

## **Annex I**

**List of the names, pharmaceutical forms, strengths of the veterinary medicinal products, animal species, routes of administration, marketing authorisation holder(s) in the Member States**

Member State EU/EEA	Marketing authorisation holder	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	UNISTRRAIN PRRS Lyophilisat und Lösungsmittel zur Herstellung einer Injektionssuspension für Schweine	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub> <sup>1</sup>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Austria	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU Lyophilisat und Lösungsmittel zur Herstellung einer Injektionssuspension für Schweine	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub> <sup>2</sup>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Austria	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac Lyophilisat und Lösungsmittel zur Herstellung einer Injektionssuspension für Schweine	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Austria	Intervet GmbH Siemensstraße 107 1210 Vienna Austria	Porcilis PRRS, Lyophilisat und Lösungsmittel zur Herstellung einer Injektionssuspension für Schweine	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use

<sup>1</sup> Cell culture infectious dose 50%

<sup>2</sup> Tissue culture infectious dose 50%

Austria	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU Lyophilisat und Lösungsmittel zur Herstellung einer Injektionssuspension für Schweine	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Belgium	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistain PRRS	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Belgium	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU & ImpranFLEX	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Belgium	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porcilis PRRS	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Belgium	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Belgium	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRS Modified Live Virus	Live attenuated PRRS virus, strain VR 2332	min. $10^{4.9}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use

Belgium	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac	Live PRRS virus, strain P120	$10^{4.0}$ – $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Bulgaria	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porcilis PRRS	Live attenuated PRRS virus, strain DV	$10^{4.0}$ – $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Bulgaria	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU lyophilisate and solvent for suspension for injection for pigs	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ – $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Bulgaria	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU Lyophilisate and solvent for suspension for injection for pigs	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ – $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Bulgaria	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	UNISTRRAIN PRRS Lyophilisate and solvent for suspension for injection for pigs	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ – $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Croatia	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	UNISTRRAIN PRRS, liofilizat i otapalo za suspenziju za injekciju, za svinje	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ – $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use

Croatia	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU, λιοφιλιζατ i οταπαλο za suspenziju za injekciju, za svinje	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Croatia	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU, λιοφιλιζατ i οταπαλο za suspenziju za injekciju, za svinje	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Croatia	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac, liofilizat i otapalo za suspenziju za injekciju, za svinje	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Croatia	Intervet International B.V., Podružnica u Republici Hrvatskoj, Ivana Lučića 2a, 10000 Zagreb, Croatia	PORCILIS PRRS, liofilizat i diluent za injekcijsku suspenziju, svinja	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Cyprus	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU λυοφιλοποιημένη σκόνη και Ingelvac PRRSFLEX EU διαλύτης για ενέσιμο εναιώρημα για χοίρους.	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Cyprus	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	PERSOVAC λυοφιλοποιημένο υλικό και διαλύτης για ενέσιμο εναιώρημα για χοίρους	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use

Cyprus	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	PORCILIS PRRS	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Cyprus	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU λυοφιλοποιημένο υλικό και ImpranFLEX διαλύτης για ενέσιμο εναιώρημα για χοίρους	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Cyprus	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	UNISTRRAIN PRRS λυοφιλοποιημένη κόνις και διαλύτης για ενέσιμο εναιώρημα για χοίρους	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Czech Republic	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	UNISTRRAIN PRRS lyofilizát a rozpouštědlo pro injekční suspenzi pro prasata	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Czech Republic	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU lyofilizát a rozpouštědlo pro injekční suspenzi pro prasata	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Czech Republic	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU lyofilizát a rozpouštědlo pro injekční suspenzi pro prasata	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use

Czech Republic	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac lyophilisate and solvent for suspension for injection for pigs	Live PRRS virus, strain P120	$10^{4.0}$ – $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Czech Republic	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porcilis PRRS lyofilizát pro přípravu injekční suspenze s rozpouštědlem	Live attenuated PRRS virus, strain DV	$10^{4.0}$ – $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Czech Republic	Bioveta, a. s. Komenského 212/12 683 23 Ivanovice na Hané Czech Republic	BIOSUIS PRRS live lyofilizát a rozpouštědlo pro injekční suspenzi	Live attenuated PRRS virus, strain BIO 60 - EU	$10^{3.4}$ – $10^{6.8}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Denmark	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRS Vet.	Live attenuated PRRS virus, strain VR 2332	min. $10^{4.9}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Denmark	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porcilis PRRS Vet.	Live attenuated PRRS virus, strain DV	$10^{4.0}$ – $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Denmark	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistrain PRRS	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ – $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use

