



**FOOD & VETERINARY DIVISION  
ALBERTOWN  
MARSA-MALTA**

14<sup>th</sup> December, 2004

**To: Licensed Distributors of Veterinary Pharmaceuticals**

As you are aware, from the 1<sup>st</sup> of January 2005, all veterinary pharmaceuticals being placed on the Maltese market, are subject to an annual LM25.00 (approx. EURO 65.00) per product as an administrative fee.

Marketing Authorisation Holders in EU countries are informed that in order for a veterinary pharmaceutical product to be placed on the Maltese market, the following minimum documentation is required:

1. An authenticated copy of the Marketing Authorisation issued by the Authority of an EU Member State.
2. Mock-ups of the packaging to be placed on the market. All packaging is to be labelled in the English or Maltese language.
3. Sections A & B of Part I of the Dossier approved in the EU Member state where the product is registered.
4. Copy of any approved variations as yet not included in the original dossier.

Please liaise with the Veterinary Medicines Unit prior to placing any orders for importation of products, which are registered in Europe, but coming from countries outside the EU.

Regards,

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C L Vella  
Dir. Gen. FVRD