

Vaccination – Can we do it better in the future?

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Contents

- Benefit/Risk Assessment
- Antigen/Vaccine Bank Development
- EU Decision
- Food Safety
- Rapid Assessment
- Multi-Strain Dossier
- Conclusions

Benefit/Risk Assessment

- If the risk is high mortality or morbidity, the main concern is safety
 - ensure vaccine is free of dangerous contaminants that could spread disease (Extraneous Agents)
- Member States use emergency powers (Article 8) to do this in effect
- CVMP cannot do this!
- The future legislation (currently under review) should allow a true benefit/risk striking a more meaningful balance
- Enable benefit/risk focus under the 'Minimum Data Requirements' aspect of the legislation

EU Decision

- Linking in to benefit/risk, the CVMP should have greater powers to recommend the granting of an EU authorisation – Commission need to propose decision
- Ensures greater availability
- Enables trade in animals & produce (for countries with a similar disease status)
- Helps to ensure Single Market operates
- Enable via 'Exceptional Circumstances' powers in the legislation

Antigen/Vaccine Bank Development - 1

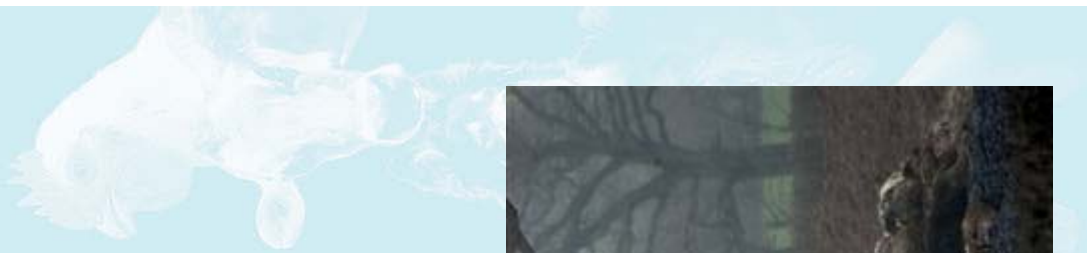
- As part of the Animal Health Law initiative, DG Sanco has developed a draft paper concerning the contents and updating of the Community antigen & vaccine bank
- This paper should be finalised as a matter of priority
 - Define what diseases/strains should be added to the bank based on current risk assessment
- Bank is part of preparedness for future disease threats
 - FMD, Bluetongue (exotic strains), AHS, AI, CSF, ASF, RVF, etc.

Antigen/Vaccine Bank Development - 2

- Vitally important that the bank contents are accepted by all Member States as appropriate for use across the EU
 - We should not have a situation where a Member State that is free of a disease refuses to accept produce from vaccinated animals from another Member State that have been treated with contents from the bank (subject to risk assessment from the threat of disease transmission via produce)



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Food Safety

- Produce from vaccinated animals is safe!!!!
- Practically all animals are vaccinated
- We must have common sense along the food chain
- We must avoid mass slaughter to the greatest extent possible by using vaccines as appropriate
- Every stakeholder along the food chain has a responsibility to ensure that we apply the concept of 'vaccination to live'

Rapid Assessment

- The rapid assessment powers in the legislation are greatly welcomed
- However, confined to AI, FMD & Bluetongue
- Extend rapid assessment possibility to all diseases when the legislation is reviewed
- Concerning subsequent data requests, this should be deferred if the disease disappears
 - We risk the loss of products if data is demanded where there is no likelihood of future sales

Multi-Strain Dossier

- Where we have a 'frame formulation' (well established formulation used in a species), we should be able to change the antigen as a Variation (fast track this process where there is an urgent need)
- Currently, we must seek a new license going through a full evaluation procedure for each antigen
 - This is unnecessary
- Facilitating such an approach will allow rapid response to 'antigenic drift' (where the target virus changes a little and is no longer adequately controlled by the vaccine)
- It also allows rapid response to the arrival of a new strain of a disease
- The revised legislation should facilitate this approach

Summary

- We should have pragmatic benefit/risk assessment
- The CVMP should have the power to propose an EU authorisation based on a benefit/risk assessment
- The antigen/vaccine bank should be completed with all Member States accepting use of such products
- Food safety should not be challenged
- We need rapid assessment powers for all vaccines to be able to respond to crises
- Facilitate replacement of an antigen via a Variation – fast track in a crisis
- We can do it better in the future!