Estonia	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Estonia	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Estonia	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Estonia	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistain PRRS	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
France	Intervet Rue Olivier de Serres Angers Technopole 49071 Beaucouze Cedex France	Porcilis PRRS	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
France	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistain PRRS lyophilisat et solvant pour suspension injectable pour porcins	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use



France	Boehringer Ingelheim Animal Health France 29 avenue Tony Garnier 69007 Lyon France	Ingelvac PRRSFLEX EU lyophilisat et Ingelvac PRRSFLEX EU solvant pour suspension injectable pour porcins	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
France	Boehringer Ingelheim Animal Health France 29 avenue Tony Garnier 69007 Lyon France	ReproCyc PRRS EU lyophilisat et ImpranFLEX solvant pour suspension injectable pour porcins	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
France	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac lyophilisat et solvant pour suspension injectable pour porcins	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Germany	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Germany	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRS MLV	Live attenuated PRRS virus, strain VR 2332	min. $10^{4.9}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Germany	Ceva Tiergesundheit GmbH Kanzlerstr. 4 40472 Düsseldorf Germany	Persovac	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use

Germany	Intervet Deutschland GmbH Feldstraße 1a 85716 Unterschleissheim Germany	Porcilis PRRS	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Germany	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Germany	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistrain PRRS	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Greece	Intervet Hellas 63 Agiou Dimitriou St., 17456, Alimos, Athens Greece	Porcilis PRRS	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Greece	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistrain	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Greece	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use

Greece	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Hungary	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU vakcina A.U.V.	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Hungary	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac vakcina A.U.V.	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Hungary	Intervet Hungaria Kft. Budapest, Lechner Odon fasor 8., 1095, Hungary	Porcilis PRRS vakcina A.U.V.	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Hungary	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU vakcina A.U.V.	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Hungary	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistrain PRRS vakcina A.U.V	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use

Ireland	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU lyophilisate and solvent for suspension for injection for pigs	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Ireland	Intervet Ireland Limited Magna Drive Magna Business Park, Citywest Road, Dublin 24, Ireland	Porcilis PRRS lyophilisate and solvent for suspension for injection for pigs	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Ireland	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU lyophilisate and solvent for suspension for injection for pigs	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Ireland	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	UNISTRAIN PRRS lyophilisate and solvent for suspension for injection for pigs	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Italy	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU liofilizzato e Ingelvac PRRSFLEX EU solvente per sospensione iniettabile per suini	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Italy	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac liofilizzato e diluente per sospensione iniettabile per suini	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use

Italy	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU liofilizzato e ReproCyc PRRS EU solvete per sospensione iniettabile per suini	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Italy	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porsilis PRRS liofilizzato e solvete per sospensione iniettabile per suini	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Latvia	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU liofilizāts un šķīdinātājs suspensijas injekcijām pagatavošanai cūkām	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Latvia	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac liofilizāts un šķīdinātājs suspensijas injekcijām pagatavošanai cūkām	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Latvia	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU liofilizāts un šķīdinātājs suspensijas injekcijām pagatavošanai cūkām	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Latvia	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porcilis PRRS liofilizāts un šķīdinātājs suspensijas injekcijām pagatavošanai cūkām	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use

Latvia	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistain PRRS liofilizāts un šķīdinātājs suspensijas injekcijām pagatavošanai cūkām	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Lithuania	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	INGELVAC PRRS MLV, gyva liofilizuota vakcina ir skiediklis	Live attenuated PRRS virus, strain VR 2332	min. $10^{4.9}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Lithuania	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU, lioilizatas ir skiediklis injekcinei suspensijai ruošti kiauļēms	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Lithuania	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU, lioilizatas ir skiediklis injekcinei suspensijai ruošti kiauļēms	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Lithuania	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	UNISTRAIN PRRS, lioilizatas ir skiediklis injekcinei suspensijai ruošti kiauļēms	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Lithuania	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN Nyderlanda	Porcilis PRRS, liofilizatas ir skiediklis injekcinei suspensijai kiauļēms	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use

Luxembourg	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistain PRRS lyophilisat et solvant pour suspension injectable	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Luxembourg	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU & ImpranFLEX	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Luxembourg	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porcilis PRRS	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Luxembourg	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Luxembourg	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRS Modified Live Virus	Live attenuated PRRS virus, strain VR 2332	min. $10^{4.9}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Luxembourg	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use

Malta	Intervet Ireland Ltd., Magna Drive, Magna Business Park City, Dublin 24, Ireland	Porcilis PRRS lyophilisate and solvent for suspension for injection for pigs	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Malta	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistrain PRRS	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Poland	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistrain PRRS	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Poland	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Poland	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Poland	Ceva Animal Health Polska Sp. z o.o. ul. Okrzei 1A 03-715 Warsaw Poland	Persovac	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use



