Maisons-Alfort, 20 July 2012

Press release

The Agency invites veterinarians to declare any adverse effects that may be linked to the veterinary medicinal product CLOSAMECTIN POUR-ON SOLUTION FOR CATTLE

Within the framework of the veterinary drug monitoring system ANSES has implemented via the French Agency for Veterinary Medicinal Products, the Agency recently registered several cases of adverse reactions in cattle treated with CLOSAMECTIN POUR-ON SOLUTION FOR CATTLE. The Agency invites veterinarians to send in declarations of adverse effects that may be linked to this product.

ANSES, *via* the French Agency for Veterinary Medicinal Products (ANMV), has recorded several cases of adverse reactions in cattle treated with CLOSAMECTIN POUR-ON SOLUTION FOR CATTLE. This medication, marketed in France since August 2011, is an internal and external anti-parasitic containing ivermectin and closantel. The marketing authorisation (MA) for the product is held by NORBROOK laboratories.

Analysis of pharmacovigilance data by ANMV experts has shown that the adverse effects described mainly include neurological symptoms (ataxia, locomotor problems), vision loss which may sometimes be irreversible, eating behaviour disorders (anorexia) and digestive disorders (diarrhoea). These symptoms may be due to closantel poisoning, although no evidence of overdoses or licking was reported. Adverse reactions to the product were reported in 32 cattle and led to death or euthanasia in 11 of the animals.

Although symptoms are very rare (approximately one out of 50 000 treated animals is affected), the Agency and the National Veterinary Drug Commission wish to inform veterinary practitioners about these possible adverse effects. The Agency is therefore requesting that veterinarians pay special attention to any possible new cases they may hear about, and encourages them to submit their declarations via the veterinary drug monitoring system. For information, a declaration form is available on the ANSES and ANMV websites. Thanks to the expert assessment of cases declared using this method, details can be added to the clinical picture for these adverse effects and their frequency can be more clearly ascertained in order to establish the necessary management measures to be taken.

The French Agency for Veterinary Medicinal Products (ANMV), under the authority of ANSES's Director General, ensures missions in the field of veterinary pharmaceuticals. To carry out these missions, it has been given scientific assessment, surveillance and decision-making powers. Among its tasks, it is in charge of providing authorisations for veterinary medicinal products. It also coordinates inspections of veterinary pharmaceutical companies and the pharmacovigilance system and provides drug quality monitoring and control.

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