

Rick Clayton
Technical Director

Ref.: RC/mhd-0040

Mr. Peter Arlett
DG Enterprise
European Commission
Rue d'Auderghem 45
B-1049 Brussels

19th May 2006

Subject: Consultation on the Community system of Pharmacovigilance for human medicinal products

Dear Mr. Arlett,

I have noted with interest the launch of a public consultation on the Community system of Pharmacovigilance for human medicinal products. IFAH-Europe, representing European manufacturers of veterinary medicinal products, is not directly concerned by this consultation. However there is one general point we wish to make, of a fundamental nature to our industry sector.

In brief, IFAH-Europe fully supports the strengthening of the Community system of Pharmacovigilance; however, it cannot be assumed that any proposed solutions or improvements to the human system can be automatically transferred to the veterinary sector.

Although it is sensible to keep legislation and systems aligned wherever possible between the two sectors, it is critical that any measures adopted for the veterinary sector are specifically devised with careful consideration for the needs and resources of this sector. In the past the veterinary sector has suffered unnecessary costs due to the inappropriate transfer of certain "human" provisions.

The need for this differentiation stems from the considerable differences that exist between the human and veterinary sectors. These differences relate to both the objectives of the legislation, and the scale of the economics.

For example:

1. Our objectives include animal health and welfare, as well as public health.
2. There are no national health re-imburements for animals; the animal owner must pay the full cost of treatment.
3. The veterinary market is 3-5% of the value of the human market; therefore you must assume we only have 1/20th of the resources.
4. Our 'patients' often only have a certain value; if the cost of treatment is too high then the 'final option' is chosen.



5. The agricultural market is affected by animal health issues; these can reduce public confidence in food of animal origin, which in turn can drastically reduce the value of livestock (sometimes close to zero!).

All these factors mean that the veterinary sector is very cost sensitive. Consequently it is paramount that any measures adopted must be proportionate to both the identified risks and also the limited resources of the sector. To ensure this it will be necessary to also carry out a full consultation within the veterinary sector should the Commission wish to consider improvements to the veterinary Pharmacovigilance system.

Yours sincerely,

A handwritten signature in blue ink that reads "Rick Clayton". The signature is written in a cursive, flowing style.

Rick Clayton
Technical Director