Annex I

List of the names, pharmaceutical forms, strengths of the Veterinary medicinal product, animal species, routes of administration, withdrawal period, marketing authorisation holders in the Member states

Member State / EEA	Marketing Authorisation Holder	Product name	Strength	Pharmaceutical form	Animal species	Indications	Withdrawal period
Austria	Intervet GmbH Siemensstrasse 107 1210 Wien Austria	PORCILIS M HYO	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Belgium	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	PORCILIS M HYO	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Cyprus	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	PORCILIS M. HYO	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Czech Republic	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M HYO	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days

Denmark	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Estonia	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Finland	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days

France	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	PORCILIS Mhyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Germany	Intervet Deutschland GmbH Postfach 1130 85701 Unterschleißheim Germany	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Greece	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	PORCILIS M.Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days

Hungary	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Ireland	Intervet Ireland Limited, Magna Drive Magna Business Park Citywest Road Dublin 24 Ireland	Porcilis M Hyo, suspension for injection	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Italy	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porsilis M-HYO	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days

Latvia	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	PORCILIS M HYO	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Lithuania	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Luxembourg	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M. Hyo, suspension injectable	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days

Malta	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Norway	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	PORCILIS M HYO	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Poland	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days

Portugal	Intervet Portugal – Saúde Animal, Lda Rua Agualva dos Açores, n.º 16, 2735 – 557 Agualva-Cacém Portugal	Porcilis M hyo, suspensão para injecção	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Slovakia	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcillis M.Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Slovenia	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days

Spain	POLIG. INDUSTRIAL EL MONTALVO, PARCELA 39 CARBAJOSA DE LA SAGRADA 37188 SALAMANCA Spain	PORCILIS Mhyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
Sweden	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days
The Netherlands	Intervet International bv Wim de Koerverstraat 35 5831 AN Boxmeer The Netherlands	Porcilis M Hyo	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days

United Kingdom	Intervet International B.V. represented by Intervet UK Ltd Walton Manor Walton Milton Keynes Bucks MK7 7AJ	Porcilis M Hyo, suspension for injection	Inactivated whole cell concentrate of *Mycoplasma hyopneumoniae* strain 11: ≥ 7.0 log2 Ab titre	Suspension for injection	Pigs (finishing pigs)	For the active immunisation of pigs to reduce pulmonary lesions due to infection by *Mycoplasma hyopneumoniae*.	Zero days

Annex II

Scientific conclusions and grounds for the granting of the variation of the marketing authorisations

OVERALL SUMMARY OF THE SCIENTIFIC EVALUATION OF PORCILIS M HYO (SEE ANNEX I)

1. Introduction

Porcilis M Hyo is an immunological veterinary medicinal product containing *Mycoplasma hyopneumoniae* and dl-α-tocopherol acetate as adjuvant. The inactivated vaccine is a suspension for injection. It is indicated for finishing pigs from 1 week of age. Pigs should be vaccinated twice with a 3 week interval. It should be administered intramuscularly (2 ml in the neck).

The marketing authorisation holder Intervet International BV submitted a Type II variation application subject to the Mutual Recognition Procedure to the Marketing Authorisations of the veterinary medicinal product Porcilis M Hyo in the framework of Article 6 of Commission Regulation (EC) No 1084/2003.

The variation of concern consists of allowing the mixing of two vaccines, Porcilis PRRS and Porcilis M Hyo, before administration. The lyophilised fraction of Porcilis PRRS (containing the live virus antigen) would be reconstituted in the inactivated vaccine Porcilis M Hyo. The proposed vaccination scheme for finishing pigs with the mixed product is: first administration of Porcilis M Hyo from one week of age followed by the administration of Porcilis PRRS mixed with Porcilis M Hyo from 4 weeks of age.

Following the absence of agreement between the Reference Member State (the United Kingdom acted on behalf of France as the Reference Member State in a work-sharing arrangement) and one of the Concerned Member States (Spain) at day 90 of the CMDv procedure, the matter was referred to the CVMP on 2 October 2009. The National Competent Authority of Spain was concerned that some aspects regarding the quality, safety and the efficacy after mixing the two products (Porcilis PRRS and Porcilis M Hyo) were not adequately justified.

