

<b>Health and Safety Executive</b>		<b>Sector Information Minute</b>	
<b>Agriculture and Food Sector</b>		<b>SIM 01/2004/06</b>	
<b>Accidental injection of Micotil</b>			
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#### Target Audience

All Inspectors dealing with Agriculture

### **ACCIDENTAL SELF-INJECTION OF DRUGS OF LETHAL POTENTIAL – FATALITIES ASSOCIATED WITH MICOTIL (ACTIVE INGREDIENT TILMICOSIN)**

This SIM draws Inspectors attention to the consequences of accidental self-injection of the drug Micotil used by farmers and veterinary staff, following reports of two fatal accidents in the USA.

#### BACKGROUND

1 Micotil is a sterile solution of the antibiotic Tilmicosin. It is available as a Prescription Only Medicine (POM) and the Marketing Authorisation holder in the UK is Elanco Animal Health, a division of Eli Lilly and Company Ltd. POMs can only be supplied where a veterinarian has issued a prescription, but can be administered to livestock by farmers or veterinary staff. Micotil is supplied in 25 mL, 50 mL, 100 mL and 250 mL multidose amber glass bottles as a liquid injectable only. It is injected subcutaneously (beneath the skin).

2 The product is used for the treatment of pneumonia in cattle and sheep, for the treatment of ovine mastitis, and for foot rot in cattle.

3 Two fatal incidents involving farmers have been reported in the USA in the past 18 months as a result of accidental self-injection whilst attempting to administer the drug to cattle. The incidents apparently involved between 6 and 15 ml of Tilmicosin, although the exact amount remains unknown.

4 To date there have been no reported fatalities in the UK associated with the accidental self-injection of Micotil but there have been a number of reports of suicides resulting from the use of Tilmicosin (based products) or mixtures containing it.

## INFORMATION

### **Action taken by Elanco**

5 In May 2004 Elanco informed the Veterinary Medicines Directorate (VMD) that it would draft a letter to be sent to individual veterinary surgeons advising of the lethal potential of Micotil: to be followed up by practice visits by company representatives to reinforce the message.

6 A news release from Elanco was published in The Veterinary Record magazine, (29 May 2004).

7 The VMD was further informed that labels with strengthened operator warnings would be introduced. The warnings include details of therapeutic agents that should not be used in the treatment of adverse reactions resulting from accidental self-injection or deliberate misuse.

## ACTION BY INSPECTORS

8 During visits to large animal veterinary practices and livestock farms, Inspectors should ensure that veterinary staff and farmers are aware of the risks associated with handling and administering drugs of lethal potential such as Micotil and that safe working practices are followed. Appropriate precautions include:

- (1) Arrangements for the safe storage and handling of the product both on and off the farm
- (2) The provision of a suitable and sufficient COSHH assessment, instructions and training to ensure the competency of staff required to handle or use the product
- (3) Ensuring that adequate and suitable facilities are available for the restraint of animals to be injected
- (4) Arrangements to prevent the risk of accidental self-injection arising from contact with other persons or animals moving in the environment eg unsecured animals nearby
- (5) The provision of information (including operator warnings) to those persons administering the drug

(6) Ensuring that persons using the product are aware of the action to be taken in the event of accidental self- injection.

(7) Ensuring that the instructions for use of the product are followed.

9 Users should be aware that there is currently no antidote or other reversing agent available commercially that can be administered following self-injection and therefore in the event of such an incident urgent medical attention should be sought. It is essential that the package insert (product information) is given to the doctor or other medical staff so that the correct treatment may be given.

10 Further information can be obtained from Elanco Animal Health, Eli Lilly & Co. Ltd, Kingsclere Road, Basingstoke, Hampshire RG2 6XA (Tel: +44 (0) 1256 353131).

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