EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 June 2014
EMA/CVMP/301696/2014
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Versican Plus Pi/L4R

Common name: Canine parainfluenza virus, *Leptospira* and rabies virus.

On 5 June 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 Pi/L4R, a lyophilisate and solvent for suspension for injection, intended for the active immunisation of dogs from six weeks of age

- 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,
- to prevent mortality, clinical signs and infection caused by rabies virus.

The applicant for this veterinary product is Zoetis Belgium S.A.

The active substances of Versican Plus Pi/L4R are:

Lyophilisate (live attenuated)	**Minimum**	**Maximum**
Canine Parainfluenza Type 2 virus, strain CPiV-2-Bio 15	$10^{3.1}$ $TCID_{50}$ *	$10^{5.1}$ $TCID_{50}$
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		

[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.

serovar Bratislava, strain MSLB 1088	ARL** titre ≥ 1:51
Inactivated rabies virus, strain SAD Vnukovo-32	≥ 2.0 IU***

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

The benefits of Versican Plus Pi/L4R are its prevention of canine parainfluenza virus as well as the prevention of leptospirosis and rabies.

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 Pi/L4R and therefore recommends the granting of the marketing authorisation.