



European Medicines Agency  
*Veterinary Medicines and Inspections*

London, 4 March 2008  
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Rick Clayton  
Rue Defacqz  
1000- Brussels  
Belgium

Dear Mr. Clayton,

Subject: Request for fee waivers for inactivated Blue tongue vaccines

I am pleased to inform you that your letter of 30 January 2008 with regard to fee waivers for Bluetongue vaccines was considered at the meeting of the Committee for Medicinal Products for Veterinary use (CVMP) on 12-14 February 2008.

The Committee on the basis of the current epidemiological situation in relation to Bluetongue, the lack of authorised vaccines in the market and the potential impact to animal health considered favourably your request for fee reductions regarding inactivated vaccines against Bluetongue.

The Executive Director, Thomas Lönngren, has consequently decided to grant fee waivers in relation to all applications made to the Agency for inactivated vaccines against Bluetongue as follows:

- 0% for the first application and 50% for the second and subsequent applications for identical vaccines that vary only in the strain(s) of Bluetongue virus included.
- 100% of the annual fee for any Bluetongue vaccine that has not been marketed within the EU/EEA during the year and 0% for any Bluetongue vaccine that has been marketed within the EU/EEA.

Yours sincerely,

David Mackay  
Head of Unit, Veterinary Medicines and Inspections

Enclosed: Executive Director Decision