ANNEX I

NAME, PHARMACEUTICAL FORM, STRENGTH OF THE MEDICINAL PRODUCTS, ANIMAL SPECIES, ROUTES OF ADMINISTRATION, AND MARKETING AUTHORISATION HOLDER

Member State	Marketing Authorisation Holder	Applicant	Product invented name	Pharmaceutical form	Strength	Animal species	Frequency and route of administration	Recommended dose
Austria	Wyeth Lederle Pharma GmbH, Fort Dodge Waidhausengasse 19/9, A-1140, Vienna Austria Contact: Dr. Attila Romváry Tel: +43 1 912 28 40 Fax: +43 1 911 51 00 Email: romvara@fdah.com	Wyeth Lederle Pharma GmbH, Fort Dodge	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml
Belgium	Fort Dodge Animal Health Holland C.J. van Houtenlaan 36, 1381 CP Weesp The Netherlands Contact: Dr. Durk Stellingwerf Tel: +31 35 6993 372 Fax: +31 35 6993380 Email: stellid@fdah.com	Fort Dodge Animal Health Holland	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml

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France	Fort Dodge Santé Animale, S.A. 24, Avenue Marcel Dassault, BP 440, 37204 Tours Cedex 3 France Contact: Mr. Yves Dehon Tel: +33 2 4774 8979 Fax: +33 2 47748999 Email: dehony@ahp.com	Fort Dodge Santé Animale, S.A.	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml
Germany	Fort Dodge Veterinär GmbH Adenauerstrasse 20, 52146 Würselen Germany Contact: Dr. Elisabeth Stangl Tel: +49 2405454216 Fax: +49 24 05454 461 Email: stangle@fdah.com	Fort Dodge Veterinär GmbH	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml

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Greece	Wyeth Lederle Pharma GmbH, Fort Dodge Waidhausengasse 19/9, A-1140, Vienna Austria Contact: Dr. Eusebio Uruburu Tel: +34 91 598 1344 Fax: ++34 91 597 2434 Email: urubure@fdah.com	Wyeth Lederle Pharma GmbH, Fort Dodge	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml
Ireland	Fort Dodge Animal Health Limited Flanders Road, Hedge End, Southampton S030 4QH, UK Contact: Dr. Germán Lastra Tel: +44 1489774221 Fax: +44 1489 774 251 Email: lastrag@fdah.com	Fort Dodge Animal Health Limited	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml

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Luxembourg	Fort Dodge Animal Health Holland C.J. van Houtenlaan 36, 1381 CP Weesp The Netherlands Contact: Dr. Durk Stellingwerf Tel: +31 35 6993 372 Fax: +31 35 6993380 Email: stellid@fdah.com	Fort Dodge Animal Health Holland	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml
Netherlands	Fort Dodge Animal Health Holland C.J. van Houtenlaan 36, 1381 CP Weesp The Netherlands Contact: Dr. Durk Stellingwerf Tel: +31 35 6993 372 Fax: +31 35 6993380 Email: stellid@fdah.com	Fort Dodge Animal Health Holland	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml

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Norway	Fort Dodge Veterinaria S.A. c/ Camprodón s/n "La Riba" Vall de Bianya (Girona), Spain Contact: Dr. Germán Lastra Tel: +44 1489774221 Fax: +44 1489 774 251 Email: lastrag@fdah.com	Fort Dodge Veterinaria S.A.	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml
Slovak Republic	**Not licensed in SK**							
Sweden	Fort Dodge Animal Health Holland C.J. van Houtenlaan 36, 1381 CP Weesp The Netherlands Contact: Dr. Germán Lastra Tel: +44 1489774221 Fax: +44 1489 774 251 Email: lastrag@fdah.com	Fort Dodge Animal Health Holland	Suvaxyn Parvo/E vet	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml

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United Kingdom	Fort Dodge Animal Health Limited Flanders Road, Hedge End, Southampton S030 4QH, UK Tel: +44 1489774221 Fax: +44 1489774 251 Email: lastrag@fdah.com	Fort Dodge Animal Health Limited	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml
Spain	Fort Dodge Veterinaria, S.A. Ctra. Camprodón s/n "La Riba" 17813 Vall de Bianya (Girona) Spain Tel: +34 915981336 Fax: +34 915972434 Email: rodrigv2@fdah.com	Fort Dodge Veterinaria, S.A.	Suvaxyn Parvo/E	Emulsion for injection	-PPV inducing a HIA titre of at least 160 (in rabbits). - *E. rhusiopathiae*: RP >1 in accordance with the EP	Porcine	From 5 months: 2 inj. 3-4 wks apart. 2nd dose at least 4 wks before mating. Annual Revacc-ination: 1 dose during each lacta-tion period 3 to 4 wks before mating. Intramuscular injection	2 ml

ANNEX II

SCIENTIFIC CONCLUSIONS

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During assessment of a Type II variation for changing the mouse potency test to comply with the revised Ph.Eur monograph for erysipelas vaccines, vaccine batch 8500 was accepted as being a reference vaccine and therefore this batch and those prior to it have to be accepted as being compliant with the conditions of the Marketing Authorisations for both products. Issues that related to the equivalence of reference vaccine batches arose during subsequent variations. The reference vaccine changes included in this referral relate to the replacement of batch 8500 with 9097 and the subsequent replacement of batch 9097 with 9861. In both cases the Marketing Authorisation Holder (MAH) has shown that these batches qualify as reference vaccine batches because

- The batches passed the Ph.Eur. potency test in pigs at 1/3 dose, which provides evidence of target animal efficacy.
- The batches are formulated with a fixed quantity of bacteria, quantified using an approved and validated method.
- The batches passed the test for target animal safety according to Ph. Eur monograph 0064.
- The batches were commercial batches manufactured to the production methods and specification described in the MA.
- The potencies of the two reference batches (9097 and 9861) are higher than the PEI reference serum and the reference vaccine batch 8500.
- The MAH followed the correct SOP for replacement at the time the replacements were made.

However, the submitted data demonstrated large variability in the test results of the reference batches in the serological potency test. This was explained as an inherent variability in the *in-vivo* part of the test, because of variability between batches of mice. This variability reduced the ability of the test to demonstrate equivalence between reference batches.

The CVMP considers that based on all available data, there is no concern regarding safety or efficacy for the product. However, it is important to ensure that the pass limits of the potency test do not drift from the original. In addition, a more robust test for potency should be applied to the product in the future.

The CVMP therefore recommends a variation of the Marketing Authorisation.

The Marketing Authorisation(s) should be varied to reduce the variability of the serological potency test in mice by appropriate measures such as the replacement of the use of a reference vaccine in the serological potency test in mice with the use of reference serum.