Poland	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRS MLV	Live attenuated PRRS virus, strain VR 2332	min. $10^{4.9}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Portugal	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU liofilizado e solvente para suspensão injetável para suínos	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Portugal	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRS MLV liofilizado e solvente para suspensão injetável para suínos	Live attenuated PRRS virus, strain VR 2332	min. $10^{4.9}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Portugal	Ceva Saúde Animal - Produtos Farmacêuticos e Imunológicos, Lda. Rua Doutor António Loureiro Borges, 9/9A, 9ªA Miraflores- 1495-131 Algés Portugal	Persovac liofilizado e solvente para suspensão injetável para suínos	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Portugal	MSD Animal Health Lda. Edifício Vasco da Gama, n.º 19 Quinta da Fonte, Porto Salvo 2770 192 Paço de Arcos Portugal	Porcilis PRRS liofilizado e solvente para suspensão injetável para suínos	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use

Portugal	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU liofilizado e solvente para suspensão injetável para suínos	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Portugal	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	UNISTRRAIN PRRS liofilizado e solvente para suspensão injetável para suínos	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Romania	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porcilis PRRS	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Romania	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistrain PRRS	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Romania	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Romania	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use

Slovenia	CEVA-Phylaxia Veterinary Biologicals Co. Ltd. Szállás Utca 5 1107 Budapest Hungary	Persovac liofilizat in vehikel za suspenzijo za injiciranje za prašiče	Live PRRS virus, strain P120	$10^{4.0}$ – $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Slovenia	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU liofilizat in vehikel za suspenzijo za injiciranje za prašiče	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ – $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Slovenia	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistain PRRS liofilizat in vehikel za suspenzijo za injiciranje za prašiče	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ – $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Slovenia	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porcilis PRRS liofilizat in topilo za raztopino za injiciranje za prašiče	Live attenuated PRRS virus, strain DV	$10^{4.0}$ – $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Slovenia	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU liofilizat in vehikel za suspenzijo za injiciranje za prašiče	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ – $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Slovak Republic	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU lyofilizát a rozpúšťadlo na injekčnú suspenziu pre ošípané	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ – $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use

Slovak Republic	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porcilis PRRS lyofilizát a rozpúšťadlo na injekčnú suspenziu pre ošípané	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Slovak Republic	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU lyofilizát a rozpúšťadlo na injekčnú suspenziu pre ošípané	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Slovak Republic	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistain PRRS lyofilizát a rozpúšťadlo na injekčnú suspenziu pre ošípané	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Spain	Merck Sharp & Dohme Animal Health, S.L. Polígono Industrial El Montalvo I C/ Zeppelin, nº 6, parcela 38 37008 Carbajosa de la Sagrada Salamanca Spain	Porcilis PRRS, liofilizado y disolvente para suspensión inyectable para porcino	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
Spain	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistain PRRS liofilizado y disolvente para suspensión inyectable para porcino.	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use

Spain	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU, líoilizado y disolvente para suspensión inyectable para porcino	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Spain	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU, líoilizado y disolvente para suspensión inyectable para porcino	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Spain	Ceva Salud Animal, S.A. Avenida Diagonal 609-615 08028 Barcelona Spain	Persovac líoilizado y disolvente para suspensión inyectable para porcino	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Spain	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRS MLV	Live attenuated PRRS virus, strain VR 2332	min. $10^{4.9}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Spain	Laboratorios Syva, S.A.U., Avda. Parroco Pablo Diez, 49-57, San Andres Del Rabanedo, 24010 Leon, Spain	Pyrsvac-183	Live attenuated PRRS virus, strain ALL 183	min. $10^5$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
Spain	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Amervac PRRS	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use

The Netherlands	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	ReproCyc PRRS EU, lyofilisaat en suspenseervloeistof voor suspensie voor injectie voor varkens	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
The Netherlands	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRS MLV	Live attenuated PRRS virus, strain VR 2332	min. $10^{4.9}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
The Netherlands	Kernfarm B.V. De Corridor 14 d Breukelen 3621 ZB The Netherlands	Ingelvac PRRSFLEX EU, Lyofilisaat en suspenseervloeistof voor suspensie voor injectie voor varkens	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
The Netherlands	Boehringer Ingelheim Vetmedica GmbH Binger Straße 173 55216 Ingelheim am Rhein Germany	Ingelvac PRRSFLEX EU, lyofilisaat en suspenseervloeistof voor suspensie voor injectie voor varkens	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
The Netherlands	Intervet International B.V. Wim de Körverstraat 35 Boxmeer 5831 AN The Netherlands	Porcilis PRRS	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
The Netherlands	Kernfarm B.V. De Corridor 14D Breukelen 3621 ZB The Netherlands	Porcilis PRRS	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use

