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Committee for Medicinal Products for Veterinary Use (CVMP)

Public statement

Routes of administration of vaccines to poultry

PROBLEM STATEMENT

Apparent inconsistencies in the different legal provisions have been identified for the routes of administration for immunological veterinary medicinal products (IVMPs) in poultry.

These apparent inconsistencies could lead to diverging interpretations by either regulators or industry and it was therefore decided to publish this statement to clarify the regulatory requirements for proving the safety and efficacy for the different routes of administration of IVMPs in poultry.

LEGAL PROVISIONS

Commission Directive 2009/9/EC of 10 February 2009 states in Annex 1 Title II on requirements for IVMPs under Part 3 Safety Tests that

"The immunological veterinary medicinal product shall be administered at the recommended dose and **by each recommended route of administration** to animals of each species and category in which it is intended for use, including animals of the minimum age of administration."

In Part 4 Efficacy Tests it states that

"The efficacy of an immunological veterinary medicinal product shall be demonstrated for each category of target animal species recommended for vaccination, **by each recommended route of administration** and using the proposed schedule of administration."

In the European Pharmacopoeia Monograph 01/2008:0062, Vaccines for Veterinary Use it states in 2-2-2 Route of administration that

"…safety and immunogenicity are demonstrated **for each route of administration** to be recommended."

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However, in Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products it states in Annex 1, 2 e, Footnote that

"For administration to poultry, respiratory, oral and ocular (nebulization) **routes used for vaccination are considered to be equivalent routes of administration**"

SCIENTIFIC JUSTIFICATION

The safety and efficacy of a product can be different depending on the route of administration and the safety and efficacy data for all routes of administration are necessary to determine the risk/benefit balance for all administration routes.

Examples:

- Safety: spray application can cause more adverse reactions e.g. in the respiratory tract than drinking water vaccination.
- Efficacy: induction of immunity can be very different when spray and drinking water vaccinations are compared.

On this basis safety and efficacy data supporting **all proposed administration routes** are required.

The foot note in Commission Regulation (EC) No 1234/2008 applies only to the variation categorisation i.e. variations for changes to respiratory, oral and ocular (nebulization) routes are classified according to the same category outlined in Commission Regulation (EC) No 1234/2008. It does not prejudice the scientific content of the corresponding marketing authorisation dossiers.

CONCLUSION

To justify the safety and efficacy for all recommended routes of administration of poultry vaccines, studies are required as laid down in Commission Directive 2009/9/EC, Annex 1, Title II and the European Pharmacopoeia Monograph 01/2008:0062, Vaccines for Veterinary Use.