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)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Belfer 100 mg/ml Solution for injection

Date: 07 January 2018

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0167/001/DC
Name, strength and pharmaceutical form	Belfer100 mg/ml solution for injection
Applicant	Bela-Pharm GmbH & Co.KG Lohner Str. 19 49377 Vechta Germany
Active substance(s)	Iron (III) as iron (III) hydroxide dextran complex
ATC Vetcode	QB03AC
Target species	Horse (suckling foals), cattle, pig, sheep, goat, dog
Indication for use	For treatment of iron deficiency and iron deficiency anaemia. For prophylaxis 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 13(1) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	18 October 2017
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	AT, CY, DK, EE, EL, ES, FI, HU, IS, LT, LV, PL, PT, RO, SE and SI

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.

The safety and efficacy aspects of this product are identical to the eponymous product Belfer 100 mg/ml solution for injection for horses, pigs, cattle, sheep, goats and dogs (authorisation number: 6933016.00.00, Bela-Pharm GmbH & Co.KG. The initial application for the reference product was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 100 mg/ml Iron (III) as iron (III) hydroxide dextran complex and the excipients methyl-4-hydroxybenzoate sodium, propyl-4-hydroxybenzoate sodium, sodium edetate, sodium hydroxide (for pH adjustment), hydrochloric acid (for pH adjustment) and water for injections.

The container/closure system consists of 100 ml amber glass vials with brombutyl rubber stoppers and aluminium caps.

The choice of the formulation and the presence of preservative are justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is Iron (III) as iron (III) hydroxide dextran complex, an established active substance. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on intermediate products

The tests performed during production are described and the results of 3 consecutive runs, conforming to the specifications, are provided.

E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production sites have been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

The claim of a 14-days stability after broaching is based on the demonstration of stability for a batch broached and stored 14 days at +25 °C.

G. Other Information

Not applicable.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A Safety Testing

As this is a generic application submitted in accordance to Article 13 (1) of Directive 2001/82/EC, as amended, and bioequivalence with the reference product Belfer 100 mg/ml solution for injection for horses, pigs, cattle, sheep, goats and dogs of the same company has been demonstrated, pharmacological studies and toxicological studies are not required. The safety claims for this product are equivalent to those of the reference product.

In addition, a complete user safety risk assessment has been provided. The proposed user safety warnings are adequate to ensure the safety of the user when the product is used as recommended.

Pharmacological Studies

Because of the type of application pharmacological studies are not required.

Toxicological Studies

Because of the type of application pharmacological studies are not required.

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline including a hazard identification, exposure assessment, risk characterization and a formulation of corresponding warning phrases.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the active substance is a natural substance, the use of which will not alter the concentration or distribution of the substance in the environment.

III.B Residues documentation

Residue Studies

No residue depletion studies were conducted because this is a generic application submitted in accordance to Article 13 (1) of Directive 2001/82/EC, as amended, and bioequivalence with the reference product of the same company can be assumed.

MRLs

Iron-Dextran is included in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal Species	MRL	Target tissues	Other provision	Therapeutic Classification
Iron dextran	NOT APPLICABLE	All food producing species	No MRL required	NOT APPLICABLE	NO ENTRY	NO ENTRY

Withdrawal Periods

Based on the data provided above, a withdrawal period of zero days for meat in horse, cattle, pig, sheep and goat and zero hours for milk are justified.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13(1) of Directive 2001/82/EC, as amended, and bioequivalence with the reference product Belfer 100 mg/ml solution for injection for horses, pigs, cattle, sheep, goats and dogs of the same company has been demonstrated, efficacy studies are not required. The product literature has been updated as requested by the RMS and CMSs.

IV.A Pre-Clinical Studies

This is a generic application according to Article 13(1) of Directive 2001/82/EC, as amended. The reference and the generic product are identical in composition and, therefore, the applicant has applied for exemption from need to demonstrate bioequivalence *in vivo* according to the Guideline for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMEA/CVMP/016/00-Rev. 2, section 7.1 d). It is justified that no data on pharmacodynamics/ pharmacokinetics, target animal tolerance or resistance are provided.

IV.B Clinical Studies

Since this is an generic application according to Article 13(1) of Directive 2001/28/EC as amended, and bioequivalence is ensured (Guideline for the Conduct of Bioequivalence Studies for Veterinary Medicinal Products (EMEA/CVMP/016/00-Rev. 2, exemption 7.1 d), no data on clinical efficacy are required.

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.

<None>