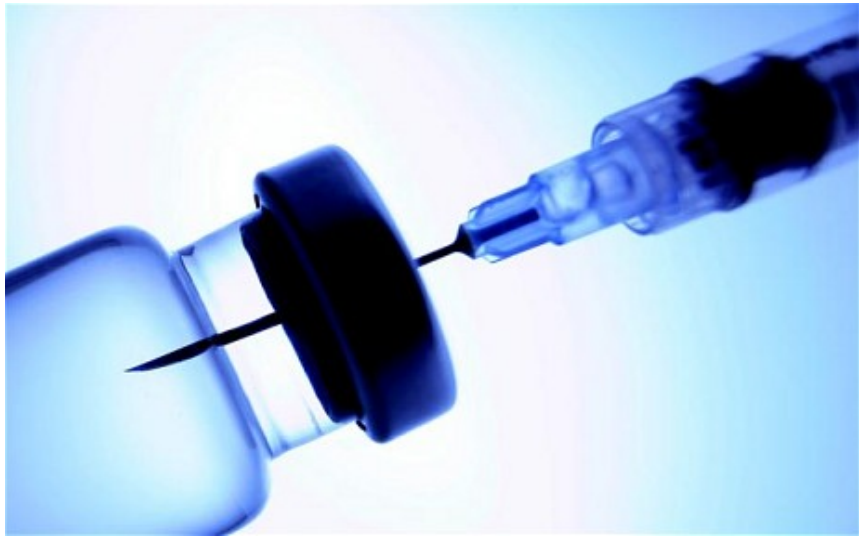
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



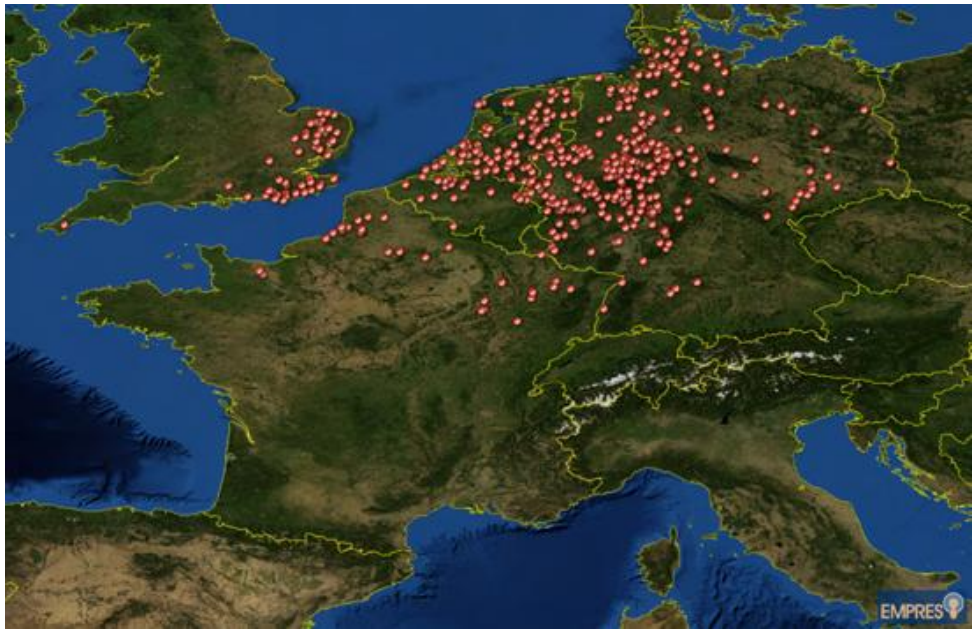
Immunologicals

Review of recent activities, developments and plans

Presented by: Nikolaus Križ
Secretary of the CVMP Immunologicals Working Party

Thank you to all stakeholders!

