

What is it?

Answer overleaf....

THE PAST TWELVE MONTHS

1. Following the Equine Infectious Anaemia outbreak in Ireland last year Veterinary Immunogenics Ltd (VIL) reviewed its protocols to assure product safety through improved Biosecurity (see overleaf).

2. The application made in May 2006 to the Veterinary Medicines Directorate (VMD) for a Marketing Authorisation for Hypermune-RE resulted in success in April 2007. Under new EU regulations much detailed information relating to this product is available on the VMD website <http://www.vmd.gov.uk>, product information, UKPARS, Hypermune-RE, Module 2, as also is the Summary of Product Characteristics (eSPC). Hypermune-RE is not only licensed to assist in the control and management of *R. equi* disease in foals but is also licensed to treat Failure of Passive Transfer.

3. This dossier has now been reviewed, updated and submitted under the EU Mutual Recognition Procedure for a full Marketing Authorisation in The Republic of Ireland. VIL has been advised that this process may take months and it is hoped that AR16s will be granted in Ireland until the process is complete.

4. The EU is introducing its revised Pharmacovigilance requirement which has been adopted by VIL. (see overleaf)

5. Broken Bags are reported every year by a very small number of users. This is avoidable by following simple guidelines. Please consult our web site to see our Plasma Handling and Management leaflet.

Veterinary Immunogenics Carleton Hill Penrith Cumbria CA11 8TZ UK

Topics:

- Biosecurity
- Marketing Authorisations
- Pharmacovigilance
- Research & Development
- Equine Plasma Products
- Shipping at Christmas and New Year
- Forthcoming Events

6. On site studies have revealed that Hypermune & Hypermune-RE contain noteworthy amounts of gram negative endotoxin antibodies. Consideration can be given to administering either of these products in the septic situation where gram negative bacteria are implicated.



The Application for a Marketing Authorisation by Mutual Recognition Procedure.....all seventeen files of it!!!

CHRISTMAS & NEW YEAR

Public holidays prevent normal shipping schedules being met over Christmas and New Year. Regrettably plasma cannot be dispatched to you from 19th December 2007 to 2nd January 2008

REQUEST PLEASE

Please supply us with your email contact details. It will enable more efficient contact, especially when you are expecting shipments enabling up to the minute information on consignment progress.

**TEL: +441768863881; FAX: +441768891389
EMAIL: tombarr@veterinaryimmunogenics.com**

BIOSECURITY

VIL continually monitors the DEFRA web site, the veterinary press and other disease surveillance web sites for exotic disease status of the UK and neighbouring countries. Particular attention is paid not only to specific diseases such as Equine Virus Arteritis and Equine Infectious Anaemia but also West Nile Virus and African Horse Sickness. The current Bluetongue outbreak in the UK is providing up to date knowledge of the vector which may be implicated in transmission of some of these diseases. VIL's location in the North of England at present provides added security. However, when necessary extra blood samples are tested from all the horses in the donor herd and the VMD is informed of the results.

MARKETING AUTHORISATIONS

Veterinary Medicinal Products are available following the grant of a Marketing Authorisation by the regulatory authority when satisfied that the product is of consistent high quality, is safe and is efficacious. The data is presented following safety studies, field studies and stability studies. The concomitant costs are high but you are assured of consistent product quality, safety and efficacy.

PHARMACOVIGILANCE

Pharmacovigilance activities come within the scope of each veterinary medicinal product's Marketing Authorisation criteria for quality, safety and efficacy as new information is accumulated on its use under field conditions. Suspect Adverse Reactions (SARs) are investigated in three main areas-**the product itself, the recipient animal and how the product is stored handled and administered.** Each or all of these may contribute to SARs as also can drug incompatibilities and "off label" use.

HYPERMUNE EQUINE PLASMA

Hyperimmune equine plasma is designed to be:

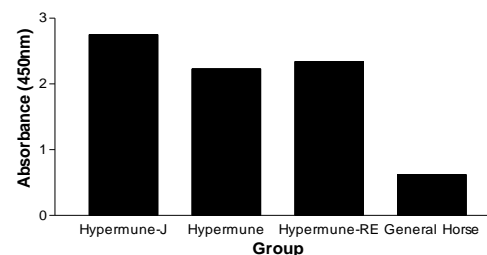
- Red cell group compatible with recipient horses
- Produced by a consistently repeatable process
- Free from endotoxins
- Free from external contaminants
- Free from important named viruses
- Free from pathogens
- Consistent with normal fresh equine plasma
- More consistent in its immunoglobulin and total protein content than plasma from the foal's dam or a random donor, specifically IgG \geq 24g/l
- More value in its IgG content due to VIL's vaccine protocols than plasma from the foal's dam or a random donor
- Immediately available
- Free from excess citrate

In addition Hyperimmune-RE contains specific antibodies to European strains of pathogenic *R. equi*.

RESEARCH & DEVELOPMENT

The recent on site use of an ELISA test for detecting gram negative endotoxin antibodies has revealed that Hyperimmune and Hyperimmune-RE have only slightly lower levels than Hyperimmune-J. These arise from the unique hyper immunisation programme developed by VIL over 15 years.

Figure 1. Mean for each group



When compared to levels in normal healthy adult horses in the general horse population it can be seen that all three products have markedly higher levels.

HOW ARE WE DOING?

Customer feed back is an essential part of our purpose to establish Veterinary Immunogenics as the premier producer of the finest horse plasma in the world. One customer returned the data shown in Table 1 below.

Foal Identity	Before Plasma		After Plasma		Dose
	Age in hours	IgG Level	Age in Hours	IgG Level	
13/6-5	24	4-8	72	>8	1 litre
6/6-16	24	<4	72	6-8	1 litre
4/6-2	24	4	96	>8	1 litre
31/5-5	24	<4	48	>8	1 litre
21/5-8	24	<4	72	8	1 litre
3/5-3	24	4-8	48	8	1 litre
8/3-6	24	<4	120	8	1 litre
12/2	24-48	4-8	96	>8	1 litre

FORTH COMING EVENTS

15th -17th November 2007 Veterinary Immunogenics Ltd is attending the Irish Equine Veterinary Congress

17th-18th January 2008 VIL is attending Rossdale & Partners Foal Care Course, Newmarket.

Answer: Plasma destroyed by excess heat

FOR FURTHER INFORMATION

www.veterinaryimmunogenics.com