The European Agency for the Evaluation of Medicinal Products
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COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

CONCEPT PAPER

ON THE NEED TO REVISE THE NOTE FOR GUIDANCE ON REQUIREMENTS FOR COMBINED VACCINES CVMP/IWP/52/97 – FINAL

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- **Introduction**

  It is recognised that in the routine use of veterinary vaccines against different diseases and/or antigens, vaccines are often administered simultaneously or concurrently. This practice is often necessary for epidemiological reasons and is beneficial to both the owner in terms of reducing costs and to animals in terms of reducing the number of separate interventions, thus reducing stress and improving animal; welfare

- **Problem statement**

  Until quite recently, the data requirements for inclusion of compatibility statements for simultaneous or concurrent use of one vaccine with another were readily met by manufacturers on a national basis and such statements frequently appeared on SPCs and product literature. In recent years there has been a greatly increased requirement for compatibility data and divergence between Member States on the number and types of studies required.

  The situation has now been reached that many vaccine manufacturer's no longer attempt to include compatibility statements on SPCs, even when routine vaccine regimes would require products to be administered either concurrently or simultaneously. This situation is detrimental to the user, who no longer obtains advice on use that is practical in the field and may lead to animal health problems if vaccines are used incorrectly. It also encourages veterinarians and users to ignore warnings on the SPC and administer many vaccines contrary to the standard advice included on product literature.

  The CVMP have recently adopted a Guideline on concurrent use which addresses the data requirements for when IVMPs are administered at separate sites at the same time or at separate times at the same site, but further clarification is need for when products are administered simultaneously i.e. at the same site and at the same time. There is also some uncertainty on the definition of a combined vaccine versus simultaneous administration and clear guidance on the data requirements is needed to enable practical compatibility statements to be included on the SPCs and product literature of IVMPs.

- **Anticipated benefit to:**

  - **Industry and Other Interested Parties**

  Clear guidance to support the necessary safety and efficacy studies required to include compatibility statements on the SPC and product literature for immunological veterinary medicinal products. This is beneficial to both the owner in terms of reducing costs and to animals in terms of potentially reducing the number of separate interventions, thus reducing stress and improving animal welfare

  Guidance on the requirements for simultaneous administration of IVMPS in relation to the requirements for concurrent use and those for combined vaccines.

  Clear Guidance to industry on the data requirements for concurrent and simultaneous administration and for combined vaccines, which should encourage industry to undertake compatibility studies and improve the advise for users of IVMPS.

  - **Regulatory Authorities**

  Guidance on the quality, safety and efficacy data requirements to support an application for simultaneous use or for a combined vaccine.

- **Discussion**

  Subsequent to the adoption of the Guideline on the requirements for concurrent administration of immunological veterinary medicinal products it is considered that there is a need to revise the NfG on combined vaccines to address the requirements for these products and include the requirements for simultaneous use. The Guideline on the requirements for concurrent administration of immunological veterinary medicinal products addresses the compatibility requirements for administering IVMPs at the same site at different times and at different sites at the same time. For completeness and for practical reasons where many products are mixed prior to administration to animals and therefore administered at the same site and at the same time, it is considered that a NfG should address the data requirements for including compatibility statements for this practice. It is not clear whether the mixing of products prior to administration to the animal would create a new combined product or whether this could be included in the requirements for simultaneous administration. Revising the NfG on combined vaccines to include simultaneous use should resolve most of the remaining issues surrounding compatibility statements for IVMPs. This would benefit regulatory authorities, industry and the users of IVMPs by improving the regulatory guidance in this area and increasing the practical information on the use of IVMPs in many husbandry systems.

- **Recommendation (points to be addressed)**

  Revision of the NfG "Requirements For Combined Vaccines"CVMP/IWP/52/97 – FINAL to include the requirements for simultaneous administration of vaccines

  Data requirements for combined vaccines and simultaneous administration

  Harmonisation of terms between NfG on concurrent administration and new Guideline

- **Timetable**

  Referred to IWP February 2004 and appointment of Rapporteur

  Work on first draft May 2004

  Draft Guideline September 2004

  Adopted by CVMP for consultation in December 2004

- **Resource requirements for preparation**

  Appointment of Rapporteur

  Adequate time for discussion at IWP

  EMEA secretariat to manage the development of the NfG and consultation process

  Discussions at CVMP

- **Impact for Industry and other Interested Parties**

  It is considered that the revised NfG would have minimal impact on industry and other interested parties in respect to the additional resources and costs from meeting the requirements of the revised NfG. The Guideline should clarify the data requirements for compatibility statements and combined vaccines and improve information on SPCs and product literature regarding the practical application of IVMPS to many husbandry systems.

- **Impact assessment for Regulatory Authorities**

  The revised NfG on combined vaccines should be beneficial to regulatory authorities in assessing the requirements for compatibility statements and combined vaccines. The new NfG would have no additional resource issues for regulatory authorities.

- **References to literature, guidelines, etc.**

  Note for Guidance for combined vaccines CVMP/IWP/52/97 – FINAL

  Guideline on Requirements for concurrent administration of Immunological veterinary medicinal products EMEA/CVMP/550/02 -FINAL