



European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency to grant fee waivers to applications for Bluetongue Vaccines

The European Medicines Agency has decided to grant fee reductions to all applications for inactivated vaccines against Bluetongue, 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.

The fee reductions will be implemented 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 during the year.

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1. Decision of the EMEA Executive Director regarding fee reductions for centralised application of inactivated Bluetongue vaccines ([EMEA/54433/2008](#))
2. Letter to IFAH-Europe regarding their request for fee waivers for centralised applications of inactivated bluetongue vaccines ([EMEA/111981/2008](#))
3. The CVMP reflection paper on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue (EMEA/CVMP/IWP/105008/2007) was published on 23 April 2007 and can be found here <http://www.emea.europa.eu/pdfs/vet/iwp/10500807en.pdf>

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