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Post Authorisation Assessments

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

Cytopoint 20 mg/ml Solution for Injection for Dogs Vm 42058/5018

•	08 December 2023	Update to the GB national SPC QRD template.
•	19 January 2023	Addition of a secondary packaging site.
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•	05 December 2022	Introduction of an alternative bioreactor for use during seed
		scale-up of the drug substance production process.
•	31 May 2022	Renewal.
•	14 January 2022	Replacement of a test procedure for the active substance.
	-	Replacement of a test procedure for the active substance.
		Replacement of a test procedure for the finished product.
•	22 September 2021	Minor change in the manufacturing process of the active
		substance.
•	27 August 2021	Change(s) in the SPC, Labelling or Package Leaflet products
		intended to implement the outcome of a procedure concerning
		PSUR
•	26 February 2021	Grouped variation for the deletion of a specification
		parameter used in the manufacturing process of the
		active substance and minor change in the manufacturing
		process of the active substance
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