The Netherlands	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistain PRRS lyofilisaat en suspenseervloeistof voor suspensie voor injectie bij varkens	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
United Kingdom (Northern Ireland) <sup>3</sup>	Boehringer Ingelheim Animal Health UK Ltd Ellesfield Avenue Bracknell RG12 8YS United Kingdom	Ingelvac PRRSFLEX EU Lyophilisate and Solvent for Suspension for Injection for Pigs	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{4.4}$ - $10^{6.6}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
United Kingdom (Northern Ireland)	Ceva Animal Health Ltd Unit 3, Anglo Office Park White Lion Road Amersham HP7 9FB United Kingdom	Persovac lyophilisate and solvent for suspension for injection for pigs	Live PRRS virus, strain P120	$10^{4.0}$ - $10^{7.3}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
United Kingdom (Northern Ireland)	Intervet UK Ltd Walton Manor Walton Milton Keynes MK7 7AJ United Kingdom	Porcilis PRRS Lyophilisate and Solvent for Suspension for Injection for Pigs	Live attenuated PRRS virus, strain DV	$10^{4.0}$ - $10^{6.3}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use
United Kingdom (Northern Ireland)	Boehringer Ingelheim Animal Health UK Ltd Ellesfield Avenue Bracknell RG12 8YS United Kingdom	ReproCyc PRRS EU Lyophilisate and Solvent for Suspension for Injection for Pigs	Live attenuated PRRS virus, strain 94881 (genotype 1)	$10^{3.9}$ - $10^{7.0}$ TCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use
United Kingdom (Northern Ireland)	Laboratorios Hipra, S.A. Avda. la Selva, 135 17170 Amer (Girona) Spain	Unistain PRRS Lyophilisate and Solvent for Suspension for Injection for Pigs	Live attenuated PRRS virus, strain VP-046 BIS	$10^{3.5}$ - $10^{5.5}$ CCID <sub>50</sub>	Lyophilisate and solvent for suspension for injection	Pigs	Intramuscular use Intradermal use

<sup>3</sup> For the United Kingdom, as from 1 January 2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

## **Annex II**

### **Scientific conclusions and grounds for amendment of the summary of product characteristics**



# Overall summary of the scientific evaluation of modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines (see Annex I)

## 1. Introduction

Modified live porcine respiratory and reproductive syndrome virus vaccines, or PRRS MLV, are widely used to reduce the clinical impact of the disease, reduce viraemia and virus transmission in vaccinated populations. The disease in gilts/sows may result in lowered farrowing (birth) rates, increase in abortions, stillborn, mummified as well as weak live born piglets and deaths, whilst the respiratory disease in suckling and weaned pigs can lead to high mortality rates. Live vaccines contain strains of live PRRS virus, which have been weakened so that they do not cause disease but shedding of the vaccine strain may occur for a variable period of time after vaccination, depending on the vaccine strain. Traditionally, two genotypes of the PRRS virus, PRRSV-1 (or European type) and PRRSV-2 (or American type) have been distinguished, with a high genetic variability between them and within each type.

In July 2019, PRRS virus type 1 was detected in samples collected as part of the routine PRRSV surveillance in a PRRSV-negative boar station in Denmark. PRRSV infections and PRRS viruses were subsequently detected and isolated in approximately 40 herds that had received semen from the boar station. The clinical signs observed in the herds included reproductive failures, piglet mortality up to 60% and in some cases sow mortality. A full genome sequencing of the virus, collected from the boar station and named 'Horsens virus strain', was performed<sup>4</sup> and analysed<sup>5</sup>.

The phylogenetic analysis carried out by Kvisgaard *et al.* (2020)<sup>2</sup> reported that this virus was significantly different from all known Danish PRRS viruses and furthermore, that it was a recombinant. A recombination analysis was performed which concluded that the strain was a recombination between the strain VP-046 BIS included in the vaccine Unistrain PRRS (authorised via decentralised procedure IE/V/0287/001/DC; marketing authorisation holder: Laboratorios HIPRA) and the strain 96V198 included in the vaccine Suvaxyn PRRS MLV (authorised via centralised procedure EU/2/17/215/001-003; marketing authorisation holder: Zoetis Belgium SA). It was hypothesised that the recombinant strain originated in and spread to the boar station from a neighbouring herd which had a vaccination history with both Unistrain PRRS and Suvaxyn PRRS MLV vaccines and in which the 'Horsens virus strain' was detected.

