Credelio

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/0014	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	17/04/2020		SPC and PL	The Agency accepted the variation to update SPC section 4.6 Adverse reactions and corresponding section 6 of the package leaflet for Credelio dog and cat following assessment of a PSUR.
IB/0013	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	04/03/2020		SPC	The Agency accepted the variation to extend the shelf-life of the finished product as packaged for sale from 24 months to 36 months for the chewable tablets for dogs 900mg presentations.
IB/0011/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	09/10/2019	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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	Replacement/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				
IA/0012/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	01/10/2019	n/a		n/a
IA/0010	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	26/07/2019	n/a		n/a
IB/0009/G	This was an application for a group of variations. B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) 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	17/04/2019		SPC and PL	The Agency accepted the variation to amend the section of the SPC and package leaflet on adverse events, as well as to extend the shelf-life of the finished product from 24 months to 36 months.
IB/0008	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	26/03/2019	n/a		The Agency accepted the variation to update the parameters of the active substance specification following the addition of an alternative manufacturing site.
IB/0006/G	This was an application for a group of variations. B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer 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.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation 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.3.a - Change in batch size (including batch size	01/02/2019	n/a		The Agency accepted the group of variations to: add an additional manufacturing site for the active substance; to add a supplier of a starting material; to introduce a minor change to the manufacturing process of the active substance; to increase the batch size of the active substance and to add a batch control/testing site.

	ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size				
IA/0007	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	11/01/2019	n/a		The Agency accepted the variation to change the name of the manufacturer for an intermediate active substance.
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
T/0004	Transfer of Marketing Authorisation	28/08/2018	27/09/2018	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Elanco Europe Ltd' to 'Elanco GmbH'.
IA/0003	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	17/08/2018	n/a		The Agency accepted the variation to add an alternative batch size.
X/0001	Annex I_2.(c) Change or addition of a new strength/potency	19/04/2018	09/07/2018	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new target species (cat) with lower-strength tablets.
IA/0002	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	01/12/2017	n/a		The Agency accepted the variation to change the name of a raw material supplier used in the manufacture of the API.