Metacam

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]
IG/1466/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	07/01/2022		Annex II and PL	The Agency accepted the group of variations to delete four manufacturing sites.
IA/0146	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	16/12/2021	n/a		n/a
IB/0144	B.II.z - Quality change - Finished product - Other variation	28/05/2021	n/a		n/a
IA/0145	B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	03/05/2021	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/1350	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	05/03/2021	n/a		n/a
IG/1337	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	10/02/2021	n/a		n/a
IA/0141	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	16/12/2020	n/a		n/a
IG/1314/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.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	08/12/2020	n/a		n/a
IA/0140	A.7 - Administrative change - Deletion of manufacturing sites	02/12/2020	n/a		n/a
IA/0138	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	05/10/2020	n/a		n/a
WS/1813	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	20/05/2020	04/05/2021	SPC and PL	The Agency accepted the variation to update section 4.5 of the SPC and section 12 of the package leaflet following assessment of a PSUR.
IA/0136	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	20/03/2020	n/a		n/a
IB/0135	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	20/11/2019	n/a		n/a
IG/1128/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	17/07/2019	n/a		n/a

IG/1031/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure 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 C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	14/12/2018	n/a		n/a
IB/0132/G	This was an application for a group of variations. B.IV.1.a.2 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device without CE marking for veterinary products only B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information B.IV.2.f - Change in specification parameters and/or limits of a measuring or administration device for veterinary medicinal products - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	07/12/2018	n/a		n/a
II/0127	C.II.1 - Variations concerning a change to or addition of a non-food producing target species	15/02/2018	19/03/2018	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to register an additional non-food producing target species, the guinea pig, for treatment with Metacam 0.5 mg/ml oral suspension.
IB/0131	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	12/01/2018	19/03/2018	SPC and PL	The Agency accepted the variation to extend the shelf-life of the finished product as packaged for sale from 24 months to 36 months.
IG/0831	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	01/09/2017	25/09/2017	PL	The Agency accepted the variation to delete the list of local representatives from the package leaflet.
IG/0813/G	This was an application for a group of variations. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release	13/07/2017	n/a		The Agency accepted the group of variations to register two additional testing sites for the finished product for the conducting of physical/chemical tests and the conducting of sterility tests.

	arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
IB/0128	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	17/03/2017	25/09/2017	SPC and PL	The Agency accepted the variation to update the SPC following the assessment of a PSUR.
IB/0126/G	This was an application for a group of variations. B.II.b.3.f - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process of an aqueous oral suspension B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	19/01/2017	n/a		The Agency accepted the group of variations for a change to the manufacturing process and deletion of a test method.
II/0123/G	This was an application for a group of variations. B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	10/11/2016	n/a		The Agency accepted the variation to introduce a change outside the approved specifications limits range and to delete the test parameter.
IB/0124	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	05/10/2016	n/a		The Agency accepted the variation for a change to a testing procedure for the finished product.
IG/0722	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	27/09/2016	25/09/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
X/0119	Annex I_2.(e) Change or addition of a new route of administration	16/06/2016	12/08/2016	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new route of administration (subcutaneous use) for the 40 mg/ml solution for injection for cattle.
IA/0122	A.7 - Administrative change - Deletion of manufacturing sites	18/07/2016	n/a		The Agency accepted the variation to delete a site responsible for manufacturing the active substance for Metacam 40 mg/ml solution for injection (EU/2/97/004/050-053).
IA/0121	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	18/07/2016	n/a		The Agency accepted the variation to add a minor change to the test procedure for the finished product.
IB/0120	B.IV.1.a.2 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device without CE marking for veterinary products only	17/06/2016	n/a		The Agency accepted the variation to replace the 24 ml measuring syringe with a 30 ml measuring syringe.
II/0118/G	This was an application for a group of variations. B.II.d.1.e - Change in the specification parameters	21/04/2016	n/a		The Agency accepted the variation to amend the testing specification of the finished product.

	and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
IB/0117	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	08/07/2015	21/06/2016	SPC and PL	The Agency accepted the variation to delete a precautionary statement for cats from the SPC (section 4.5) and the package leaflet (section 12).
IB/0116	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	03/06/2015	n/a		The Agency accepted the variation to register a new manufacturer of the active substance for the Metacam 40 mg/ml solution for injection for cattle and horses.
IB/0115/G	This was an application for a group of variations. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	03/06/2015	21/06/2016	Annex II and PL	The Agency accepted the variation to replace manufacturing site of finished product and batch release and to make consequential changes to the manufacturing process, in-process tests, batch size and packaging of the finished product.
X/0107	Annex I_2.(c) Change or addition of a new strength/potency	12/02/2015	09/04/2015	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include a new strength, 40 mg/ml solution for injection for cattle and horses.
IB/0114/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	18/02/2015	n/a		The Agency accepted the variation to register additional manufacturing sites and some minor changes to the manufacturing process.

