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Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

(CVMP)

CONCEPT PAPER ON MINIMUM DATA REQUIREMENTS FOR AN AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES FOR VACCINES FOR EMERGENCY USE AGAINST BLUETONGUE

AGREED BY IMMUNOLOGICALS WORKING PARTY	February 2008
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1. INTRODUCTION

Bluetongue (BT) is a non-contagious, insect-transmitted disease that is caused by BT virus (BTV). It is principally a disease of sheep and other domestic and wild ruminant species. Cattle and goats are usually sub-clinically infected, thus the occurrence of severe BT amongst cattle during the ongoing epidemic in northern Europe is notable. BT has a big economic impact on the sheep, goats and cattle industry. The Bluetongue disease is normally confined to the more southern parts of Europe such as the Balearic Islands, Sardinia, Sicily, Corsica and some areas of Italy, Spain, France and Portugal. In August 2006, the first ever outbreak above the 50°N parallel was reported by the Dutch authorities. This was followed by reports from Belgium, Germany and France. In 2007, outbreaks of bluetongue (serotype 8) have been confirmed in Germany, Belgium, France, the Netherlands, Luxembourg, Denmark, Czech Republic and United Kingdom. These outbreaks indicate that bluetongue virus has survived the winter successfully. The disease is spreading fast through Europe and may become endemic in many European Union countries.

2. PROBLEM STATEMENT

The fight against Bluetongue through the use of vaccines is a priority and the measures to stimulate the development of vaccines should be encouraged.

While in the case of a lack of suitably authorised products National Competent Authorities can respond to an outbreak of Bluetongue with emergency vaccination by implementing Article 8 of Directive 2001/82 /EC and provisionally allow the use of vaccines without an authorisation, there is an unequivocal preference to have access to vaccines with a Marketing Authorisation.
The use of unauthorised vaccines could potentially have negative effects in the field (especially for live vaccines, introduction of exotic extraneous agents or reversion to virulence).

In consideration of the urgent need to make authorised products available, vaccines a similar approach could be followed as the one that was recently applied for Avian Influenza vaccines.
The purpose of the proposed guideline is to provide minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue

3. DISCUSSION (ON THE PROBLEM STATEMENT)

The advantages of Bluetongue vaccines being submitted via the centralised procedure in the interests of achieving a harmonised pan-European approach to BT vaccines are indisputable.

Similar to the recommendations for avian influenza vaccines it is proposed to have legislative amendments in place, which would allow the authorisation of vaccines against avian influenza, Foot-and-Mouth Disease (FMD) and Bluetongue, in order to permit authorised vaccines that can be adapted quickly to the incursion of a new strain.

The concept of a multistrain dossier as currently proposed in the draft proposal for a revision for Annex I of Directive 2001/82/EC should also apply to Bluetongue vaccines. A multistrain dossier contains a large pool of authorised Master Seeds from which the manufacturer can then select a number of antigens, up to a specified limit, to formulate each batch of product.

4. RECOMMENDATION

The Working Party recommends to draft a guideline on minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against bluetongue to facilitate a rapid authorisation of vaccines. The scientific requirements on quality, safety and efficacy data for these vaccines should be defined.

5. PROPOSED TIMETABLE

Draft guideline: June 2008
Adoption by CVMP for consultation: June 2008

6. RESOURCE REQUIREMENTS FOR PREPARATION

Appointment of a rapporteur
Time to discuss at the June IWP meeting
EMEA secretariat to manage the consultation process

7. IMPACT ASSESSMENT (ANTICIPATED)

The guideline will have significant consequences for the animal health and the farming industry as it will facilitate the authorisation of essential vaccines. For MAHs and regulatory authorities, the guideline will give advice on which data will be necessary to authorise an emergency vaccine against Bluetongue. This harmonised data set can also be used by National Competent Authorities to authorise vaccines they might wish to use if emergency vaccination is applied.

8. REFERENCES TO LITERATURE, GUIDELINES ETC

Reflection Paper: Minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against bluetongue EMEA/CVMP/IWP/105008/2007