ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

GLEPTOVEX 200 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Iron (III)	200.0 mg
(as Gleptoferron	532.6 mg)

Excipients:

Phenol	5.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Dark brown, slightly viscous solution

4. CLINICAL PARTICULARS

4.1 Target species

Pigs (piglets)

4.2 Indications for use, specifying the target species

For the prevention and treatment of iron deficiency anaemia in piglets.

4.3 Contraindications

Do not administer to piglets suspected to suffer from deficiency of vitamin E and/or selenium. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in clinically diseased animals, especially not in cases of diarrhoea.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

It is advisable to stretch the skin at the injection site to minimize leakage after withdrawal of the needle. Observe aseptic precautions. Avoid the introduction of contamination during use.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to the active substance (gleptoferron) or with hemochromatosis should avoid contact with the veterinary medicinal product. Take care to avoid accidental self-injection and contact with mucous membranes. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Discolouration of the tissue and/or slight, soft swelling may be observed uncommonly at the site of injection. This should disappear within a few days. Also hypersensitivity reactions can occur.
Deaths have occurred rarely in piglets following the administration of parenteral iron dextran preparations. These deaths have been associated with genetic factors or deficiency of vitamin E and/or selenium.
Piglet deaths which have been attributed to an increased susceptibility to infection due to temporary blocking of the reticuloendothelial system have been reported very rarely.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated report

4.7 Use during pregnancy, lactation or lay

Not applicable

4.8 Interaction with other medicinal products and other forms of interaction

The absorption of concomitantly administered oral iron may be reduced.

4.9 Amounts to be administered and administration route

For intramuscular use only.

Piglets:

The product is administered as a single 1 mL (200 mg iron) dose by deep intramuscular injection. Inject once between the 1st and the 3rd day of life.
The use of a multidose syringe is recommended. To refill the syringe use a draw-off needle to avoid excessive broaching of the stopper.

Do not broach the 100 ml vial more than 20 times and a 200 ml vial more than 50 times.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Large amounts of iron administered by the parenteral route may result in transient reduced capacity of the immune system due to iron overload of lymph macrophages. Pain, inflammation reactions, abscess formation as well as persistent discolouration of muscle tissue at the injection site may occur.

Iatrogenic poisoning may result in the following signs: pale mucous membranes, haemorrhagic gastroenteritis, vomiting, tachycardia, hypotension, dyspnoea, oedema of the limbs, lameness, shock, death, liver damage. Supportive measures such as chelating agents can be used.

4.11 Withdrawal period(s)

Meat and offal: Zero days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Iron, parenteral preparations

ATCvet Code: QB03AC

5.1 Pharmacodynamic properties

Iron is an essential micronutrient. It plays a major role in the oxygen transport of haemoglobin and myoglobin, as well as a key role in enzymes, such as cytochromes, catalases, and peroxidases.
Iron has a high recovery rate from metabolism and food ingested. Thus, deficiency occurs only very rarely in adult animals.

5.2 Pharmacokinetic particulars

After intramuscular injection, the iron complex is absorbed into the lymphatic tissue within 3 days. Here, the complex is split to release Fe^{3+} which is stored as ferritin in the main storage organs (e.g. liver, spleen and the reticuloendothelial system). In the blood, free Fe^{3+} binds to transferrin (transport form) and is mainly used for the synthesis of haemoglobin.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage

Do not freeze.
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Polypropylene vials of 100 ml and 200 ml nominal fill volume, provided with a grey (100 ml) or pink (200 ml) bromobutyl rubber stopper and aluminium seal with a Flip-off sealing.

Pack sizes:
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 200 ml
Cardboard box with 10 vials of 100 ml
Cardboard box with 10 vials of 200 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

SP VETERINARIA SA
Ctra Reus Vinyols km 4.1
Riudoms (43330)
Spain

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:> <{DD/MM/YYYY}>
Date of last renewal:> <{DD/MM/YYYY}>

10 DATE OF REVISION OF THE TEXT

{DD/MM/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE