



ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES

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ATI 312

Request

From: [Redacted under section 40 of the FOIA]
Sent: 16 September 2014
Subject: Request under the Freedom Of Information Act

Dear FOI Officer,

I would like to make a request for information relating to the clinical test trials of Prednicare (Prednisone, Prednisolone) as used during the clinical trials on dogs.

I would like to obtain the detailed test results, so that I can assess whether the drug consistently raises inter-ocular pressure and causes muscle weakness with long term use.

Please confirm receipt of this request.

VMD Reply

Sent: 23 September 2014
To: [Redacted under section 40 of the FOIA]
Subject: Request under the Freedom Of Information Act

Your Request

Thank you for your email dated 16 September 2014.

We are dealing with it under the Freedom of Information Act 2000.

You asked for information relating to the clinical test trials of Prednicare (Prednisone, Prednisolone) as used during the clinical trials on dogs.

Our Reply

We do not hold any information relating to clinical test trials of Prednicare (Prednisone, Prednisolone) as used during the clinical trials on dogs. This is because the original application for the product was made in 1972 when it was not necessary for companies to submit such data.

Since authorisation the VMD has considered Prednicare a number of times, first when the product was re-approved as a reviewed product in 1993 and later under the processes by which products are renewed or varied. From this post-authorisation scrutiny (which did not require data relating to clinical test trials) we are satisfied that Prednicare meets the safety, efficacy and quality standards required for veterinary medicines.

Our Service

If you are unhappy with the service you have received in relation to your request and wish to make a complaint, you may request an internal review within two calendar months of the date of this e-mail. If you would like to request an internal review please write to [Redacted under section 40 of the FOIA] at the VMD via ati@vmd.defra.gsi.gov.uk. If you are not content with the outcome of the internal review you have the right to apply directly to the Information Commissioner for a decision. The Information Commissioner can be contacted at: Information Commissioner's Office

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