



ASSURING THE SAFETY, QUALITY & EFFICACY  
OF VETERINARY MEDICINES

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**ATI 318**

**Request**

**From:** [Redacted under section 40 of the FOIA]

**Sent:** 3 November 2014

**Subject:** Access to information under the Freedom of Information Act

Dear Madam/Sir,

I would like to make a request for information under the Freedom of Information Act (FOIA) 2000.

For the product Ketofen 10% solution for injection for cattle (nationally registered in the UK under Vm 08327/4067), we would like to have access to the assessment of the clinical studies which have led to a positive decision for the indication "reducing pain associated with lameness".

**VMD Reply**

**Sent:** 20 November 2014

**To:** [Redacted under section 40 of the FOIA]

**Subject:** Access to information under the Freedom of Information Act

Thank you for your email, dated 3 November 2014.

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

**Your Request**

You asked:

For the product Ketofen 10% solution for injection for cattle (nationally registered in the UK under Vm 08327/4067), we would like to have access to the assessment of the clinical studies which have led to a positive decision for the indication "reducing pain associated with lameness".

## **Our Reply**

The VMD does not hold an assessment of clinical studies that supported the cattle lameness indication. The VMD approved the addition of the cattle lameness indication to the UK reference product Ketofen 10% solution for injection on the basis of the product's identical formulation compared with a relevant EU reference product, and by extending the same principle of recognition of other member states' assessments that it had previously applied to assessment of ketoprofen generics.

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## **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](mailto: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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