

Bluetongue Conference

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The views of the Animal Health Industry - Introduction



- Disease information
- Disease prediction
- Vaccine development
- Mass vaccination & Trade issues
- Conclusions

All comments in the context of BTV 8

Disease information



- Orbivirus that is well identified
- May infect sheep, goats, cattle, buffalo, camels, antelope and deer
- Not zoonotic
- Transmission via Culicoides midge
- Culicoides is ubiquitous with more than 1,000 species
- Whilst we understand the virus, we know little about Culicoides – daytime activity, overwintering, reservoir for virus, control???

Disease prediction - 1



- Nobody predicted the arrival of BTV 8 into Northern Europe
- It was predicted that other BTV strains would spread northwards
- The European Technology Platform for Global Animal Health (ETPGAH) is working on disease prediction
 - Database of disease information Wikipedia model
 - Analysis of gaps in ability to control
 - Prioritisation

Disease prediction - 2



- ETPGAH will enable better preparation
- Continuously learn from experience
- Which disease will arrive next?
 - African Horse Sickness, African Swine Fever,
 Rift Valley Fever, West Nile Disease, etc.?
- Prioritisation will allow us to focus
- Develop prevention strategies
- Develop control strategies

Disease prediction - 3



- Community Animal Health Strategy has a key lead role to play
- Institutions/Stakeholders must decide priorities
- Institutions/Stakeholders must decide if antigen and/or vaccine banks are necessary and for which diseases
- We all fail if a disease arrives & we are unprepared
 - We need to protect animal welfare (prevent animal suffering and avoid mass slaughter)

Vaccine development - 1



- Based on expert input to the Action Plan for the ETPGAH, it takes 5 to 7 years to develop a new or improved vaccine serotype at a cost of €6m!
- We are struggling to shorten the process to less than 2 years with the cost unknown
- Commission have negotiated mass vaccination plans
- Predictability is vital industry needs to know that a market will exist
- Production of 150m doses needs 6 to 8 months planning

Vaccine development - 2



- As night follows day, bluetongue will be a major problem in Northern Europe in 2008 – not a secret - not speculation!!
- Experts agree on the need for mass vaccination
- Lack of orders from Member States has prevented timely planning
- France & UK are to be commended for issuing tenders & the UK for placing an order
- How will a decision taken by a Member State in February 2008 differ from a decision taken in November 2007?
- How can we have more timely planning in the future?
- How do we distribute limited supplies?

Vaccine development - 3



- Companies continue their development programmes
- Licensing criteria must be fulfilled
 - EMEA "Reflection Paper: Minimum data requirements for an authorisation under exceptional circumstances for vaccines for emergency use against Bluetongue"
 - EMEA "Concept paper on requirements for multi-strain dossiers"
 - Risk assessors (EMEA/CVMP) and risk
 managers (DG Sanco) need to work together

Mass vaccination & Trade issues



- Appreciate the work on the legislation mass vaccination, "exceptional" licensing option & multi-strain approach
- Planning framework in place
- Member States to implement
- Emergency funding mechanism
- Animal welfare can be protected
- Trade can continue

Conclusion



- We need a lot more information on Culicoides
- Improved prediction ability via the ETPGAH
- Vaccine development takes time, is costly & industry needs predictability
- If a case ever demonstrated the need for greater publicprivate partnership, this is it!
- All stakeholders need to be aligned in the decision & supply chain
- Risk assessors & risk managers must be aligned
- Lack of orders from Member States is the most critical bottleneck
- How do we distribute limited supplies?