Schmallenberg workshop 10 April 2012



GL on requirements for the production and control of IVMPs – in effect 1 January 2013

- **Replaces 12 GLs, NfGs and position papers**
- **GLs on the general requirement for production and control of live / inactivated bacterial and viral vaccines for veterinary use**
- **GLs on specific requirements for avian, bovine, ovine and caprine, equine, dogs, cats, pigs and fish**
- **GLs on immunosera and colostrum substitutes**
- **NfG on antimicrobial preservatives**
- **Public statement on inactivation**

GL on requirements for the production and control of IVMPs

- **Clarifies issues not sufficiently defined in the existing texts such as**
  - Devices
  - Antibiotics
  - Preservatives
  - diluents
  - inactivation requirements
  - pass criteria for safety tests

- **Highlights importance of Dir. 2010/63/EC on animal welfare**
- **Extraneous agents in a separate text**

Table of extraneous agents to be tested for in relation to the guideline on requirements for the production and control of IVMPs

- **Intensive discussions with industry including bilateral discussions and recommendations – ongoing**
  - **A list of EA is necessary and will need updating**
  - **IFAH-Europe will provide a list of cell lines / cell types which can grow EA**
  - **A list of primers should be established**
  - **Clarification on scope re testing on raw material / finished product is necessary**
  - **Exclude retro-active application to seed material**

Table of extraneous agents to be tested for in relation to the guideline on requirements for the production and control of IVMPs

- **GL out for consultation until 31 May 2013**
  - **Explanatory note**
  - **1) Justification for exclusion from testing**
  - Disease does not occur in country of origin or herd of origin
  - Substance cannot be contaminated with agent (e.g. does not cross placenta)
  - Agent can be inactivated
  - **2) Characterisation of testing**
  - Validated or already accepted in MA dossiers
  - cell cultures, embryonated eggs, animal inoculation
  - PCR possible but validated
  - Detection of agent based on detection of antibodies

GL on the design of studies to evaluate the safety and efficacy of fish vaccines

- **Came into effect on 1 May 2012**
- **Specific aspects include**
  - **Considerations for fish**
  - **Fish to be used**
  - **Water conditions**
  - **Laboratory studies**
    - **SAFETY and EFFICACY aspects**
  - **Field studies**
  - **Duration of immunity claims**

GL on the requirements for combined vaccines and associations of IVMPs

- **2nd consultation until 15 January 2013**
- **Combined vaccine is against one or more diseases, comes in one or more containers but has 1 MA**
- **Association is**
  - Mixing of 2 or more vaccines prior to administration at 1 site
  - Administration of 2 or more vaccines at the same time but at different sites
  - Administration of 2 or more vaccines at different times
  - BUT an association achieved by the mixing of two products from two separate applicants cannot be authorised.

GL on the requirements for combined vaccines and associations of IVMPs

- **Main comments as follows**
  - Requirements still too demanding (e.g. for different site administration complete new data)
  - Directive 2010/63 not rigorously applied (e.g. serological marker possible if correlation with protection – rare)
  - Cases where applicants have extensive knowledge of strains should be considered
- **Re-Discussion at June IWP necessary for finalisation**

Other GLs of interest

- **Criteria for inclusion and exclusion as an IVMP MUMS/limited market product**
  - connected to updating of MUMS policy

- **Revised Guideline on indications for veterinary vaccines**
  - for adoption in Q4 2013

Other GLs of interest

- **Guideline on updating equine influenza strain – for release**
  - for consultation by CVMP April 2013
- **Recommendation of considerations of the risk associated with the use of unauthorised vaccines in emerging situations**
  - for adoption in Q4 2013

Other GLs of interest

- **Requirements for adding different routes of administration**
  - documents to be provided for different routes of administration are more demanding for original authorisation procedures therefore different requirements when e.g. having a drinking water application and later on sending a variation for spray application.
  - This demonstrates the concern as spray application can cause more adverse reactions (e.g. in the respiratory tract than drinking water vaccination) and efficacy induction can be very different when spray and drinking water vaccinations are compared.

Other GLs of interest

- **Data requirements for removing the target animal batch safety test in the EU – As of April 2012 deletion of TABST**
  - **Letter to all companies informing them of possibility to delete TABST completely for most veterinary vaccines – deadline 1 April 2013**

- **Guidance on statistical principles for veterinary clinical trials for immunological veterinary medicinal products**
- **Revision of the guideline on DNA vaccines non-amplifiable in eukaryotic cells for veterinary use**

Other topics

- **Transparent packaging – influence of light on stability**

- **Contribution to discussions on Bovine Neonatal Pancytopenia**

Other topics

- **Contribution to the review of the veterinary legislation**
- **Contribution to the biologics debate**

Thank you for your attention