EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Flexicam

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2]/ amended on	Product Information affected[3]	Summary
IAIN/0013	C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV	15/07/2011	15/07/2011		The European Medicines Agency approved a Type IA_{IN} variation to change the contact details of the Qualified Person for Pharmacovigilance
IB/0012	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the summary of product characteristics	08/07/2011	08/07/2011	PL	The European Medicines Agency accepted a Type IB variation to delete local representative from the package leaflet
IA/0010	B.III.2.c - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur.	24/06/2011	24/06/2011		The European Medicines Agency accepted a Type IA variation to update the specification for the active ingredient to comply with the current edition of the European Pharmacopoeia
IAIN/0011	B.III.1.a.1 - Submission of a new or updated Ph.Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an	24/06/2011	24/06/2011		The European Medicines Agency accepted a Type IA_{IN} variation to introduce a new certificate of suitability

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	already approved manufacturer				
R/0009	Renewal	12/01/2011	10/03/2011	SPC, Labelling, PL	The European Commission renewed the marketing authorisation.
ART45/0008	Article 45 Referral	14/07/2010	27/09/2010		The European Commission suspended the marketing authorisation for Flexicam 1.5 mg/ml oral suspension for dogs. This decision was based on a referral procedure pursuant to Article 45 of Regulation (EC) No 726/2004, when the European Commission requested on 21 June 2010, in the interests of animal health, the opinion of the CVMP on the measures necessary to ensure the quality of the above mentioned veterinary medicinal product further to the CVMP review of the out of specification results further to the 2009 Sampling and Testing Programme and subsequent batch recall and a stop on sales.
IA/0007	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	23/02/2010	10/06/2010	SPC, Labelling, PL	The European Medicines Agency accepted a type IA variation for a change to batch release and quality control arrangements for the finished product.
IB/0006	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	18/03/2010	10/06/2010	SPC	The European Medicines Agency accepted a type IB variation to increase in shelf life of finished product, as packaged for sale, to 3 years.
T/0004	Transfer of Marketing Authorisation	03/12/2009	21/12/2009	SPC, Labelling, PL	The European Commission approved a transfer of the marketing authorisationfrom "Omnipharm" to "Dechra Veterinary Products A/S".
X/0001	X-3-IV Change or addition of a new pharmaceutical form	15/10/2008	09/12/2008	SPC, Labelling, PL	The European Commission granted an extension to the marketing authorisation for Flexicam to add a new strength (5 mg/ml) and form of administration (solution for injection) and to add cats as a new target species.