EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 May 2014
EMA/CVMP/229798/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Versican Plus DHPPi

Common name: Canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus.

On 8 May 2014, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Versican Plus DHPPi, a lyophilisate and solvent for suspension for injection, intended for the active immunisation of dogs from six weeks of age

- to prevent mortality and clinical signs caused by canine distemper virus,
- to prevent mortality and clinical signs caused by canine adenovirus type 1,
- to prevent clinical signs and reduce viral excretion caused by canine adenovirus type 2,
- to prevent clinical signs, leucopoenia and viral excretion caused by canine parvovirus,
- to prevent clinical signs (nasal and ocular discharge) and reduce viral excretion caused by canine parainfluenza virus.

The applicant for this veterinary product is Zoetis Belgium S.A.
The active substances of Versican Plus DHPPi are:

Lyophilisate (live attenuated)

	Minimum	Maximum
Canine distemper virus, strain CDV Bio 11/A	$10^{3.1}$ $TCID_{50}$ *	$10^{5.1}$ $TCID_{50}$
Canine adenovirus Type 2, strain CAV-2 Bio 13	$10^{3.6}$ $TCID_{50}$ *	$10^{5.3}$ $TCID_{50}$
Canine parvovirus Type 2b, strain CPV-2b Bio 12/B	$10^{4.3}$ $TCID_{50}$ *	$10^{6.6}$ $TCID_{50}$
Canine parainfluenza Type 2 virus, strain CPiV-2 Bio 15	$10^{3.1}$ $TCID_{50}$ *	$10^{5.1}$ $TCID_{50}$

* Tissue culture infectious dose 50%

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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The benefits of Versican Plus DHPPi are its prevention of the major diseases affecting dogs caused by canine distemper virus, canine adenovirus types 1 and 2, canine parvovirus and canine parainfluenza virus.

The most common side effect is a transient swelling (up to 5 cm) at the injection site. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination. In rare cases gastrointestinal signs such as diarrhoea and vomiting or anorexia and decreased activity are possible.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Versican Plus DHPPi and therefore recommends the granting of the marketing authorisation.