EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

RevitaCAM

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
T/0006	Transfer of Marketing Authorisation	18/09/2015	05/10/2015	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to transfer the marketing authorisation from 'Abbott Laboratories Limited' to 'Zoetis Belgium SA.
IG/0419	C.I.9.d - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	17/04/2014	n/a		The Agency accepted the variation on the changes to DDPS.
IB/0004	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) products	05/12/2013	12/03/2014	SPC, Labelling and PL	The Agency accepted a variation to introduce a small fill product version of each of the three current authorisations in order to enable the utilisation of the product by veterinarians for short / acute use or for trial before prescribing the full sized products.
IB/0003	B.II.d.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	05/04/2013	12/03/2014	SPC and PL	The Agency accepted a variation to increase the shelf life of 5 mg/ml oromucosal spray for dogs from 24 months to 30 months. A change of address for a local representative for

[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] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

					the Netherlands was also made.
IA/0002	B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place	15/02/2013	n/a		The Agency accepted a variation to change the name of a testing site
IB/0001	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	26/09/2012	29/10/2012	PL	The Agency accepted a variation to amend the local representatives in the package leaflet.