2. Discussion

2.1 In-use shelf-life proposed after mixing the two products (Porcilis PRRS and Porcilis M Hyo)

The marketing authorisation holder has provided data of the PRRS virus titration after mixing Porcilis PRRS with Porcilis M Hyo at 0, 1, 2 and 3 hours. The results indicated that there was a limited drop in the PRRS virus titre after mixing with Porcilis M Hyo (average drop after the claimed 1 hour in-use shelf life of 0.05 log). This would support an in-use shelf life of one hour, except for the lack of information necessary to properly evaluate the results: the batch release protocols of the batches used and the protocols with the conditions of the assay were not provided. In order to ascertain that there is no significant decrease in the titre right after mixing (i.e., at t=0), it was considered important to know the titre at release (or after reconstitution in the diluent fraction of Porcilis PRRS). In addition, it was not known whether the studies were performed with batches of vaccines approaching the end of their shelf life.

Concerning Porcilis M Hyo the marketing authorisation holder has submitted data of adjuvant content (dl-α-tocopherol acetate), pH and sterility of the mixture after reconstitution of 2 batches of Porcilis PRRS in 2 batches of Porcilis M Hyo after storage for 3 hours at room temperature. In addition, it is considered that potency of the Porcilis M Hyo component after

mixing should have been analysed in order to the exclude a quality interference right after mixing (at t=0) and after the proposed in-use shelf life.

Batch release protocols for the in-use stability studies of Porcilis PRRS and Porcilis M Hyo were provided. The marketing authorisation holder provided data for PRRS virus titres of two batches of Porcilis PRRS reconstituted with each of ten batches of Porcilis M Hyo after 0, 1, 2 and 3 hours of storage at room temperature.

As regards why the stability studies were not performed with batches approaching the end of their shelf-life, the marketing authorisation holder has commented that there is no impact on the existing minimum titre proven to be efficacious:

1) the claimed in-use shelf life for the "mixed" product is one hour;
2) the apparent drop over 1 hour from the titre at release (6.4/6.2 $TCID_{50}$) is 0.12/-0.02 (mean 0.05) which is within assay variability;
3) the minimum efficacious titre is 4.0 $TCID_{50}$
4) this means that in the worst case scenario of a batch at the end of shelf being mixed there will be no statistically significant drop below the minimum titre over the claimed in-use shelf life of 1 hour.

As regards justifying why no potency test of the Porcilis M Hyo component has been carried out on the mixed vaccines both immediately after mixing and after the proposed in-use shelf life, the marketing authorisation holder has justified not performing a potency test for the Porcilis M Hyo component on the mixed vaccines that by provision of safety and efficacy studies using the mixed product the marketing authorisation holder has shown that there are no interactions within the mixture affecting the potency of the mixed product. The guideline on data requirements to support in-use stability claims for veterinary vaccines[*], states that "*For inactivated vaccines, if the proposed in-use shelf-life is within one working day (maximum 10 hours) it is acceptable to omit the potency testing from the in-use shelf-life stability study*."

2.2 Justification regarding the approach followed to demonstrate the safety of the individual vaccination schemes when the two products are administered together.

The proposed vaccination scheme for the mixed product is:

- First vaccination: Porcilis M Hyo at 1 week of age.
- Second vaccination: Porcilis M Hyo mixed with Porcilis PRRS from 4 weeks of age.

The marketing authorisation holder has presented data on safety studies (single dose, overdose, repeated dose) starting at 4 weeks of age with Porcilis PRRS mixed with Porcilis M Hyo, considering that 4 weeks is the youngest age recommended for the administration of the mixed product.

The marketing authorisation holder was requested to justify why the proposed vaccination scheme (Porcilis M Hyo at 1 week of age and Porcilis M Hyo mixed with Porcilis PRRS at 4 weeks of age) was not followed to show the safety of the mixed administration.

