



IMM-033

SAFETY PROFILE OF THE NEWLY REGISTERED SWINE INFLUENZA VACCINE RESPIPORC® FLUPAN H1N1

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Introduction

Since the emergence of pandemic H1N1 in 2009, this subtype has become endemic in pigs. European Pharmacopoeia requires inter alia safety profile to gain market authorisation in Europe. Balance between broad efficacy and excellent safety is crucial in particular for inactivated vaccines. This abstract summarizes the safety profile data of Respiporc® FLUpan H1N1.

Material & Methods

In total, four registration trials were performed on 77 influenza seronegative pigs. First vaccination was performed between 53rd and 56th day of life followed by a second vaccination three weeks later. Pigs were systemically scored on alterations of temperature, systemic and local reactions at up to 10 different time points after first and second vaccination.

Results

In summary, all pigs showed a good general condition. A transient increase in rectal temperature occurred in less than 10% of the pigs after vaccination, but did not exceed 2°C and did not persist for more than one day. A transient swelling of up to 2 cm³ occurred in less than 10% of the vaccinated animals. The swelling resolved within 5 days. No other clinical signs or impairment of general condition was observed within 2 weeks after vaccination.

Discussion

In conclusion, Respiporc® FLUpan H1N1 meets the requirements of a safety profile as specified by the European Pharmacopoeia. Furthermore, the balance between good safety and efficacy is given using a highly efficacious and safe adjuvant. The same adjuvant is used in Respiporc® FLU3 showing the same good safety profile in pigs. Thus, Respiporc® FLUpan H1N1 is a vaccine that is safe for use in pigs from the age of 8 weeks following Good Veterinary Practise.

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