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

Felidale 5 mg Coated Tablets for Cats

Date: 30 July 2018

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0308/002/DC
Name, strength and pharmaceutical form	Felidale 5 mg Coated Tablets for Cats
Applicant	Dechra Limited Snaygill Industrial Estate, Keighley Road BD23 2RW Skipton, North Yorkshire United Kingdom
Active substance(s)	Thiamazole
ATC Vetcode	QH03BB02
Target species	Cats
Indication for use	For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy. For the long-term treatment of feline hyperthyroidism.

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 (c) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	22nd February 2012
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	United Kingdom (former RMS)

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product is/are identical to the original product. The initial application for Felimazole 2.5 mg Coated Tablets for Cats was assessed in UK before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. 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 benefit/risk 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.

•	30 July 2018	Change in RMS from UK to DE.
•	02 February 2018	Change in immediate packaging of the finished product
•	09 August 2017	Addition of a site where batch control/testing takes place
•	14 June 2017	Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer
•	31 March 2017	Renewal – UK as RMS.
•	17 September 2015	Change of MAH address.
•	16 August 2012	Variation for the replacement of a colourant; change in composition of ingredients used for the tablet coating process; increase in batch size of finished product.