

Notice Information: - Advisory
20 May 2011

Part 1. Product Information

a) Title: Caution in use of veterinary antibacterial drugs in dairy cows

b) Product Name/Type: Veterinary medicines administered to food-producing animals

Part 2. Problem/Issue

a) Problem/Issue: Through its work in reviewing reports of suspected adverse reactions to veterinary medicines (e.g. untoward effects, lack of effectiveness, detection of drug residues etc .) over recent years, the IMB has become aware that residue standards for milk being operated by creameries for certain animal remedies might not always be exactly the same as those which have been set internationally to protect public health. This issue applies primarily to antibacterial drugs given intramammarily as a means to control mastitis in cows. The effect of this means that farmers supplying milk to creameries might need to observe additional precautions in order to ensure that they meet the creamery standards for milk delivery.

Part 3. Background Information

a) Background Information: The benchmark used by the IMB and other EU Member States to set withdrawal periods for animal remedies is the Maximum Residue Limit (MRL) established by Codex Alimentarius or by the European Commission (in cases where there is no suitable Codex standard). These standards have been elaborated following a detailed scientific review of the toxicology of the drug as well as an analysis of the metabolism and elimination of the drug from treated animals.

In respect of individual animal remedies authorised by the IMB, studies are required that demonstrate the depletion of residues in treated animals to concentrations below those of the established MRL. These residue studies are used by the IMB as the means to establish appropriate withdrawal periods for milk and meat of treated animals. Antibacterial screening tests used by creameries might not be calibrated precisely in line with the MRL or may be exquisitely sensitive for certain classes of antibacterial drugs (e.g. penicillins and cephalosporins) while being less sensitive to other drugs.

Part 4. Action to be taken

a) Action to be taken:

The IMB would like to recommend the following precautionary measures to individuals and their health-care professions who are involved in supplying milk to creameries:

1. Farmers should continue to be vigilant regarding the use of animal remedies and the avoidance of unwanted residues.
2. Farmers should follow the directions of use stated on the product labeling and package leaflet unless directed otherwise by their veterinary practitioner.
3. Creameries operating residue standards should clearly communicate those standards to farmers and their veterinary practitioners.
4. An increase to the stated withdrawal period might be necessary where the creamery standard is more sensitive than the MRL established in the European Union.
5. Users of veterinary medicines should continue to report any suspected adverse reactions either to the company concerned (i.e. the marketing authorisation holder of the animal remedy concerned) or to the IMB.

Part 5. Enquiries

a) All enquiries should be made to:

Commensurate with its role in the protection of animal health, the IMB will continue to monitor reports of suspected adverse reactions and to provide further advice as necessary.