European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
POST-AUTHORISATION SUMMARY OF OPINION[*]
RABIGEN SAG2

On 12 March 2008, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion,[**] recommending to grant a variation to the terms of the Marketing Authorisation for the veterinary medicinal product Rabigen SAG2. The Marketing Authorisation Holder for this veterinary medicinal product is Virbac S.A.

The change agreed by the CVMP concerns an extension of the indications of the existing Marketing Authorisation for red foxes to include raccoon dogs as a target species. Rabigen SAG2 is a single-strain, live modified rabies virus vaccine indicated for the oral vaccination of free-ranging red foxes (*Vulpes vulpes*) against rabies. It has been authorised in the EU since April 2000.

Detailed conditions for the use of this product will be described in the updated Summary of Product Characteristics (SPC) which will be published in the revised European Public Assessment Report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[*] Summaries of opinion are published without prejudice to the Commission Decision.
[**] Applicants may appeal any CVMP opinion, provided they notify the EMEA in writing of their intention to appeal within 15 days of receipt of the opinion.

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