WS/0667	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	12/02/2015	n/a		The Agency accepted the variation on the introduction of some minor changes of the manufacturing process at the new manufacturer.
WS/0661/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place 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.7 - Administrative change - Deletion of manufacturing sites B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	15/01/2015	09/04/2015	Annex II and PL	The Agency accepted the variation to register new manufacturing sites for bulk manufacturing, primary packaging, labelling and secondary packaging, final batch release and additional secondary packaging site. The company would also like to delete final batch release site. At the new manufacturing site, some minor changes related to in process controls, have been implemented compared to the specification of the current site.
IAIN/0111/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging	26/09/2014	n/a		The Agency accepted the variation to change the name of the manufacturing site responsible for EU batch testing and to register a new manufacturing site for additional secondary packaging and labelling for the Metacam® 1 mg and 2.5 mg chewable tablets.

	site				
IB/0110	B.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	06/08/2014	n/a		The Agency accepted the variation to delete one of the parameter from the specifications for release and shelf life.
II/0108/G	This was an application for a group of variations. B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	08/05/2014	n/a		The Agency accepted the variation to adapt the currently approved finished product release and shelf life specification limits for test parameter "active ingredient degradation", to delete the test parameter "odour" and to include a second identity test for the active substance meloxicam.
IB/0109	B.IV.1.a.2 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device without CE marking for veterinary products only	11/04/2014	06/06/2014	SPC	The Agency accepted the variation to register an alternative measuring syringe to the already registered measuring syringe for Metacam 15 mg/ml oral suspension for horses.
WS/0473/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method 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.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	12/12/2013	n/a		The Agency accepted the variation to introduce a new specification parameter, to replace the current registered analytical method with a new method and to remove an obsolete test parameter in the 5 mg/ml presentations.
WS/0447/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	12/12/2013	n/a		The Agency accepted the variation to introduce a new specification parameter and to replace the current registered analytical method for the identity and assay test for ethanol with a new method for the 20 mg/ml presentations.
IG/0380	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	05/12/2013	n/a		The Agency accepted the variation to harmonise the Detailed Description of the Pharmacovigilance System (DDPS).

	MAH				
IB/0103	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	14/06/2013	06/06/2014	SPC	The Agency accepted the variation to extend the shelf life of the finished product as packed for sale from 30 months to 3 years for the 1.0 mg and 2.5 mg chewable tablets for dogs.
WS/0264	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	08/11/2012	10/12/2012	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on the addition of a new therapeutic indication ("dehorning claim") to the product information due to new clinical data.
IAIN/0101	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/10/2012	n/a		The Agency accepted the variation to add a secondary packaging site for all Metacam oral suspensions.
IA/0099	A.7 - Administrative change - Deletion of manufacturing sites	22/06/2012	n/a		The Agency accepted the variation to delete two manufacturing sites for packaging and labelling
IAIN/0098	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	08/06/2012	n/a		The Agency accepted the variation to add a secondary packaging site for all Metacam chewable tablets for dogs.
IAIN/0095	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	02/03/2012	n/a		The Agency accepted the variation to add a secondary packaging site for all Metacam chewable tablets for dogs.
IA/0094/G	This was an application for a group of variations. 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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	12/01/2012	n/a		The Agency accepted the variations to add a batch control testing site and minor changes in finished product testing specifications for all Metacam chewable tablets for dogs.
IA/0093	B.IV.3.b - Change in test procedure of a measuring or administration device for veterinary medicinal products - Other changes to a test procedure (including replacement or addition)	22/12/2011	n/a		The Agency accepted the variation to change the material identification method.
IB/0092	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	12/10/2011	12/10/2011	SPC	The Agency accepted the variation to extend the shelf-life of the finished product, packed into 250 ml colourless glass vials from currently 24 months to proposed 36 months, in order to harmonise the shelf-life with the other registered presentations of the veterinary medicinal product.
IB/0091	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	25/08/2011	25/08/2011	SPC, Labelling and PL	The Agency accepted the variation to add a 30ml fill volume presentation in addition to currently approved presentations for Metacam 0.5 mg/ml oral suspension for cats.
IB/0090	C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a	08/07/2011	08/07/2011	SPC and PL	The Agency accepted the variation to include additional adverse reactions in section 4.6 of the SPC and other minor

	PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH				changes in the product information for Metacam 0.5 mg/ml and 1.5 mg/ml oral suspension for dogs, 0.5 mg/ml oral suspension for cats, 15 mg/ml oral suspension for horses, 2 mg/ml solution for injection for cats, 5 mg/ml solution for injection for dogs and cats, for cattle and pigs, 20 mg/ml solution for injection for cattle, pigs and horses, 1 mg and 2.5 mg chewable tablets for dogs.
IB/0089	B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation	06/04/2011	23/06/2011	SPC	The Agency accepted the variation to extend the shelf-life of the finished product from 18 months to 30 months for Metacam 1 mg and 2.5 mg chewable tablets for dogs.
IB/0088/G	This was an application for a group of variations. B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data) B.II.c.1.b - Change in the specification parameters and/or limits of an excipient - Addition of a new specification parameter to the specification with its corresponding test method	10/02/2011	23/06/2011	SPC	The Agency accepted the group of variations to extend the shelf life from 18 months to 2 years and to include an additional batch size of 500 kg for Metacam 0.5 mg/ml oral suspension for cats.
IAIN/0087	B.II.b.2.b.1 - Change to batch release arrangements and quality control testing of the FP - Not including batch control/testing	24/11/2010	23/06/2011	Annex II and PL	The Agency accepted the variation for the addition of a manufacturer responsible for batch release.
IB/0086	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	17/11/2010	23/06/2011	SPC	The Agency accepted the variation to extend the shelf-life of the finished product from 18 months to 2 years for Metacam 2 mg/ml solution for injection for cats.
II/0084	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	05/05/2011	23/06/2011	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new therapeutic indication, "alleviation of inflammation and pain in acute and chronic musculo-skeletal disorders in cats" for Metacam 0.5 mg/ml oral suspension for cats.
II/0083/G	This was an application for a group of variations. B.II.a.3.b.5 - Changes in the composition (excipients) of the finished product - Other excipients - Change that is supported by a bioequivalence study B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	10/11/2010	20/12/2010	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to replace the flavouring agent and addition of colouring components; a change in qualitative composition of the immediate packaging and a change to the currently approved pack sizes (from 2, 10 or 50 blisters containing 10 tablets to 1, 12 or 36 blisters containing 7 tablets in cardboard box) of the finished product for Metacam 1 mg and 2.5 mg chewable tablets for dogs.
IAIN/0082	B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale	17/05/2010	20/12/2010	SPC	The Agency accepted the variation to reduce the shelf-life for Metacam 0.5 mg/ml oral suspension for dogs (15 ml and 30 ml presentations) from 60 months to 36 months (3 years).

X/0079	X-4-I Addition or change of target species	14/04/2010	05/07/2010	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add an extension to include 15 mg/ml oral suspension for pigs, representing a new strength and pharmaceutical form for pigs.
X/0074	X-3-III Extension to a new strength	14/04/2010	02/07/2010	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add an extension to include a new strength 2 mg/ml solution for injection for cats, representing a new strength, and also an additional claim for the post-operative use of Metacam in cats.
II/0081	II - New Indication (same therapeutic area)	14/04/2010	02/06/2010	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation concerning the addition of a new indication (post-operative pain and inflammation) for Metacam 0.5 mg/ml oral suspension for cats.
II/0075	II - New Indication (same therapeutic area)	09/12/2009	12/01/2010	SPC, Labelling and PL	The European Commission approved a type II variation concerning the addition of a new therapeutic indication in pigs for the relief of stress and post-operative pain associated with pain causing procedures such as castration, as well as the addition of four new presentations to the already approved pack sizes.
II/0078	II - Other quality changes II - Other quality changes	14/10/2009	20/11/2009	SPC, Annex II, Labelling and PL	The European Commission approved the addition of a new fill volume of 3 ml in a 5 ml polypropylene bottle.
IB/0076	1B-41-b Change in pack size of finished product	20/07/2009	20/11/2009	SPC, Labelling and PL	The EMEA accepted a variation for a new fill volume of 10 ml in the already approved 15 ml polyethylene bottle.
IB/0080	1B-07-c Replacement or addition of a manufacturing site for part or all of manufacturing process	30/10/2009	30/10/2009		The European Medicines Agency accepted a type IB variation for the addition of a manufacturing site for all manufacturing operations of the finished product except final batch release.
II/0077	II - Other quality changes	14/10/2009	21/10/2009		The European Commission approved a type II variation concerning the addition of a manufacturing site for all manufacturing operations of the finished product except final batch release.
IB/0073	1B-25-a-1 Change to comply with Eu. Ph. or with the national pharmacopoeia of a Member State	11/12/2008	11/12/2008		The EMEA accepted a type I variation for a change in the specification for active substance.
IB/0072	1B-37-a Change in specification of the finished product-tightening of specification limits	11/12/2008	11/12/2008		The EMEA accepted a type I variation for tightening of shelf life specification for the sum of the degradation products to 2.0% and also adapting parameters of microbial determination to the current edition of the Ph. Eur.
II/0071	II - New presentation	16/04/2008	21/05/2008	SPC, Labelling and PL	The European Commission approved a type II variation for additional pack sizes for a 250 ml presentation.
IB/0070	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	22/02/2008	21/05/2008	SPC	The EMEA accepted the change in shelf-life of the finished

