Cortavance

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/0015	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	18/03/2021	20/04/2021	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add a new therapeutic indication: "for alleviation of clinical signs associated with atopic dermatitis in dogs". In addition, the applicant takes the opportunity to update the list of local representatives.
IA/0014/G	This was an application for a group of variations. B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	01/07/2019	n/a		The agency accepted the group of variations to delete an obsolete parameter from the specifications of an excipient and finished product.
IG/0808	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	29/05/2019	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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IG/0984	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	26/10/2018	13/05/2019	PL	The Agency accepted the variation to update the local representatives in the package leaflet.
IB/0011/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.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data B.I.d.1.b.1 - Stability of AS - Change in the storage conditions - Change to more restrictive storage conditions of the AS	06/09/2018	n/a		The Agency accepted the group of variations related to the update of the restricted and applicant's open parts of an ASMF.
IB/0010/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms B.II.e.1.b.1 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Solid, semi-solid and non-sterile liquid pharmaceutical forms	08/05/2018	13/05/2019	SPC, Labelling and PL	The Agency accepted the group of variations to add two new presentations: one HDPE container for each volume for the finished product, to update the manufacturer's technical drawings of the 75 and 30 ml PET bottle and its corresponding mechanical pump, to add an alternative analytical procedure for the assay of hydrocortisone aceponate in the finished product and to update the product information in line with the latest version of the QRD template version 8.1.
IA/0009	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	17/11/2017	n/a		The Agency accepted the variation to make minor changes to an approved test procedure for the finished product.
IG/0724	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	21/12/2016	09/01/2018	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
WS/0925	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF	10/11/2016	n/a		The Agency accepted the variation to add a manufacturer for the active substance hydrocortisone aceponate, supported by an ASMF.
IB/0006	B.II.e.5.d - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use)	16/08/2013	26/08/2014	SPC, Labelling and PL	The Agency accepted the variation to add a 31 ml white opaque PET bottle which is more adapted to small dogs.

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II/0005	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	11/10/2012	n/a		The Agency accepted the variation to increase the specifications of the known impurity cortisone aceponate (impurity E) at the end of shelf life and, consequently, increase the end of shelf life specification of the total impurities.
IA/0004/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	20/01/2012	n/a		The Agency accepted the group of variations to add minor changes to an approved test procedure
R/0003	Renewal of the marketing authorisation.	14/07/2011	13/09/2011	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for CORTAVANCE.
II/0002	C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	19/05/2010	02/07/2010	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to amend section 4.5 of the SPC and relevant parts of package leaflet.
IA/0001	1A-28 Change in any part of the (primary) packaging material not in contact with finished product	09/02/2007	07/09/2007	SPC	The Agency accepted the variation to add a 20 mm white plastic screw cap equipped with a triseal joint.