Institute for State Control of Veterinary Biologicals and Medicines
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(Reference Member State - CZ)

MUTUAL RECOGNITION PROCEDURE – REPEAT USE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Dexashot 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats

MODULE 1

PRODUCT SUMMARY

EU Procedure number	CZ/V/0132/001/E/001
Name, strength and pharmaceutical form	Dexashot 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats
Applicant	Vet-Agro Multi-Trade Company Sp. z o.o. Gliniana, 32 20-616 Lublin Poland
Active substance(s)	Dexamethasone
ATC Vet code	QH02AB02
Target species	cattle, horses, pigs, dogs and cats
Indication for use	Horses, cattle, pigs, dogs and cats: Treatment of inflammatory or allergic conditions. Cattle: Induction of parturition Treatment of primary ketosis (acetonaemia). Horses: Treatment of arthritis, bursitis or tenosynovitis

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic application in accordance with Article 13.1. of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	28.04.2016
Date product first authorised in the Reference Member State (MRP only)	Not applicable
Concerned Member States for original procedure	AT, BE, BG, EL, ES, NL, PL, PT, RO
Concerned Member States for repeat use procedure	FR, IE

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.
It has been shown that the product can be safely used in the target species; the slight reactions observed are indicated in the SPC.
The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The efficacy of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The product contains 2 mg of dexamethasone as dexamethasone sodium phosphate per ml and the excipients benzyl alcohol, sodium chloride, sodium citrate, sodium hydroxide, citric acid (monohydrate) and water for injections.

The container/closure system consists of 100 ml amber co-ex plastic (PP) vials closed with bromobutyl rubber stoppers and aluminium caps. Vials are individually packed in cardboard boxes.

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.

The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post-authorisation.

C. Control of Starting Materials

The active substance is dexamethasone sodium phosphate, an established active substance described in the European Pharmacopoeia. 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, if an additional parameter is added to the specification post-authorisation via a variation as committed during the authorization procedure. Batch analytical data demonstrating compliance with this specification have been provided.

Certificate of suitability issued by the EDQM 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, if an additional parameter is added to the specification post-authorisation via a variation as committed during the authorization procedure.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from the proposed production site 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.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, results of toxicological, pharmacological, safety of residues tests are not required.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users / the environment / consumers.

III.A Safety Testing

User Safety

The applicant has provided a user safety assessment in compliance with the relevant guideline. 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 assessment can stop at question no. 3 of the decision tree for dogs and cats (non-food animals) and for cattle, pigs and horses the assessment can stop at question no. 5 of the decision tree as the veterinary medicinal product will be used to treat a small number of animals in a flock or herd.

The product is not expected to pose an unacceptable risk for the environment when used according to the SPC.

III.B Residues documentation

Residue Studies

The applicant has submitted a generic application for the product Dexashot in accordance with Article 13(1) of Directive 2001/82/EC as amended. No residue depletion studies were conducted because the origin of the application was submitted as generic and bioequivalence between the generic product and the reference product was established.

MRLs

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

Pharmacologically active substance	**Marker residue**	**Animal species**	**MRLs**	**Target tissues**	**Other provisions**	**Therapeutic classification**
Dexamethasone	Dexamethasone	Bovine, caprine, porcine, *Equidae*	0.75 µg/kg 2 µg/kg 0.75 µg/kg	muscle liver kidney	NO ENTRY	Corticoides/ Glucocorticoides

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification
		Bovine, caprine	0.3 µg/kg	milk		

Withdrawal Periods

Based on the data provided above, the following the withdrawal periods were established:

Cattle:
Meat and offal: 8 days
Milk: 72 hours
Pigs:
Meat and offal: 2 days
Horses:
Meat and offal: 8 days
Not authorised for use in horses producing milk for human consumption.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

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 Medicines 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**
CZ/V/0132/001/IB/001 – C.I.2a – change of SPC, labelling and package leaflet to harmonise the product information with the reference VMP.	III, IV	28/08/2018
CZ/V/0132/001/II/002 – C.I.z – change of SPC, labelling and package leaflet after repeat use procedure	Only changes in Module 2	06/08/2019