[*] CVMP Guideline on data requirements to support in-use stability claims for veterinary vaccines (EMEA/CVMP/IWP/250147/2008-CONSULTATION) - http://www.ema.europa.eu/pdfs/vet/iwp/25014708en.pdf

The marketing authorisation holder examined the repeated administration of a single dose of each vaccine administered simultaneously at an interval of 14 days in animals of 4 weeks of age. According to the advised vaccination schedule, Porcilis M Hyo and Porcilis PRRS are used simultaneously for the first time at the second administration of Porcilis M Hyo. This is at three weeks after the first injection with Porcilis M Hyo which is to be given from one week of age onwards. The youngest age for the two products to be used simultaneously is thus four weeks of age. The Ph.Eur. and EU guidelines require safety studies to use animals which are seronegative for the antigens of the vaccine components. This was regarded as the worst case scenario using the most susceptible animals. The marketing authorisation holder has complied with these requirements with the design of this study. While it was suggested that the provided data was not adequate because the animals had not received a single M Hyo vaccination at 1 week of age within the design of this study and therefore the safety of the overall schedule was unproven, the marketing authorisation holder has proven the worst case scenario of a repeated dose of simultaneous vaccination with the two vaccines in susceptible animals (seronegative) of the minimum age.

2.3 Potential impact on the efficacy parameter of duration of immunity due to an interference caused by mixing of the two products.

Data on laboratory efficacy studies and on one field study were provided showing that the reduction of lung lesion score of pigs vaccinated with the mixed product is similar to the reduction of lung lesion score of pigs vaccinated with Porcilis M Hyo alone.

The marketing authorisation holder considered that, based on the "Guideline on requirements for concurrent administration of immunological veterinary medicinal products[*], the efficacy data of the individual products, including duration of immunity, can be applied for the concurrent use of them if absence of immunological interference is demonstrated. Since the protective immunity against lung lesion score is not altered by the mixed administration, the marketing authorisation holder considered that all the other efficacy parameters will also not be altered, and therefore, no more data are required in support of the duration of immunity for the mixed administration.

The marketing authorisation holder has justified that the current duration of immunity for Porcilis PRRS is still supported when the two products are mixed. The marketing authorisation holder has demonstrated that the degree of protection conveyed by the individual products has not been altered by mixing the products by several laboratory challenge studies and field studies. These can be regarded as demonstrating equivalence of immune response and it would not be expected that if the immune response is not altered at one point in time that the duration of that response will be any different. The marketing authorisation holder has demonstrated that there is no immunological interference when the vaccines were mixed resulting in maintenance of the same level of efficacy by investigating one efficacy parameter, reduction in viraemia (reduction of 70-75% after simultaneous use and reduction of 72-75% after use of Porcilis PRRS alone). It should be borne in mind that PRRS is a multifactorial disease and therefore all clinical signs may not always be seen in laboratory studies (animals kept free from other agents) as in field studies. There is no reason to believe that other efficacy parameters would be influenced any differently in the field.

[*] CVMP Guideline on requirements for concurrent administration of immunological veterinary medicinal products (EMEA/CVMP/550/02-FINAL) - http://www.ema.europa.eu/pdfs/vet/iwp/055002en.pdf

However the argumentation provided by the marketing authorisation holder to date raises some concerns that by mixing the products some of the efficacy claims for the monovalent products would not be achieved. The marketing authorisation holder was requested to provide additional data and justification that the efficacy claims and duration of immunity of Porcilis PRRS are not altered when the vaccine is administered mixed with Porcilis M Hyo. The general claim to reduce viraemia has only been demonstrated in laboratory studies. The specific claims for finishing pigs to improve the rearing results have not been demonstrated. Duration of immunity of Porcilis PRRS has also not been demonstrated for simultaneous administration. Nevertheless absence of immunological interference has not been inferred but has been clearly demonstrated by providing laboratory challenge data which showed that there is not significant difference in protection between animals vaccinated with the mixed products and those vaccinated with single products.

3. Benefit / Risk assessment

There are both practical reasons as well as clinical advantages to administering these 2 products together which leads to an overall improvement in animal welfare. The in-use stability of the mixed vaccines has been adequately demonstrated over an in-use period of an hour which is sufficient to vaccinate the number of animals representative of a realistic scenario. The safety of the regimen for the both individual and mixed vaccines has been supported. The efficacy studies using appropriate challenges for Porcilis M Hyo and Porcilis PRRS have shown that there is no affect of simultaneous administration on the efficacy parameters of reduced viraemia and a reduction in lung lesions. Given that a lack of interference has been demonstrated a specific time point the duration of immunity remains the same as originally proven. It should be noted that local and systemic reactions were unremarkable (mild and seen in a small proportion of animals) and consistent with those seen when vaccines were used alone. Thus, the overall the benefit/risk balance is considered to be positive.

