ASSURING THE SAFETY, QUALITY & EFFICACY
OF VETERINARY MEDICINES

ATI 304

Request

From: [Redacted under section 40 of the FOIA]
Sent: 25 June 2014
Subject: Request for information

Dear Mme/Sir,

May I have free access to information on ecotox data for preparing phase 1 and 2 evaluation of florfenicol applied to chickens (20 mg/kg bw) for 5 days?

VMD Reply

Sent: 27 June 2014
To: [Redacted under section 40 of the FOIA]
Subject: Request for information

Your Request

Thank you for your email below dated 25 June 2014.

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

You asked for all information on ecotox data for preparing phase 1 and 2 evaluation of florfenicol applied to chickens (20 mg/kg bw) for 5 days?

Our Reply

We fully recognise and respect the obligations imposed by the FOIA on the VMD to act in a manner that is transparent and open in the public interest. However the very real harm likely to ensue from the disclosure of the information you request warrants the balance to be taken in favour of non-disclosure.

Through the marketing authorisation system the VMD receives information from commercial entities that constitutes trade secrets and information protected by patent, the publication of which would create significant commercial harm to the manufacturer. The commercial entities are required by law to provide the information and are put to great expense to generate it. In this case, the information you request could be used by other manufacturers to formulate, develop or market products that would compete with these products.

Further, the market as a whole benefits from establishing and upholding a robust process for marketing authorisations; this in turn requires appropriate protection of confidentiality, and the honouring of expectations of confidentiality.

We consider such factors weigh against the public interest in disclosing the information in question. In these circumstances, we consider that sections 41 and 43 of the FOIA apply to this request and that it would not be in the public interest for the VMD to release this information. Publishing such information could undermine the veterinary pharmaceuticals industry's trust in the regulatory process as well as the companies' commercial position. This could lead to companies becoming unwilling to place product on the UK market, which would have a detrimental impact on animal welfare.

You may want to look at the VMD's website via the link below to see what kind of information we do release, particularly those related to end-point data.

http://webarchive.nationalarchives.gov.uk/20140304235049/http://www.vmd.defra.gov.uk/business/ati_disclosure.aspx

In relation to the end point data we release you should note that such end point values could not be used as a substitute for Environmental Risk Assessment (ERA) data. The document "Guidance on the Assessment of environmental risks of veterinary medicinal products" published in the Notice to Applicants, Volume 6C, June 2009 in respect of the assessment of environmental risks of veterinary medical products, sets out what data can be accepted when preparing an ERA, as follows:

"Published data provided must be of a quality to enable an assessment of the risks to the environment which is equivalent to that enabled by specifically generated studies in accordance with agreed guidelines, i.e. they can only be used to substitute studies, if the publication contains a sufficient amount of data and sufficient details on the design and conduct of the study to allow a full and independent assessment. Therefore, the provision of only end point values or a published summary of an assessment is not sufficient to substitute ERA data."

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
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF