Centralised Authorisation of bluetongue vaccines

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- Currently no centrally authorised vaccines against Bluetongue (BT).
- The EMEA and its Immunologicals Working Party (IWP) strongly recommends central authorisation of BT vaccines in the interest of a harmonised pan- European approach to such products.
- Legal basis: Council Regulation (EC) No 726/2004 *(Possibility to use the centralised procedure for the authorisation of veterinary medicinal products used, within the framework of Community provisions regarding prophylactic measures for epizootic diseases*).

Initiatives taken by the EMEA regarding Bluetongue

- Establishment of a subgroup of experts in order to address bluetongue related issues.
- Production of a reflection paper, adopted by the CVMP on 18 April 2007, regarding the minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against bluetongue.

  http://www.emea.europa.eu/pdfs/vet/iwp/10500807en.pdf

- Minimum data requirements cover quality, safety and efficacy parts of applications.

Possible EMEA initiatives in case of central applications for BT vaccines

- Accelerated assessment: Reduction of the assessment time (according to the relevant guideline the assessment time can be reduced to 150 days from 210 days).

- Authorisation under exceptional circumstances:

✓ provision of authorisation based on minimum requirements,

✓ additional data to be provided as post- authorisation commitments

✓ annual re-assessment of benefit/risk balance

✓ expectation to revert the authorisation to a normal one.

- Enhanced pharmacovigilance: Strengthened safety monitoring following authorisation.

Current situation

- There has been interest by a number of companies.
- The issue of financial incentives has been raised by the industry and is being investigated.
- The EMEA encourages centrally authorised vaccines against Bluetongue and is prepared to assess them against a set of minimum data requirements.

Thank you for your attention