Based on these findings, the Danish Veterinary and Food Administration suspended the use of the vaccine Suvaxyn PRRS MLV in Denmark on 5 November 2019, "based on the precautionary principle, aiming to protect animal health and prevent new virus variants from occurring in the future". On 6 November 2019, in accordance with Article 45(4) of Regulation (EC) No. 726/2004, Denmark notified the European Commission and the European Medicines Agency of the suspension of the use of the product Suvaxyn PRRS MLV. Therefore, on 7 November 2019, the European Commission initiated a procedure under Article 45 of Regulation (EC) No. 726/2004 and requested the CVMP to assess the above concerns and their impact on the benefit-risk balance for Suvaxyn PRRS MLV.

Following a review of the available data, the CVMP adopted an opinion on 18 June 2020<sup>6</sup> and concluded that there was no product-specific concern identified for Suvaxyn PRRS MLV that would make the

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<sup>4</sup> Porcine reproductive and respiratory syndrome virus isolate DK-2019-10166-107, complete genome (GenBank: MN603982.1) – <https://www.ncbi.nlm.nih.gov/nuccore/MN603982>

<sup>5</sup> Kvisgaard LK, Kristensen CS, Ryt-Hansen P, *et al.* A recombination between two Type 1 Porcine Reproductive and Respiratory Syndrome Virus (PRRSV-1) vaccine strains has caused severe outbreaks in Danish pigs. *Transbound Emerg Dis.* 2020; 00:1-11. <https://doi.org/10.1111/tbed.13555>

<sup>6</sup> CVMP Scientific conclusions and grounds for amendment of the summary of product characteristics and package leaflet of Suvaxyn PRRS MLV – [link](#)

product different from other authorised modified live PRRS virus vaccines in terms of potential for recombination. Furthermore, the CVMP opinion states that:

*“Genetic recombination of PRRS viruses cannot be excluded and may therefore occur under field conditions. It is generally acknowledged that such recombination can occur between PRRSV field strains including PRRS MLV strains. This has been known for decades and is well described in scientific literature.”*

*“Thus, the well-known general possibility of recombination of PRRSV field strains and PRRS MLV strains and the potential implications of such recombination events should be considered when using modified live PRRS vaccines. In addition, the opportunity for PRRS viruses to circulate and disseminate should be limited by specific precautionary measures (e.g. vaccination, use of vaccines under specific rules, biosafety/biosecurity measures). However, these precautions are relevant not only for Suvaxyn PRRS MLV but also for all modified live PRRS vaccines authorised in the EU.”*

The Committee concluded that overall, the benefit-risk balance for Suvaxyn PRRS MLV is positive, subject to changes in the product information. Several warnings were included in the product information for Suvaxyn PRRS MLV, aimed at limiting the opportunity for the modified live PRRS virus to circulate and at reducing the risk and frequency of recombination between PRRS viruses, including PRRS vaccine strains. In this respect, the CVMP opinion states that:

*“In addition, the Committee recognised that such warning sentences would also be applicable to other PRRS MLV vaccines authorised in the EU and further considerations on this matter should be given at a future date.”*

In view of the concerns above and in line with the aforementioned considerations from the CVMP opinion, the European Commission considered that the marketing authorisations and product information of all modified live PRRS virus vaccines authorised in the EU should be reviewed to ensure protecting animal health and limiting the risk of recombination between PRRS viruses, including PRRS vaccine strains.

## **2. Discussion of data available**

The concerned MAHs provided pharmacovigilance data, studies on vaccine virus shedding and spreading, scientific literature as well as proposals for risk mitigation measures in response to the questions raised by the CVMP.

### **Recombination events involving PRRS vaccine strains and field strains or between modified live vaccine strains of PRRSV**

In general, homologous recombination is a process by which related segments of genetic material (RNA or DNA) may be exchanged between related organisms. This process occurs naturally in essentially all micro-organisms and is believed to be important for the evolution of species. Recombination enables different beneficial mutations in separate genomes to be combined into a single genome, resulting in an organism that shows advantages over its predecessors in terms of an increased “fitness” (e.g. replication, survival).

PRRS viruses are small, enveloped RNA viruses and belong to the genus Arterivirus (family Arteriviridae, order Nidovirales). They are subdivided in two major types, PRRSV-1 (European) and PRRSV-2 (North American). Due to the nature of PRRSV, genetic recombination cannot be excluded and will occur under field conditions within each type; however, no cases of a recombination between PRRSV-1 and PRRSV-2 have been reported so far. Evidence that homologous recombination events occur at high frequency in PRRS viruses has been widely available for decades and is well described in

scientific literature. Such events include recombination between PRRSV field strains, but also recombination involving modified live vaccine strains of PRRSV vaccines.

