2 NOVEMBER 2007

EQUINE INFLUENZA

CHIEF VETERINARY OFFICER COMMUNICATION # 12

URGENT FOR ALL VETERINARIANS

Investigation Treatment and Reporting of Adverse Reactions following Vaccination with ProteqFlu or ProteqFlu TE

Horses vaccinated with ProteqFlu or ProteqFlu TE vaccine may experience a range of adverse reactions. They may involve a range of symptoms including:

- A transient swelling at the injection site (max. diameter 5cm) which regresses within 4 days.
- Pain and local hyperthermia in rare cases.
- A slight increase in temperature (max 1.5ºC) for one (1) day, exceptionally two (2) days.
- In exceptional circumstances, apathy and reduced appetite the day after vaccination.
- In exceptional circumstances a hypersensitivity reaction, which may require appropriate symptomatic treatment.

Owners/managers who notice any serious effects are advised to contact their veterinary surgeon. The NSW Department of Primary Industries (DPI), as part on the Equine Influenza (EI) control program has agreed to pay veterinarians for the investigation and treatment of adverse reactions related to vaccination. The payment will cover an initial investigation visit and all subsequent treatment required for symptoms deemed to be related to vaccination reactions. This payment will be subject to the submission of the completed attached report that includes full details of the clinical sign and treatment and all related invoices. The report should be faxed to SDCHQ on 02 6361 9976, marked ‘attention Veterinary Liaison’.

Please note all serious adverse reactions as defined below should be reported within 7 days.

Definitions

The following definitions are included to provide veterinarians with guidance on this reporting process.

Adverse Reaction

“An adverse experience is an unintended or unexpected effect on animals, human beings or the environment, including injury, sensitivity reactions or lack of efficacy associated with the clinical use of a veterinary chemical product.”

Serious Adverse Reaction

“A serious adverse experience is any adverse experience that results in death, is life-threatening, results in persistent or significant disability/incapacity, prolonged duration of serious signs or is a congenital abnormality or birth defect. A serious adverse experience in humans is one that requires medical treatment or involves death.

In horses a serious adverse reaction involves:

- Death
- Welfare implications
- Hospitalisation
- More than one veterinary visit

Serious reactions should be reported within 7 days.

Australian Government
Australian Pesticides and Veterinary Medicines Authority

ADVERSE EXPERIENCE REPORTING FORM FOR VETERINARY MEDICINES (PROTEQFLU/PROTEQFLU TE)

Please attach any material that may help to clarify details of the incident being reported.

TYPE OF REPORT:

☐ **Adverse animal reaction** ☐ **Adverse human reaction** ☐ **Lack of effect** ☐ **Other**

PRODUCT DETAILS:

APVMA/NRA No *(required information – check product label)*: PER10313 or PER10306

Full Product Name: ProteqFlu or ProteqFlu TE_____

Batch No: _____ Expiry Date: _____

Registrant (or manufacturer): Animal Health Australia

Active constituent(s): _____

Storage details: _____
(eg at room temperature, air conditioning, refrigerated, stored in shed etc)

Is a product sample available? ☐ Yes ☐ No

Has the product Registrant been notified of the incident? ☐ Yes ☐ No

ANIMAL DETAILS:

Species: _____ **Breed:** _____ **Sex:** _____

Weight: _____ Age: _____ ☐ Desexed ☐ Pregnant ☐ Lactating

Number of animals: Treated: _____ Affected: _____ Deceased: _____

TREATMENT DETAILS:

Date and time of treatment: _____

Dose/frequency/duration as used: _____

Environmental conditions (eg weather, feed, availability of water): _____

Disease/condition being treated / relevant medical history: _____

All other product(s) given at time of treatment: _____

* *APVMA/NRA numbers required to identify products*

_____

_____

_____

EVENTS FOLLOWING TREATMENT:

Date and time symptoms first noticed: _____

Description of symptoms, management and outcome: _____

Outcome: ☐ **Recovery** ☐ **Death** ☐ **Euthanased** ☐ **Ongoing**

As at (date): _____

REPORTING PERSON:

☐ Veterinarian ☐ Animal Owner ☐ Affected Human ☐ Other

Name:

Address: _____

Telephone: _____ *Fax:* __

Email: _____

Signature: _____ ***Date:***

ADDITIONAL NAMES / CONTACT DETAILS *as required*:

Veterinarian: _____

Animal Owner or *Affected Human:* _____

Animal name: _____

You may also wish to contact the Registrant directly at the contact details provided on the product label.