					product as packaged for sale.
R/0069	Renewal of the marketing authorisation.	10/10/2007	06/12/2007	SPC, Annex II, Labelling and PL	The European Commission approved an indefinite renewal for the product.
IB/0068	1B-41-b Change in pack size of finished product	25/06/2007	06/12/2007	SPC, Labelling and PL	The EMEA accepted a type I variation for additional pack sizes.
IB/0067	1B-41-b Change in pack size of finished product	25/06/2007	06/12/2007	SPC, Labelling and PL	The EMEA approved a type I variation for additional pack sizes.
II/0065	II - New presentation	18/04/2007	15/05/2007	SPC, Labelling and PL	The European Commission approved a type II variation for additional pack sizes for a 20 ml presentation.
IA/0066	1A-08-a Change to batch release arrangements and quality control testing of the finished product	03/05/2007	03/05/2007		The EMEA accepted a type I variation for changes to the batch release arrangements.
II/0058	II - New presentation	14/03/2007	20/04/2007	SPC, Labelling and PL	The European Commission approved the extension to cats of Metacam 0.5 mg/ml oral suspension.
IA/0064	1A-08-a Change to batch release arrangements and quality control testing of the finished product	15/03/2007	15/03/2007		The EMEA accepted a replacement of the batch control testing site.
IB/0060	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	26/10/2006	20/02/2007	SPC, Annex II, Labelling and PL	The EMEA accepted a type I variation for a change in shelf-life for the 2.5 mg tablets.
IB/0059	1B-41-a-2 Change in pack size of finished product-change in number of units in pack	26/10/2006	20/02/2007	SPC, Labelling and PL	The EMEA accepted a type I variation for additional pack sizes for the 10-tablet blisters.
II/0061	II - Other quality changes	17/01/2007	20/01/2007	SPC, Labelling and PL	The EMEA accepted a type II variation to reduce the currently approved daily maintenance dose to the lowest effective dose and the administration with or without food.
II/0057	II - Other quality changes	19/07/2006	20/07/2006		The EMEA accepted a type II variation for the addition of an alternative stopper.
X/0050	X-3-IV Change or addition of a new pharmaceutical form	18/01/2006	23/03/2006	SPC, Annex II, Labelling and PL	The European Commission approved an extension to chewable tablets for dogs. The tablets contain 1.0 mg or 2.5 mg of meloxicam.
IA/0056	1A-36-b Change in shape or dimensions of the container or closure	02/02/2006	02/02/2006		The EMEA accepted a type I variation for the addition of an alternative stopper.
II/0055	II - Update of SPC and PL	07/12/2005	25/01/2006	SPC, Labelling and PL	The European Commission issued a Decision approving an extension to include the indication of colic in horses.
IB/0054	1B-41-a-2 Change in pack size of finished product-change in number of units in pack	23/07/2005	25/01/2006	SPC, Labelling and PL	The EMEA accepted a type I variation to add multi-packs of 12 bottles per pack for the 100 ml presentations.
IB/0053	1B-41-a-2 Change in pack size of finished product-change in number of units in pack	23/07/2005	25/01/2006	SPC, Labelling and PL	The EMEA accepted a type I variation to add multi-packs of 12 bottles per pack for the 50 ml presentations.

