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Post Authorisation Assessments

Multishield DC Intramammary Suspension for Cows Vm 50146/4005

	4 4 6 6 6 6	
•	August 2022	Change of distributor from Cross Vetpharm Group (UK) Ltd, Unit 2 Bryn Cefni, Llangefni, LL77 7XA, United Kingdom to DUGV (UK) Ltd, Union House, 111
		New Union Street, Coventry, CV1 2NT, United Kingdom.
•	25 May 2021	Change in the QPPV of an existing pharmacovigilance
		system as described in the DDPS.
•	23 September 2020	Submission of an updated Ph. Eur. certificate of
	22 January 2020	suitability for an active substance manufacturer. Changes to the date of the audit to verify GMP
•	22 January 2020	compliance of the manufacturer of the active substance.
		Changes to the date of the audit to verify GMP
		compliance of the manufacturer of the active substance.
•	2 September 2019	Change in the name only of control testing site.
		Change in the name and address of a manufacturer of
		the finished product, also responsible for batch release.
		Change of the back-up procedure of the QPPV of an
		existing pharmacovigilance system as described in the DDPS.
•	14 January 2019	Increase in batch size (1200kg) of the finished product.
•	18 October 2018	Change of MAH, from Cross Vetpharm Group Ltd.,
		Broomhill Road, Tallaght, Dublin 24, Ireland to Bimeda
		Animal Health Limited, 2 / 3 / 4 Airton Close, Tallaght,
	05 A m mil 0040	Dublin 24, Ireland.
•	05 April 2018	Renewal - UK as CMS
•	01 March 2017	Minor changes to an approved test procedure of the finished product.
		Minor changes to an approved test procedure of the
		finished product.
		Minor changes to an approved test procedure of the
		finished product.
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		finished product.
		Minor changes to an approved test procedure of the finished product.
_	04 December 2015	Addition of a new site of manufacutuer for the finished
	5 . D555111101 2010	product, and as a consequence a new site of batch
		release and secondary packaging
		Addition of a new PHEur method.
		Submission of an updated Certificate of suitability.
•	22 July 2015	Change in the specification limits of the finished product.
•	16 January 2015	Minor change in test procedure for the finished product.

•	30 January 2014	Submission of an updated Ph. Eur certificate of
		suitability.
		Change in the name of a manufacturing site.
		Changes to the specification parameters of a starting
		material.
•	24 January 2014	Change to the specification parameters of the finished
		product.
•	16 December 2013	Change in invented name of the product in Czech
		Republic, Hungary and Slovakia only.