Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

**Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety Mauerstraße 39-42 10117 Berlin (Germany)**

MUTUAL RECOGNITION PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

FERROFERON 200 mg/ml

Date: 25.09.2013

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0157/001/MR
Name, strength and pharmaceutical form	FERROFERON **200 mg/ml**, 200, mg/ml
Applicant	Iron4u ApS Dronninggards Alle 136 DK-2840 Holte Denmark
Active substance(s)	Gleptoferron
ATC Vetcode	QB03AC91
Target species	Pig (piglet)
Indication for use	For prophylaxis and treatment of iron deficiency anaemia in piglets.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13c of Directive 2001/82/EC as amended.
Date of completion of the original Mutual recognition procedure	22.07.2013
Date product first authorised in the Reference Member State (MRP only)	04 August 2011
Concerned Member States for original procedure	BE, DK, NL

I. SCIENTIFIC OVERVIEW

The quality, safety and efficacy aspects of this product are identical to Ursoferran 200 mg/ml.

II. QUALITY ASPECTS

This is an application under Article 13c of Directive 2001/82/EC. No data are presented but the holder of the original veterinary product Ursoferran 200 mg/ml (DE/V/0149/001/MR), Serumwerk Bernburg AG, has given Iron4u ApS his consent to refer to Parts 2, 3 and 4 of the dossier of that product.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACOTOXICOLOGICAL)

This is an application under Article 13c of Directive 2001/82/EC. No data are presented but the holder of the original veterinary product Ursoferran 200 mg/ml

(DE/V/0149/001/MR), Serumwerk Bernburg AG, has given Iron4u ApS his consent to refer to Parts 2, 3 and 4 of the dossier of that product.

IV. CLINICAL ASSESSMENT (EFFICACY)

This is an application under Article 13c of Directive 2001/82/EC. No data are presented but the holder of the original veterinary product Ursoferran 200 mg/ml (DE/V/0149/001/MR), Serumwerk Bernburg AG, has given Iron4u ApS his consent to refer to Parts 2, 3 and 4 of the dossier of that product. No further data are required to support this application.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Heads of Veterinary Medicinal Agencies website (www.hma.eu).

This section contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

Summary of change **(Application number)**	**Section updated in Module 3**	**Approval date**
B.II.e.5.c) – Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products (DE/V/0157/001/II/010)	N/A	03/05/2017
A.2.b. – Change in the (invented) name of medicinal product for nationally authorised products (BE, NL) B.II.b.2.c.1 (DE/V/0157/001/IB/012/G)	N/A	26/09/2018