X/0042	X-3-III Extension to a new strength	18/05/2005	01/08/2005	SPC, Labelling and PL	The European Commission approved an extension to a new strength, Metacam 0.5 mg/ml oral suspension for dogs.
IB/0052	1B-29A Change in qualitative or quantitative composition of the immediate packaging material	08/07/2005	08/07/2005		The EMEA accepted a change in the qualitative composition of the immediate packaging material.
IB/0051	1B-25-a-2 Change to comply with Eu. Ph. or with the national pharmacopoeia of a Member State	08/07/2005	08/07/2005		The EMEA accepted a type I variation for a change in specification for one of the excipients contained in the product.
N/0049	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/02/2005	24/06/2005	PL	A notification of a change in the local representatives was sent to the European Commission.
II/0048	II - New presentation	13/04/2005	24/06/2005	SPC, Labelling and PL	The European Commission approved a type II variation to include a new presentation (20 ml vial).
IB/0047	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	11/03/2005	24/06/2005	SPC, Labelling and PL	The EMEA accepted a type I variation for a change in the shelf life of the product.
IA/0044	1A-08-b-01 Change to batch release arrangements and quality control testing of the finished product	10/08/2004	27/04/2005	SPC, Annex II, Labelling and PL	The EMEA accepted a change in the package insert.
IA/0043	1A-08-b-01 Change to batch release arrangements and quality control testing of the finished product	10/08/2004	27/04/2005	SPC, Annex II, Labelling and PL	The EMEA accepted a type I variation to change batch release arrangements.
N/0041	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/06/2004	27/04/2005	PL	A notification of a change in the local representatives was sent to the European Commission.
N/0039	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/04/2004	27/04/2005	PL	A notification of a change in the local representatives was sent to the European Commission.
N/0038	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/04/2004	27/04/2005	PL	A notification of a change in the local representatives was sent to the European Commission.
N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/04/2004	27/04/2005	PL	A notification of a change in the local representatives was sent to the European Commission.
N/0036	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/04/2004	27/04/2005	PL	A notification of a change in the local representatives was sent to the European Commission.
IB/0046	1B-14-b Change in manufacturer active substance or starting material-new manufacturer	11/03/2005	11/03/2005		The EMEA accepted type I variation for a change in the active substance manufacturer.
X/0040	X-4-I Addition or change of target species	10/11/2004	31/01/2005	SPC, Labelling and PL	The European Commission approved an extension to include an additional species, horses.
IA/0035	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	02/04/2004	02/04/2004		The EMEA accepted a type I variation for a minor change to an approved test procedure.
X/0033	X-4-I Addition or change of target species	10/12/2003	19/03/2004	SPC, Annex II, Labelling and	The European Commission approved an application to extend the authorisation to pigs.

				PL	
IA/0034	1A-07-a Replacement or addition manufacturing site for part or all of manufacturing process	29/01/2004	29/01/2004		The EMEA accepted a type I variation to change the packaging site.
II/0026	II - New Indication (same therapeutic area) II - Other quality changes	23/07/2003	08/10/2003	SPC, Labelling and PL	The European Commission adopted a type II variation to amend the wording of Sections 4 and 5.8 of the SPC.
X/0022	X-4-I Addition or change of target species	18/06/2003	08/10/2003	SPC, Labelling and PL	The European Commission approved an extension to include 15 mg/ml oral suspension for horses.
I/0032	27_Change in test procedures of non-pharmacopoeial excipients	05/09/2003	12/09/2003		The EMEA accepted a type I variation to relating to test procedures.
I/0031	20_Extension of shelf-life as foreseen at time of authorisation	04/07/2003	01/08/2003	SPC, Labelling and PL	The European Commission approved a type I variation to increase the shelf life.
I/0028	20_Extension of shelf-life as foreseen at time of authorisation	04/07/2003	01/08/2003	SPC, Labelling and PL	The EMEA accepted a type I variation to increase the shelf life of the finished product from 2 to 3 years.
II/0025	II - Other quality changes	09/04/2003	22/07/2003	SPC	The European Commission approved a type II variation to change the wording of Section 4 of the Summary of Product Characteristics.
I/0030	25_Change in test procedures of the medicinal product	04/07/2003	04/07/2003		The EMEA accepted a type I variation to allow a change in the test procedures for the medicinal product.
I/0029	20a_Extension of shelf-life or retest period of the active substance	04/07/2003	04/07/2003		The EMEA accepted a type I variation to change the re-test period of the active substance.
I/0027	01_Change in the name of a manufacturer of the medicinal product	15/04/2003	04/06/2003	SPC, Labelling and PL	The EMEA accepted a type I variation to change the name of the batch release site manufacturing site.
X/0018	X-2-1 Addition of an indication	15/01/2003	12/05/2003	SPC, Annex II, Labelling and PL	The European Commission approved an extension to include the additional indication of mastitis in cattle.
X/0016	X-4-I Addition or change of target species	15/01/2003	12/05/2003	SPC, Annex II, Labelling and PL	The European Commission approved an extension to include a new target species, pigs.
R/0020	Renewal of the marketing authorisation.	13/11/2002	17/03/2003	SPC, Annex II, Labelling and PL	The European Commission approved a renewal valid for 5 years.
I/0024	01_Change in or addition of manufacturing site(s) for part or all of the manufacturing process	31/01/2003	31/01/2003	SPC	The EMEA accepted a type I variation to change the content of the manufacturing authorisation.
I/0023	08_Change in the qualitative composition of immediate packaging material	22/01/2003	22/01/2003		The EMEA accepted a type I variation to change in immediate packaging material (syringe material).
X/0013	X-4-I Addition or change of target species X-2-II Change of the indication	17/04/2002	09/08/2002	SPC, Labelling and PL	The European Commission approved an extension for Metacam 5 mg/ml solution for injection for dogs to include a new target species, cats. Amendments have been

