Galliprant

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued / amended on	Product Information affected[2]	Summary[3]
IB/0015	C.I.3.z - Change(s) in the SPC, Labelling or PL of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR: implementation of wording agreed by the competent authority that does not require additional assessment	13/08/2021		SPC, Labelling and PL	The Agency accepted the variation to update section 4.6 of the SPC and section 6 of the package leaflet following assessment of a PSUR.
IA/0016	B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	28/07/2021	n/a		n/a

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).
[3] Since October 2019 summary information is no longer published for variations that do not impact upon the product information

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II/0014/G	This was an application for a group of variations. B.II.b.5.e - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	10/12/2020	n/a		B.II.b.5.e - To widen the approved finished product IPC limits for hardness and thickness. B.II.b.5.a - To update the finished product IPC limits for weight range. B.II.b.3.a - To update the currently approved manufacturing process by removing non-relevant detail on compression parameters, pre-compression and compression force targets. In addition, the MAH has taken the opportunity to introduce editorial changes in the document related to part II.B finished product.
IAIN/0013/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	11/08/2020	n/a		n/a
IB/0012/G	This was an application for a group of variations. B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.f.1.e - Stability of FP - Change to an approved stability protocol	26/06/2020	n/a		n/a
IAIN/0011	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	27/05/2020	29/03/2021	SPC and PL	The Agency accepted the variation to implement changes to section 4.6 of SPC and corresponding section 6 of the package leaflet following assessment of a PSUR.
IA/0010/G	This was an application for a group of variations. B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	01/04/2020	29/03/2021	SPC and Labelling	The Agency accepted the grouped variation to change the primary packaging of finished product. In addition, minor editorial changes have been introduced to the SPC.

IB/0009/G	This was an application for a group of variations. B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test	14/02/2020	n/a		n/a
IB/0008/G	This was an application for a group of variations. B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation B.II.f.1.e - Stability of FP - Change to an approved stability protocol	31/01/2020	n/a		n/a
IAIN/0007	B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings	10/04/2019	17/12/2019	SPC, Labelling and PL	The Agency accepted this variation to change the appearance of the 100 mg strength of Galliprant tablets for dogs with the removal of the score line. As the approved dosing schedule does not include half tablets of the 100 mg strength, the score lines are considered as 'other markings'. Reference to the 90 tablet package is editorially removed, as that package size was not approved. The MAH has taken the opportunity to include minor editorial changes to the product information.

IA/0006/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	27/03/2019	n/a		The Agency accepted this variation to implement a number of changes to the manufacturing process following Elanco Animal Health taking responsibility for the active substance in 2017. The MAH proposes to change the description and process flow diagram to more accurately reflect the manufacturing process. Editorial changes are also proposed.
IAIN/0005/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	20/12/2018	17/12/2019	Annex II and PL	The Agency accepted a group variation to update the manufacturers responsible for the quality control testing of the active substance and finished product, as well as for importation and batch release of the finished product.

IG/1041/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations, and/or change of the site undergoing PhV activities C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	18/12/2018	n/a		n/a
II/0001	B.II.b.1.d - Replacement or addition of a manufacturing site for the FP - Site which requires an initial or product specific inspection	06/12/2018	n/a		To add a manufacturing site responsible for primary packaging, secondary packaging and quality control testing of the finished product, and consequential changes.
IB/0003	C.II.7.b - Introduction of a new Pharmacovigilance system - Which has been assessed by the relevant national competent authority/EMA for another product of the same MAH	27/07/2018	n/a		The Agency accepted the variation to introduce a new detailed description for pharmacovigilance (DDPS).
T/0002	Transfer of Marketing Authorisation	30/04/2018	25/05/2018	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Aratana Therapeutics NV' to 'Elanco GmbH'.