VPA10774/054/003

Selehold 120 mg spot-on solution for dogs 10.1–20.0 kg

Variation	Summary	Date
Vet - G.I.18	VRA-S - Vet - G.I.18 - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 - G.I.18 Safety, Efficacy, Pharmacovigilance changes - One-off alignment of the product information with version 9.0 (or the latest version of the QRD templates that are in effect at the time that this one-off variation is submitted) of the QRD templates i.e. major update of the QRD templates in accordance with Regulation (EU) 2019/6, for veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004	15/09/23
Vet - B12 c)	VNRA - Vet - B12 c) - c) Minor changes to an approved test procedure for an in-process test - B12 c) Changes to the quality part of the dossier: Minor changes — to an approved test procedure for an in-process test — for active substance; — for the finished product	24/03/23
Vet - B47 d)	VNRA - Vet - B47 d) - d) To reflect compliance with the Ph. Eur. by removing reference to the internal test method and test method number - B47d) Changes to the quality part of the dossier: Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State: — to reflect compliance with the Ph. Eur. by removing reference to the internal test method and test method number	02/03/23
Vet - B4 a)	VNRA - Vet - B4 a) - a) Change in the manufacturer of the active substance (including relevant quality control testing sites) - B4 a) Changes to the quality part of the dossier: Changes to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved dossier of an active substance (including starting material, reagent or intermediate) - change in the manufacturer of the active substance (including relevant quality control testing sites)	02/03/23
Vet - F.I.d.1 c)	VRA-R - Vet - F.I.d.1 c) - c) Extension or introduction of a re-test period/storage period supported by real time data - F.I.d.1 c) Quality Changes - Active Substance - Stability -Change in the re-test period/storage period of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - Extension or introduction of a re-test period/storage period supported by real time data	08/08/22
B.II.b.5.z	IA - B.II.b.5.z - z Other variation - B.II.b.5.z - QUALITY CHANGES - FINISHED PRODUCT - Manufacture - Change to	28/02/22

	in-process tests or limits applied during the manufacture of the finished product - Other variation	
B.II.d.2.a	IA - B.II.d.2.a - a) Minor changes to an approved test procedure - B.II.d.2.a - QUALITY CHANGES - FINISHED PRODUCT - Control of finished product - Change in test procedure for the finished product - Minor changes to an approved test procedure	28/02/22