					incorporated into the Community Decision and the relevant sections of the EPAR.
N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/06/2002	10/07/2002	Labelling and PL	A notification of a change in the local representatives was sent to the European Commission.
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	25/06/2002	09/07/2002	Labelling and PL	A notification of a change in the local representatives was sent to the European Commission.
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/03/2002	13/03/2002	Labelling and PL	A notification of a change in the local representatives was sent to the European Commission.
II/0015	II - New Indication (same therapeutic area)	07/11/2001	07/02/2002	SPC, Labelling and PL	The European Commission approved a type II variation to change the target species for the respiratory claim from "Cattle (calves and young non-lactating cattle)"to "Cattle".
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/08/2001	19/11/2001	SPC and PL	A notification of a change in the local representatives was sent to the European Commission.
X/0004	X-3-IV Change or addition of a new pharmaceutical form X-3-III Extension to a new strength	10/01/2001	23/04/2001	SPC, Annex II, Labelling and PL	The European Commission approved an extension to include 20 mg/ml solution for injection for cattle.
I/0012	14_Change in specifications of active substance	19/09/2000	10/10/2000	SPC	The EMEA accepted a type I variation to change the specifications of the active substance.
I/0011	19_Change in specification of excipients in the medicinal product (excluding adjuvants for vaccines)	19/09/2000	10/10/2000	SPC	The EMEA accepted a type I variation to change the specification of excipients in the medicinal product.
I/0010	19_Change in specification of excipients in the medicinal product (excluding adjuvants for vaccines)	19/09/2000	10/10/2000	SPC and PL	The EMEA accepted a type I variation to change the specification of excipients in the medicinal product.
I/0009	23_Change in storage conditions	19/09/2000	10/10/2000	SPC	The EMEA accepted a type I variation to change the product storage conditions.
I/0008	20_Extension of shelf-life as foreseen at time of authorisation	19/09/2000	10/10/2000	SPC and Labelling	The EMEA accepted a type I variation to extend the shelf life as foreseen at time of authorisation.
X/0005	X-2-1 Addition of an indication	19/04/2000	15/09/2000	SPC, Labelling and PL	The European Commission approved an extension to include a new indication (post-operative pain) for Metacam 5 mg/ml solution for injection for dogs.
I/0007	01a-Modification of manufacturing authorisation	23/05/2000	27/07/2000	Annex II	The EMEA accepted a type I variation to change the site of finished product manufacture.
I/0006	01a-Modification of manufacturing authorisation	11/05/2000	13/07/2000	SPC	The EMEA accepted a type I variation to change the name of the manufacturer of the medicinal product.
X/0003	X-3-IV Change or addition of a new pharmaceutical form	10/11/1999	24/03/2000	SPC, Labelling and PL	The European Commission approved an extension to include 1.5 mg/ml oral suspension for dogs.
X/0002	X-4-I Addition or change of target species	10/11/1999	24/03/2000	SPC, Labelling and PL	The European Commission approved an extension to include 5 mg/ml solution for injection for dogs.

I/0001	16_Change in the batch size of finished product	14/01/1998	16/01/1998	Annex II	The EMEA accepted a type I variation to change the batch size of the finished product.