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Post Authorisation Assessments

For details of post authorisation assessments prior to 1st January 2021, please refer to the <u>EMA</u> website.

Advocate 250 mg + 62.5 mg Spot-on Solution for Large Dogs Vm 04895/5002

•	11 May 2024	Submission of an updated Ph. Eur. CEP from an already
		approved manufacturer for a non-sterile active substance.
•	18 August 2023	Change in the address of the MAH from Bayer Animal Health
	_	GmbH, 51368 Leverkusen, Germany to Elanco Animal Health
		GmbH, Alfred- Nobel- Str 50, 40789 Monheim, Germany.
•	21 February 2023	Change in the re-test period of an active substance.
•	23 June 2022	Addition of a new therapeutic indication.
•	14 January 2022	Changes in the SPC and product literature intended to
	-	implement the outcome of a procedure concerning a PSUR.
•	24 March 2021	Change in the address of a manufacture of the active
		substance.