use in pregnant maiden heifers, ewes and goats producing milk for human consumption is concerned. In effect, the current prohibition on use in dairy cattle intended for milk production for human consumption has been extended to sheep and goats. Specific direction is also provided in relation to the use of medicines containing one of these substances as the sole active substance in maiden animals e.g. prohibition on use during pregnancy or in last trimester of pregnancy depending on the class of drug, particular product dose form and animal species to be treated.

The implementation of the Commission decision has commenced and the Marketing Authorisation Holders for the medicines involved are being informed. The IMB requires them to vary the relevant marketing authorisations in this country as soon as possible and in any event bef

before 30 June 2013 to introduce the changes on the labelling in new stock of the medicines concerned. Existing products affected by the Decision already carry an instruction that the product should not be used in cattle producing milk for human consumption, including pregnant heifers intended to produce milk for human consumption. The arrival of newly-labelled stock for the Irish market could take some time depending on the volume of stock of individual products in the marketplace. Farmers should follow the label directions as stated on the product label unless otherwise directed by their veterinary practitioner .

It should be noted that many flukicides are marketed in Ireland in combination with other wormers. These combination medicines are not directly affected by the Commission Decision, but the IMB will review their labelling over the coming months for consistency of approach with the Decision.

In welcoming developments to harmonise the instructions for use of flukicidal medicines in ruminant animals producing milk for human consumption in the EU, the IMB notes that the situation may continue to evolve in the coming years, should new residue studies for specific veterinary medicines become available. If any of the Marketing Authorisation Holders do decide to generate product specific residue data this will eventually lead to further modifications to some of the instructions for use during the dry period or perhaps even during lactation.

Part 4. Enquiries

a)	All enquiries should be made to:	Queries in relation to the above item can be sent to the Veterinary Sciences Department at the following email address vetinfo@imb.ie

Part 5. Keywords

a)	Keywords:	Fluke