GROUNDS FOR THE GRANTING OF THE VARIATION OF THE MARKETING AUTHORISATIONS

Whereas:

- the CVMP considered that stability of the mixed product up to 1 hour after mixing as claimed on the Summary of Product Characteristics was supported by the data provided,
- the CVMP considered that the safety and efficacy of the mixed vaccine regarding the *Mycoplasma hyopneumoniae* component were sufficiently supported by the data provided,

the CVMP has recommended the granting of the variation of the Marketing Authorisations for Porcilis M Hyo and associated names (see Annex I). The amendments of the relevant sections of the Summary of Product Characteristics and package leaflet are set out in Annex III.

Annex III

Amendments to the summary of product characteristics and package leaflet

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE SUMMARY OF PRODUCT CHARACTERISTICS

4.6 Adverse reactions (frequency and seriousness)

A mean transient temperature increase in body temperature of about 0.3°C, in individual pigs up to 2.0°C, may occur on the first 1 to 2 days after vaccination. The animals return to normal the next day. A transient swelling/redness (max. diameter 5 cm) may occur at the injection site diminishing over a period of maximally 14 days.
In isolated cases hypersensitivity reactions may occur.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available in pigs from 4 weeks of age onwards, which demonstrate that this vaccine can be mixed with Porcilis PRRS.
The product literature of Porcilis PRRS should also be consulted before administration of the mixed product.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be decided on a case by case basis. No information is available on the safety and efficacy of the use of Porcilis M Hyo mixed with Porcilis PRRS in breeding animals or during pregnancy.

4.9 Amounts to be administered and administration route

Intramuscular injection in pigs of 2 ml per animal in the neck in the area behind the ear.

Vaccination scheme:
Vaccinate pigs twice with a three week interval. The first injection can be given from an age of 1 week onwards.

For simultaneous use with Porcilis PRRS in finishing pigs from 4 weeks of age (3 weeks after priming) the vaccine may be used for reconstitution shortly before vaccination.
Thereby the following instructions should be used:

Porcilis PRRS		Porcilis M Hyo
10 doses	+	20 ml
25 doses	+	50 ml
50 doses	+	100 ml
100 doses	+	200 ml

A single dose (2 ml) of Porcilis M Hyo mixed with Porcilis PRRS is given intramuscularly in the neck.

Before using the vaccine allow it to reach room temperature (15-25°C) and shake well before use.
Use sterile syringes and needles.
Avoid introduction of contamination.

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product except with Porcilis PRRS.

6.3 Shelf life

3 years
After opening: 3 hours.
After mixing with Porcilis PRRS: 1 hour (at room temperature)

AMENDMENTS TO BE INCLUDED IN THE RELEVANT SECTIONS OF THE PACKAGE LEAFLET

6. ADVERSE REACTIONS

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In isolated cases hypersensitivity reactions may occur.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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For simultaneous use with Porcilis PRRS in finishing pigs from 4 weeks of age (3 weeks after priming) the vaccine may be used for reconstitution shortly before vaccination. Thereby the following instructions should be used:

Porcilis PRRS		Porcilis M Hyo
10 doses	+	20 ml
25 doses	+	50 ml
50 doses	+	100 ml
100 doses	+	200 ml

A single dose (2 ml) of Porcilis M Hyo mixed with Porcilis PRRS is given intramuscularly in the neck.

9. ADVICE ON CORRECT ADMINISTRATION

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Safety and efficacy data are available in pigs from 4 weeks of age onwards, which demonstrate that this vaccine can be mixed with Porcilis PRRS.

The product literature of Porcilis PRRS should also be consulted before administration of the mixed product.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be decided on a case by case basis. No information is available on the safety and efficacy of the use of Porcilis M Hyo mixed with Porcilis PRRS in breeding animals or during pregnancy.

11. SPECIAL STORAGE PRECAUTIONS

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After mixing with Porcilis PRRS: 1 hour (at room temperature)