

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Peter Verhoeve
Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

13 February 2013
EMA/86219/2013
Veterinary Medicines and Product Data Management

Dear Mr Verhoeve,

Subject: Doxycycline 50% WSP (EMA/V/A/059) - Access to documents held by the European Medicines Agency – RFI-013 No 02-091

Thank you for your correspondence dated 7 February 2013 in which you apply for access to documents held by the European Medicines Agency.

Provision of information in an open and transparent manner is part of the mission of the Agency.

Your request has been dealt with in accordance with the principles and limits established in Regulation (EC) 1049/2001 regarding public access to European Parliament, Council and Commission documents as applicable to the EMA pursuant to Article 73 of Regulation (EC) 726/2004.

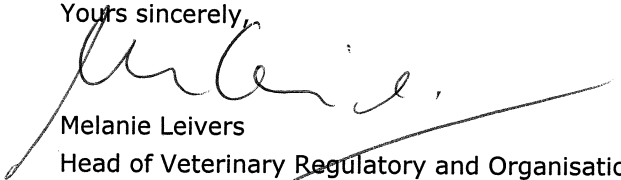
This regulation sets out provisions which guarantee openness and transparency of the activities of European Institutions, whilst also ensuring the protection of certain public and private interests.

In relation to your specific questions, I can inform you that a single residue depletion study was provided - *Pharmacokinetic and residue study of doxycycline in broilers after water medication with Doxycycline 50% WSP* (Study No 30943 dated 30 August 1993) and I am aware that this is already in your possession.

Please find enclosed a copy of the section (unredacted) of the CVMP rapporteur and co-rapporteur assessment report of 13 April 2011 that describes the evaluation of this study and the rapporteur and co-rapporteurs' conclusions. Only this section of the report is provided as this is the part of the report relevant to your enquiry.

While the rapporteur and co-rapporteurs' comments may be reproduced provided that the EMA is acknowledged as the source, the section of the report provided to you also includes tables of data taken from the study report. These should not be reproduced without the author's prior authorisation.

Yours sincerely,


Melanie Leivers
Head of Veterinary Regulatory and Organisational Support

