

VPA22020/048/001

Advantix Spot-on solution for dogs up to 4 kg

Variation	Summary	Date
Vet - C9	VNRA - Vet - C9 - - Vet - C9 - Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible	20/07/26
Vet - G.I.Z	VRA-S - Vet - G.I.Z - Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure - Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6 . Other changes under this code level, e.g. variations outlined in section 6 and 7 of this guidance	08/05/25
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	08/05/25
Vet - C1	VNRA - Vet - C1 - Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV) - C1 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)	14/10/24
Vet - C6	VNRA - Vet - C6 - Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17 - C6 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in the Annex to Regulation (EU) 2021/17	14/10/24
Vet - B3 f)	VNRA - Vet - B3 f) - f) Deletion of one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form - B3 f) Changes to the quality part of the dossier: Deletion of one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form	01/10/24

Vet - C2	VNRA - Vet - C2 - Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6 - C2 Changes to the safety, efficacy and pharmacovigilance part of the dossier: Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6	19/09/23
B.I.b.2.a	IA - B.I.b.2.a - a) Minor changes to an approved test procedure - B.I.b.2.a - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in test procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure	30/06/22
B.I.b.1.z	IB - B.I.b.1.z - z Other variation - B.I.b.1.z - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Other variation	30/06/22
B.I.b.1.d	IA - B.I.b.1.d - d) Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - B.I.b.1.d - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	30/06/22
B.I.b.1.c	IA - B.I.b.1.c - c) Addition of a new specification parameter to the specification with its corresponding test method - B.I.b.1.c - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition of a new specification parameter to the specification with its corresponding test method	30/06/22
B.I.b.1.b	IA - B.I.b.1.b - b) Tightening of specification limits - B.I.b.1.b - QUALITY CHANGES - ACTIVE SUBSTANCE - Control of active substance - Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Tightening of specification limits	30/06/22
B.I.a.2.e	IB - B.I.a.2.e - e) Minor change to the restricted part of an Active Substance Master File - B.I.a.2.e - QUALITY CHANGES - ACTIVE SUBSTANCE - Manufacture - Changes in the manufacturing process of the active substance - Minor change to the restricted part of an Active Substance Master File	30/06/22
A.7	IA - A.7 - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control	30/06/22

	takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - A.7 - ADMINISTRATIVE CHANGES - Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)*	
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