European Medicines Agency
Executive Director

EDIR Ref

EMEA/54433/2008

DECISION ON THE GRANTING OF A FEE REDUCTION

1. Background

Pursuant to paragraph 1 of Article 9 of Regulation (EC) No. 297/95 of 10 February 1995, as amended, on fees payable to the European Medicines Agency, the Executive Director in exceptional circumstances and for imperative reasons of public or animal health may grant a fee reduction after consultation of the competent scientific committee.

2. Type of reduction

2.1 Request for fee reduction

On 30 January 2008, IFAH-Europe, requested a fee reduction for Marketing Authorisations applications and for annual fees relating to inactivated Bluetongue vaccines.

2.2 Summary of the justifications for the EMEA decision

According to the fee regulation (EC) No 297/95, as amended, the fee for a veterinary marketing authorisation application for an immunological product is € 58,000 and for the annual fee is € 27,700.

The fee reduction was requested 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 Executive Director is of the opinion that the fee for authorisation should be reduced due to exceptional circumstances and for imperative reasons of public health, thus increasing the probability that high quality, safe and efficacious Bluetongue vaccines for sheep and cattle against as wide a range of serotypes as possible will be available in the EU without delay. Reduction of annual fees for vaccines that have been authorised but are not subsequently marketed is appropriate in the interests of animal health so as to ensure that such vaccines remain authorised and available for use at short notice as the epidemiological situation with respect to Bluetongue may change at any time.

The Executive Director has consequently agreed to grant a fee reduction 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.

3. Consultation of the scientific committee

The Committee for Medicinal Products for Veterinary Use was consulted on this proposal at its February 2008 meeting and did not object to the granting of such a fee reduction for the above mentioned procedures.

4. Decision

4.1 Granting of a fee reduction

A fee reduction for the above mentioned procedures for applications regarding inactivated Bluetongue vaccines is hereby granted 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.

4.2 Scope of the decision

This decision applies to applications regarding inactivated Bluetongue vaccines and is restricted to the above mentioned procedures.

This decision shall not grant any further waiver or reduction rights for fees related to the above mentioned procedure or to any other procedure or service charged by the Agency in accordance with Regulation (EC) No 297/95, as amended.

4.3 Financial and budgetary implication

The fee to be paid by the applicants for the above mentioned procedure is € 58,000 for the first application and € 29,000 for the second and subsequent applications for similar Bluetongue vaccines, and € 27,700 for an annual fee for any Bluetongue vaccine that has been marketed within the EU/EEA during the year.

This decision shall apply for a period of 5 years from the date of signature, subject to annual re-evaluation in light of epidemiological developments.

The present decision is notified to IFAH-Europe, the CVMP and the European Commission.

London, 4 March 2008

Thomas Lönngren
Executive Director