Clynav

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]
II/0010	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	18/02/2020	27/03/2020	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to extend the duration of immunity from 3 months after vaccination to 12 months after vaccination.
IB/0009	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	14/06/2019	n/a		The Agency accepted the variation to amend the test procedure for the finished product.
IB/0008	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	14/06/2019	n/a		The Agency accepted the variation to increase the batch size of the finished product.
II/0007	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	22/05/2019	n/a		The Agency accepted the variation to change the residual gDNA finished product control test specification from 14.8 - 59.8 µg / ml to 8.4 - 90.3 µg / ml.
II/0004/G	This was an application for a group of variations. B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP -	21/03/2019	n/a		The Agency accepted the group of variations to replace the current quality control testing sites by new testing sites within the European union, initiated by the upcoming withdrawal of the United Kingdom from the European

[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 for a biol/immunol product and any of the test methods at the site is a biol/immunol method B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method				Union.
IA/0006	A.7 - Administrative change - Deletion of manufacturing sites	26/02/2019	23/10/2019	Annex II and PL	The Agency accepted the variation to delete a manufacturing site for importation, testing and batch release.
IB/0005	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	15/02/2019	n/a		The Agency accepted the variation to introduce the Elanco Animal Health DDPS (version October 2018).
IAIN/0003	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	31/10/2018	23/10/2019	Annex II and PL	The Agency accepted the variation to add a batch release site.
T/0002	Transfer of Marketing Authorisation	27/07/2018	20/08/2018	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Elanco Europe Ltd' to 'Elanco GmbH'.
II/0001/G	This was an application for a group of variations. B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised	25/05/2018	n/a		The Agency accepted the group of variations to introduce a change in the manufacturing process of the active substance and to delete three redundant control test procedures for the finished product.