



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Veterinary Use

Public statement on authorisation of bluetongue vaccines

In response to the epidemiological situation of bluetongue disease in livestock in the European Union prevailing at the time, the lack of authorised vaccines on the market and the consequent potential negative impact on animal health, the European Medicines Agency (the Agency) started in 2007 a number of initiatives to promote the availability of authorised vaccines against bluetongue within the European Union.

These efforts culminated in the publication of the CVMP guideline on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against bluetongue (EMA/CVMP/IWP/220193/2008) and the decision of the Executive Director on 4 March 2008 to grant fee reductions for inactivated bluetongue vaccine authorisations (EMA/54433/2008).

The fee reductions agreed were 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.

These Agency initiatives significantly contributed to the timely availability of high quality, safe and efficacious bluetongue vaccines for sheep and cattle against a wide a range of serotypes (1, 2, 4 and 8).

The EU had already adopted [Council Directive 2000/75/EC](#), which lays down control rules and measures to combat bluetongue in the Community, including the establishment of protection and surveillance zones and a ban on animals of the susceptible species leaving those zones as well as implementing rules for the Directive (Commission Regulation (EC) No 1266/2007)¹ as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue. The legislation was expanded by [Commission Decision 2008/655/EC](#) of 24 July 2008 approving the vaccination plans against bluetongue of Belgium, Czech Republic, Denmark, Germany, Spain, France, Italy, Luxemburg, the Netherlands and Portugal. This Decision was

¹ http://ec.europa.eu/food/animal/diseases/controlmeasures/bluetongue_en.htm



amended by [Commission Decision 2009/19/EC](#), approving the vaccination plans of Austria and Sweden and the amended plans of Denmark, Spain, France, the Netherlands and Portugal.

Over the course of the following years the epidemiological situation of bluetongue in the EU has altered significantly and vaccination against some serotypes became widespread. This has now resulted in the availability on the market of several bluetongue vaccines with full authorisations.

In light of the above considerations and the experience gained with annual re-assessments for marketing authorisations under exceptional circumstances the Agency considers it appropriate to adjust its policy on the authorisation of bluetongue vaccines. This statement also provides clarification to potential applicants and to Marketing Authorisation Holders on the expectations that will apply with respect to authorisations under exceptional circumstances for bluetongue vaccines.

New applications:

Applicants should be aware that the Agency considers that there are no longer grounds to consider further requests for authorisation of vaccines against bluetongue for serotypes 1, 2, 4 and 8 under exceptional circumstances. Applications for vaccines against these serotypes will therefore be expected to fulfil the standard technical requirements as laid down in Title II of Annex I to Directive 2001/82/EC as amended.

The CVMP guideline on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against bluetongue (EMEA/CVMP/IWP/220193/2008) remains applicable, where appropriate, for applications for marketing authorisations for bluetongue vaccines against other serotypes.

Annual re-assessments and conversion to standard marketing authorisations:

The Agency has now gained sufficient experience of the annual reassessments of bluetongue vaccines under exceptional circumstances, and of the conversion of such authorisations to full authorisation status, to clarify its policy in this area. In future, marketing authorisations under exceptional circumstances for bluetongue vaccines will be expected to be converted to standard marketing authorisations as soon as possible after granting of the decision by the European Commission and at the latest **by the time of the first renewal** (i.e. 5 years after first authorisation). For continuation of an authorisation under exceptional circumstances beyond the first renewal, there would have to be objective, technical and scientific reasons why it has not been possible for the marketing authorisation holder to generate the data necessary to convert the authorisation. Financial considerations will not be taken into account in this decision. In addition, applicants are reminded that the continued need for an authorisation under exceptional circumstances shall be justified on epidemiological grounds by the marketing authorisation holder at each annual reassessment.

Fees:

The decision of the Executive Director of 4 March 2008 to grant fee reductions for inactivated bluetongue vaccine authorisations (EMEA/54433/2008) expired on 4 March 2013 thereby removing any fee reductions in place until that date.

The Agency has therefore decided to propose to the EMA Management Board that the implementing rules for the fees regulation (EMA/MB/122878/2013) be amended to introduce the following fee reductions in the case of vaccines against bluetongue:

- 1) Fees for applications for a marketing authorisation – Initial fee:
 - 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.

2) Fees for the maintenance of a marketing authorisation – Annual fee:

- For bluetongue vaccines (authorised under exceptional circumstances or standard authorisations) the following fee reductions will apply: 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.

In view of the fact that changes to the implementing rules are routinely carried out once a year in March, applicants or marketing authorisation holders seeking fee reductions in the interim period before March 2014 are advised to contact vet.applications@ema.europa.eu.