Inactivated and adjuvanted vaccine for the control of the African horse sickness virus serotype 9 infection: evaluation of efficacy in horses and guinea-pig model

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Summary
African horse sickness (AHS) is a non-contagious viral disease of solipeds transmitted by *Culicoides*. The disease is endemic in most African countries. Past experience has shown that Italy is a country exposed to emerging infectious diseases endemic to Africa; an incursion of AHS virus together with the widespread presence of *Culicoides* vectors could be the cause of a serious epidemic emergency. A live attenuated vaccine containing seven of the nine viral serotypes, serotype 5 and 9 are excluded, is commercially available from Onderstepoort Biological Products. However, the use of live vaccines is a matter of endless disputes, and therefore inactivated or recombinant alternative products have been investigated over the years. Since research on AHS is hampered by the use of horses to evaluate vaccine potency, in a previous experiment serological response to serotypes 5 and 9 was assayed in guinea-pigs and horses. A durable and comparable serological response was observed in the two animal species. In the present study antibody response in horses and guinea-pigs, immunised with the inactivated-adjuvanted vaccine formulated with serotype 9, was tested over a period of 12 months. When immunity was challenged, horses were protected from infection and disease. Antibody response in horses and guinea-pigs compared favourably.

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Introduction

African horse sickness (AHS) is a non-contagious viral disease of solipeds caused by nine virus serotypes. The virus belongs to the genus *Orbivirus*, family Reoviridae. Approximately 30 of the over 1,500 identified species of *Culicoides* are believed to be capable of *Orbivirus* transmission. The most important vector of AHSV in the field is *Culicoides imicola*, a species common throughout Africa and South East Asia (20). AHS is endemic in numerous countries in sub-Saharan Africa but disease has been recorded in North Africa (1965), Spain (1966 and 1987-1990) and the Middle East (1959, 1961 and 1989). Spreading of single serotypes caused outbreaks in the Iberian Peninsula and the Middle East: serotype 4 or 9. From 1975 the disease has also spread to West Africa: Nigeria, Senegal and Mauritania (11).

Events of recent decades have revealed that Italy is a country at risk of outbreaks of emerging infectious diseases endemic to Africa. The presence of vectors of the *Culicoides* genus makes the spread of AHS in Italy a likely event. There is, therefore, a need for readily available, innocuous and effective immunising products as well as specific and sensitive diagnostic tests.

Live attenuated vaccines could be made available by Onderstepoort Biological Products (OBP), South Africa, in a relatively short time. The vaccine commonly used in countries where the disease is endemic contains 7 of the 9 serotypes and it is manufactured in 2 components, namely: a trivalent component containing serotypes 1, 3, and 4, and a quadrivalent one containing serotypes 2, 6, 7, and 8; they are administered 21 days apart. Serotype 5 was excluded from the formulation in 1990 due to residual pathogenicity recorded in the field. Serotype 9, considered epidemiologically irrelevant in South Africa is also not included in the vaccine. These two