EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 March 2014
EMA/CVMP/92026/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Versican Plus DHPPi/L4

Common name: Live, attenuated Canine distemper virus, canine adenovirus, canine parvovirus, canine parainfluenza virus inactivated

On 13 March 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/L4, 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,
- to prevent clinical signs, infection and urinary excretion caused by *Leptospira serovar* Bratislava,
- to prevent clinical signs and urinary excretion and reduce infection caused by *Leptospira serovars* Canicola and Icterohaemorrhagiae,
- to prevent clinical signs and reduce infection and urinary excretion caused by *Leptospira serovar* Grippotyphosa.

The applicant for this veterinary product is Zoetis Belgium S.A.
The active substances of Versican Plus DHPPi/L4 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	$10^{3.1}$ $TCID_{50}$ *	$10^{5.1}$ $TCID_{50}$

[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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Solvent (inactivated)

Leptospira interrogans serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae strain MSLB 1089	ARL** titre ≥ 1:51
Leptospira interrogans serogroup Canicola serovar Canicola, strain MSLB 1090	ARL** titre ≥ 1:51
Leptospira kirschneri serogroup Grippotyphosa serovar Grippotyphosa, strain MSLB 1091	ARL** titre ≥ 1:40
Leptospira interrogans serogroup Australis serovar Bratislava, strain MSLB 1088	ARL** titre ≥ 1:51

* Tissue culture infectious dose 50 %
** Antibody micro agglutination-lytic reaction

The benefits of Versican Plus DHPPi/L4 are its prevention of the major diseases affecting dogs caused by canine distemper virus, canine adenovirus types 1 and 2, canine parvovirus, canine parainfluenza virus as well as the prevention of leptospirosis.

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/L4 and therefore recommends the granting of the marketing authorisation.