Despite the potential for recombination of PRRS field viruses and the extensive use of PRRS MLV vaccines worldwide, clear evidence of recombination between vaccine and wild type strains has hardly been reported both in scientific literature and in pharmacovigilance. The MAHs provided and analysed published literature and papers dated between 1992 and 2020, as well as own pharmacovigilance data. In general, all these papers are of the same tenor and conclude that there is an intrinsic potential for recombination and re-assortment in either PRRSV field strains or modified live PRRS vaccine strains. It is supposed that a recombinant virus emerged in a farm by recombination may also be transmitted to other farms. However, no cases were presented where such a recombinant is much more virulent than the original/parent viruses. While the recombinant virus gained some *in vivo* replication fitness, its pathogenicity or virulence did not seem to increase unambiguously even if significant clinical signs were observed in the reported cases.

Based on the data provided and taking into account the high numbers of vaccine doses administered (hundreds of millions) and the very limited number of recombination events reported in the scientific literature and through pharmacovigilance, the CVMP concluded that the risk associated with recombination of a PRRS MLV vaccine strain with a PRRS field virus or between two PRRS MLV vaccine strains, and any potential adverse events resulting from it, is low.

Recombination events of a PRRS MLV vaccine strain with a PRRS field virus or between two PRRS MLV vaccine strains can only occur in the presence of both viruses on the same farm at the same time. As live PRRS vaccine viruses behave similarly to PRRS field viruses and replicate in pigs, the potential to recombine is considered an unavoidable possibility in case of a co-infection with another PRRSV in e.g. vaccinated pigs. If such a recombination event would occur, no general prediction regarding the emergence of virulence and possible effects of the resulting recombinant PRRS virus can be made. It is generally considered that the virulence of any new recombinant virus will possibly not exceed that of the parental PRRS field virus involved.

The circulation of PRRS viruses either from vaccine or field origin is considered to increase the likelihood of recombination and possible return to virulence. Therefore, as a matter of principle, the opportunity for PRRS viruses to circulate and disseminate should be limited by specific precautionary measures such as vaccination under predefined requirements or biosafety/biosecurity measures. The Committee concluded that such precautions would be relevant for all modified live PRRSV vaccines authorised in the EU. To this end, the Committee convened an *ad hoc* expert group in order to provide expert advice on the development of recommendations on the correct and proper use of PRRS MLV vaccines aiming to limit the opportunity for PRRS viruses to circulate and to reduce the risk and the frequency of recombination between PRRS viruses including PRRS vaccine strains and the potential adverse events.

The expert group confirmed that despite the well-known general possibility of recombination of PRRSV field strains and PRRS MLV vaccine strains, modified live PRRSV vaccines continue to be an appropriate tool for the management of PRRSV infection/disease in Europe.

In terms of the identification of a potential recombination event with a live vaccine in the field and its subsequent reporting, the expert group considered that no specific clinical signs are anticipated which could indicate a recombinant virus and therefore a thorough diagnostic follow-up is recommended. Additionally, since the recombination between two closely related PRRS virus strains might be difficult to identify, the sequencing of the whole genome of the supposed recombinant with a next generation sequencing device associated with the interpretation of the raw data with several different algorithms was advised. Relevant and suitable samples should be taken from different animals of the affected age

group. Furthermore, the expert group advised that the virulence of recombinant strains can only be assessed reliably using experimental infections in pigs, including proper control animals.

### **Vaccine virus shedding and spreading**

With a view to reducing the risk of recombination events due to the circulation of PRRS vaccine viruses, as well as the definition of a transition period for transitioning from one PRRS MLV vaccine to another within a farm, the MAHs provided summary reports of studies on duration of vaccine virus shedding and excretion and results, if available, concerning vaccine virus loads in excretions (e.g. in tissues, blood and semen) after vaccination.

CVMP noted that the study designs noticeably differed in terms of the observation period of shedding after vaccination (timeframe: 3 to 12 weeks), possibly because the vaccines are intended for different target animal category (e.g. pigs for fattening, pigs including pregnant and/or lactating sows). A further important difference was the type of samples collected (e.g. blood, faecal, nasal and oral swabs, milk, colostrum, etc.). Not all detection methods included the limit of detection. In some cases, only viremia was evaluated in vaccinated animals. Furthermore, regarding spreading, the studies did not always include in-contact or sentinel animals. Therefore, the CVMP considered that it would be desirable to provide in the future clearer guidance to applicants on the study design evaluating shedding and spreading of PRRS MLV vaccines enabling a proper risk assessment in the context of the risk of recombination events and the definition of a transition period for the switching from one vaccine to another at the same farm.

With regard to the products included in the scope of this referral procedure, the CVMP concluded that the information concerning the time period of shedding and spreading of the vaccine virus after vaccination is highly important and should be maintained or added, if not already included, in the product information.

### **Proposed risk mitigation measures**

The MAHs proposed modifications to the product information to clarify in more detail those situations where recombination of the vaccine virus with PRRSV field or other vaccine strains could happen. The proposed changes were noted and considered generally adequate for the use of PRRS MLV vaccines as they were based mainly on the CVMP conclusions in procedure EMEA/V/A/139 under Article 45 of Regulation (EC) No. 726/2004 for Suvaxyn PRRS MLV<sup>6</sup>.

The expert group also generally supported the proposed warnings to be included in the product information but suggested some amendments. In particular, the expert group proposed to state that "vaccination should be performed preferably in a separated quarantine unit and a transition period should be respected". This transition period should be based on the time period of shedding and spreading of the vaccine virus after vaccination for each product. However, the expert group advised that the warning recommended in the procedure under Article 45 of Regulation (EC) No. 726/2004 for Suvaxyn PRRS MLV<sup>6</sup> "It is advised to vaccinate all target pigs within a herd from the earliest recommended age onwards" was not appropriate and should be deleted. Furthermore, the term "mass vaccination" was suggested to be deleted as it was considered unclear. An alternative sentence (e.g. "Vaccination should aim to achieve a homogenous immunity in the target population") was suggested. No further additional warnings or amendments to the product information were proposed by the expert group.

The expert group highlighted that the implementation of external and internal biosecurity measures as strict as possible is recommended to decrease the transmission of PRRS field viruses and PRRS MLV vaccine strains between and within farms, with a reference to current literature and handbooks. As such measures are not directly related to the use of vaccines, the CVMP considered that a general guidance document on the appropriate use of PRRS modified live vaccines together with further

information on other measures to reduce circulation of different PRRSV field strains and PRRS vaccine strains would be beneficial. The expert group supported this proposal and advised that such general guidance should be provided to the herd veterinarian and the farmer, preferably electronically. The CVMP will liaise with relevant bodies and organisations in the future to initiate the drafting of this guidance.

### **3. Benefit-risk assessment**

#### **Introduction**

The referral was initiated in order to review all available data for modified live PRRS virus vaccines and consider what risk management measures are appropriate and feasible for the products under consideration (e.g. changes to product information) that could protect animal health and limit the risk of recombination between PRRS viruses, including PRRS vaccine strains.

#### **Benefit assessment**

The efficacy of the concerned PRRSV vaccines has not been evaluated in terms of direct therapeutic or additional benefits in this referral procedure.

#### **Risk assessment**

Quality, target animal safety, user and consumer safety as well as the environmental risk for the concerned veterinary medicinal products have not been assessed in this referral procedure and remain unaffected in the light of the referral.

#### Specific potential risks, according to product type and application:

Unintended spread of vaccine strains can occur because the vaccines contain live attenuated virus and live organisms can be introduced into the environment.

Reversion to virulence cannot be ruled out because the vaccines contain live attenuated virus, which has replicative or integrative potential. However, corresponding safety studies and the absence of reliable pharmacovigilance data have given no indication that the vaccine virus reverted to virulence.

As the vaccine strains are able to replicate in vaccinated pigs, they have the potential to recombine with field strains or other vaccine strains that may be concurrently replicating in the same pig. Genetic recombination of PRRS viruses including PRRS MLV vaccine strains is a natural process and cannot be excluded. This feature is generally acknowledged and known for decades and is well described in scientific literature. It is assumed that possible risks related to genetic recombination have been addressed and assessed in the initial marketing authorisation procedures of the concerned veterinary medicinal products as well as in follow-up procedures.

#### **Risk management or mitigation measures**

The addition of further information in the product information in order to limit the opportunity for PRRS MLV vaccine strains to circulate and to reduce the risk and the frequency of recombination between PRRS viruses including PRRS vaccine strains was deemed necessary in the context of this referral procedure (see Annex III).

#### **Evaluation and conclusions on the benefit-risk balance**

The potential of PRRS MLV vaccine strains to recombine either with PRRSV field strains and/or with other PRRSV vaccine strains is not new. It is a natural feature of PRRS viruses, including all PRRS modified live virus vaccines authorised in the EU. Notwithstanding, PRRS modified live vaccines

continue to be considered an appropriate tool for the management of PRRSV infection/disease in Europe.

