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Press Office

Press release

European Medicines Agency recommends first vaccine for foot-and-mouth disease for authorisation at EU level

Vaccine allows for the most effective strain combination to be selected in case of an outbreak of FMD

The European Medicines Agency's Committee for Medicinal Products for Veterinary Use (CVMP) has recommended the marketing authorisation for Aftovaxpur DOE for use in response to outbreaks of foot-and-mouth disease (FMD). The vaccine is intended for active immunisation of cattle and sheep from 2 months of age and pigs from 10 weeks of age to reduce clinical signs of the disease.

While some FMD vaccines have previously obtained a marketing authorisation at the national level, Aftovaxpur DOE is the first FMD vaccine to be recommended for use across all European Union (EU) Member States.

FMD is an infectious disease affecting cloven-hoofed animals. While FMD is not normally fatal to adult animals, the disease is debilitating and causes significant loss of productivity. As observed in the EU in 2001 and 2007, outbreaks of FMD can have a severe impact on animal health and can have adverse effects not only on the livestock industry but also on the wider economy of the affected regions. Routine vaccination against FMD is prohibited by legislation in the EU but rapid access to safe and effective authorised vaccines is a key component of EU and national contingency plans against this disease.

Aftovaxpur DOE is the first vaccine using the full multi-strain dossier approach, a concept which was established in 2010 to allow the swift availability of suitable vaccines in case of outbreaks of major livestock diseases.

Seven FMD strains are included in the dossier of Aftovaxpur DOE. In response to an outbreak of FMD, national competent authorities will be able to select up to three strains which best correspond to the current epidemiological need. These strains will then be rapidly incorporated in the final product.

First use of the multi-strain dossier approach

The general regulatory model, within which applications contain a single strain combination, is impractical for certain diseases such as avian influenza, bluetongue and FMD due to the highly variable

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nature of these viruses. The strains to be included in the final product for these vaccines cannot be determined before a threat has been identified.

Therefore, following recent legislative changes, the European Medicines Agency introduced the concept of multi-strain dossiers for vaccines against avian influenza, bluetongue and FMD in 2010. This approach allows for a single marketing authorisation application to cover multiple strain possibilities ahead of outbreaks so that the most effective strain combination can be chosen in the case of an outbreak of the disease, depending on the particular type of virus that needs to be controlled.

These measures aim to promote the availability of vaccines ahead of outbreaks in a way that ensures that the most effective decision can be taken swiftly in case of outbreaks of animal diseases.

The CVMP opinion on Aftovaxpur DOE will now be sent to the European Commission for adoption of a marketing-authorisation decision.

The applicant for Aftovaxpur DOE is Merial.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. In the past, certain FMD vaccines without marketing authorisations were permitted to be used in the EU in emergency cases. Some FMD vaccines were authorised at the national level.
3. The 'Guideline on data requirements for multi-strain dossiers for inactivated vaccines against avian influenza (AI), Bluetongue (BT) and Foot-and-Mouth disease (FMD)' can be found at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/03/WC500077950.pdf
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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