Post Authorisation Assessments

AMOXICILLIN GLOBAL VET HEALTH 500 mg/g, Powder for Use in Drinking Water for Chickens, Turkeys, Ducks and Pigs

Vm 36167/4004

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•	05 January 2023	Updated certificate of suitability from an already approved manufacturer.
		Updated certificate of suitability from an already
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	10.1	approved manufacturer.
•	19 August 2022	Updated certificate of suitability from an already
		approved manufacturer.
		Updated certificate of suitability from an already
		approved manufacturer.
•	08 March 2022	Deletion of a non-significant specification parameter of
		the finished product.
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		the finished product.
•	11 January 2022	Increase in batch size (including batch size range*) of the
		finished product.
•	18 January 2021	Change in distributor details. From VETSONIC (UK) Ltd,
		Unit 1 riccal Drive, York Road Business Park, Malton,
		North Yorkshire, Y017 6YE to DUGV (UK) Ltd., Union
		House, 111 New Union Street, Coventry, CV1 2NT,
		United Kingdom.
•	15 December 2020	Renewal – UK as CMS.
•	04 June 2020	Deletion of a manufacturing site for an active substance.
		Submission of an updated Ph. Eur. certificate of
		suitability for an active substance from an already
		approved manufacturer.
•	26 June 2019	Change in the SPC, labelling or package leaflet due to
		new data.
•	01 February 2019	Change in the fill weight of the finished product.
		Increase in the shelf-life of the finished product after first
		opening, from use immediately to 7 days.
		Change in the Summary of Product Characteristics
		intended to implement the outcome of a Union referral
		procedure.
•	03 August 2018	Repeat Use application to add 4 new member states
	10 May 2017	Submission of a new Ph. Eur. certificate of suitability for
•	10 Way 2011	an active substance from a new manufacturer.
	22 Fohruary 2017	
•	23 February 2017	Submission of a new certificate of suitability.