Provided additional warnings to limit the opportunity for PRRS MLV viruses to circulate and to reduce the risk and the frequency of recombination between PRRS viruses including PRRS vaccine strains are included in the product information, the benefit-risk balance for modified live porcine respiratory and reproductive syndrome virus vaccines remains positive.

## **Grounds for amendment of the summary of product characteristics and package leaflet**

Whereas

- based on the data provided, the CVMP concluded that the risk associated with recombination of a PRRS MLV vaccine strain with a PRRS field virus or between two PRRS MLV vaccine strains, and any potential adverse events resulting from it, is low;
- the opportunity for PRRS MLV vaccine strains to circulate should be further limited in order to further reduce the risk and the frequency of recombination between PRRS viruses including PRRS vaccine strains;
- the CVMP considered that the overall benefit-risk balance for the concerned products remains positive subject to amendments in the product information;

the CVMP has recommended the amendment of the marketing authorisations for modified live porcine respiratory and reproductive syndrome (PRRS) virus vaccines as referred in Annex I for which the summary of product characteristics and package leaflet are set out in Annex III.

## Annex III

### Amendments in the relevant sections of the Summary of product characteristics and package leaflet

#### Summary of product characteristics

##### 4.5 Special precautions for use

###### Special precautions for use in animals

...

###### *For PRRS MLV vaccines authorised for use in breeding animals:*

PRRS virus-naïve breeding animals (e.g. replacement gilts from PRRS virus-negative herds) which are introduced into a PRRSV-infected herd should be vaccinated prior to first insemination. Vaccination should preferably be done in a separated quarantine unit. A transition period should be respected between vaccination and moving the animals to the breeding unit. This transition period should be longer than the shedding phase of the PRRS MLV vaccine following vaccination.

###### *For all PRRS MLV vaccines irrespective of the target animal category:*

Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd.

In order to limit the potential risk of recombination between PRRS MLV vaccine strains of the same genotype, do not use different PRRS MLV vaccines based on different strains of the same genotype on the same farm at the same time. In the case of transitioning from one PRRS MLV vaccine to another PRRS MLV vaccine, a transition period should be respected between the last administration of the current vaccine and the first administration of the new vaccine. This transition period should be longer than the shedding period of the current vaccine following vaccination.

...

Add, where applicable, information concerning the time period of shedding and spreading of the vaccine virus after vaccination.

##### 4.5 Special precautions for use **OR** 4.9 Amounts to be administered and administration route

Delete, where applicable, any reference to "mass vaccination" or any similar wording like for example "all animals in a herd should be vaccinated" or "vaccination of the entire existing herd is recommended". Furthermore, delete, where applicable, the statement „It is advised to vaccinate all target pigs within a herd from the earliest recommended age onwards.“.

The following wording could be added in section 4.5 instead: "Vaccination should aim to achieve a homogenous immunity in the target population at farm level.“.

## Package leaflet

### 12. SPECIAL WARNING(S)

#### Special precautions for use in animals

...

#### *For PRRS MLV vaccines authorised for use in breeding animals:*

PRRS virus-naïve breeding animals (e.g. replacement gilts from PRRS virus-negative herds) which are introduced into a PRRSV-infected herd should be vaccinated prior to first insemination. Vaccination should preferably be done in a separated quarantine unit. A transition period should be respected between vaccination and moving the animals to the breeding unit. This transition period should be longer than the shedding phase of the PRRS MLV vaccine following vaccination.

#### *For all PRRS MLV vaccines irrespective of the target animal category:*

Do not routinely rotate two or more commercial PRRS MLV vaccines based on different strains in a herd.

In order to limit the potential risk of recombination between PRRS MLV vaccine strains of the same genotype, do not use different PRRS MLV vaccines based on different strains of the same genotype on the same farm at the same time. In the case of transitioning from one PRRS MLV vaccine to another PRRS MLV vaccine, a transition period should be respected between the last administration of the current vaccine and the first administration of the new vaccine. This transition period should be longer than the shedding period of the current vaccine following vaccination.

...

Add, where applicable, information concerning the time period of shedding and spreading of the vaccine virus after vaccination.

### 12 SPECIAL WARNING(S) OR 8 DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Delete, where applicable, any reference to "mass vaccination" or any similar wording like for example "all animals in a herd should be vaccinated" or "vaccination of the entire existing herd is recommended". Furthermore, delete, where applicable, the statement „It is advised to vaccinate all target pigs within a herd from the earliest recommended age onwards.“.

The following wording could be added in section 12 instead: "Vaccination should aim to achieve a homogenous immunity in the target population at farm level.“.