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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]
IAIN/0006/G	This was an application for a group of variations. 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 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 A.7 - Administrative change - Deletion of manufacturing sites	18/12/2020		Annex II, Labelling and PL	The Agency accepted the group of variations to amend the sites responsible for manufacture of the active subtance and batch release. The Agency also accepted the request for provision of information via QR code on the bait label.

[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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WS/1887	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	05/11/2020	n/a		n/a
T/0003	Transfer of Marketing Authorisation	12/06/2020	20/07/2020	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'IDT Biologika GmbH' to 'Ceva Santé Animale'.
II/0002	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	23/01/2020	04/03/2020	SPC and PL	The European Commission amended the decision granting the marketing authorisation to extend the duration of immunity from 6 to 12 months.
IB/0001	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	21/09/2018	n/a		n/a