EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

MELOXIDYL

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
IA/0028/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	31/01/2019		Annex II and PL	The Agency accepted the group of variations to delete a site for batch release and a site for batch control.
IA/0026	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	14/12/2018	n/a		The Agency accepted the variation to update the Ph. Eur. certificate of suitability for the active substance from an already approved manufacturer.
II/0023/G	This was an application for a group of variations. 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.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other	18/01/2018	11/01/2019	SPC	The Agency accepted the group of variations related to changes in the manufacturing and in-process tests of the finished product, in the specifications of the excipient and in the immediate packaging.

[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).

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	variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation B.II.c.2.a - Change in test procedure for an excipient - Minor changes to an approved test procedure B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products				
IB/0025/G	This was an application for a group of variations. B.II.a.3.b.6 - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	24/11/2017	n/a		The Agency accepted the group of variations to process a change in the test procedure, to modify the approved IPC limits and to replace a single excipient with a comparable excipient.
IG/0827/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	17/07/2017	n/a		The Agency accepted the group of variations to change the named QPPV and the detailed description of the pharmacovigilance system (DDPS).
IA/0022	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	11/12/2015	n/a		The Agency accepted the variation to update the Ph. Eur. certificate of suitability for the active substance from an already approved manufacturer.
IG/0620	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	06/11/2015	n/a		The Agency accepted the variation to update the detailed description of pharmacovigilance system (DDPS).
IB/0020/G	This was an application for a group of variations. B.II.e.1.a.2 - Change in immediate packaging of the finished product - Qualitative and quantitative	01/10/2015	03/10/2016	SPC, Labelling and PL	The Agency accepted the variation to add a new pack size, a 5 ml glass bottle and to delete the 4 ml plastic bottle for Meloxidyl 0.5 mg/ml oral suspension for cats.

	composition - Semi-solid and non-sterile liquid pharmaceutical forms B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)				
IB/0019/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	20/05/2015	n/a		The Agency accepted the variation to make a minor change in the manufacturing process of the active substance and minor updates to the restricted part of the ASMF.
IB/0018	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	18/02/2015	n/a		The Agency accepted the variation to bring the active substance specification for Meloxidyl 1.5 mg/ml oral suspension for dogs in line with the Meloxidyl 0.5 mg/ml oral suspension for cats.
IB/0017	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	09/01/2014	31/03/2014	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation with regards to the therapeutic indication following the assessment of the same change for the reference product, Metacam 20 mg/ml solution for injection.
WS/0408	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.9.z - Changes to an existing pharmacovigilance system as described in the DDPS - Other variation	10/10/2013	n/a		The Agency accepted the variation on the modification of the pharmacovigilance system to be in accordance with the revised Guideline EMEA/531641/2010. The main change concerns the change of electronic database including the change of the Qualified person.
IA/0015	A.7 - Administrative change - Deletion of manufacturing sites	21/12/2012	18/12/2013	SPC, Labelling and PL	The Agency accepted the variation on the deletion of a manufacturer.
IB/0014	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	31/10/2012	n/a		The Agency accepted the variation on a minor change in the manufacturing process of the active substance.
IB/0012	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	07/06/2012	29/10/2012	SPC, Labelling and PL	The Agency accepted the variation on the addition of a 4 ml pack size to the oral suspension for cats.
IB/0013	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	18/07/2012	n/a		The Agency accepted the variation on a change of test procedure following an update of the ASMF from the active substance manufacturer.
R/0011	Renewal of the marketing authorisation.	13/10/2011	19/12/2011		The European Commission renewed the marketing authorisation for Meloxidyl.
IB/0010	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data are submitted by the MAH	08/08/2011	08/08/2011	SPC and PL	The Agency accepted the variation on a change of the SPC, labelling and package leaflet for Meloxidyl 0.5 mg/ml oral suspension for cats following assessment of the same change for the reference product, Metacam 0.5 mg/ml oral suspension for cats.

IB/0009	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	08/02/2011	08/02/2011		The Agency accepted the variation on the addition of a filtration step prior to filling of the vials
IB/0007	B.II.a.3.b.6 - Changes in the composition (excipients) of the finished product - Other excipients - Replacement of a single excipient with a comparable excipient with the same functional characteristics and at a similar level	01/07/2010	27/01/2011	SPC	The Agency accepted the variation on the change of the composition of the finished product (replacement of a single excipient with a comparable excipient) with no impact on the quality, safety and efficacy of the veterinary medicinal product.
IA/0008	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 already approved manufacturer	27/10/2010	27/10/2010		The Agency accepted the variation on the submission of a new European Pharmacopoeia certificate of suitability from an approved manufacturer.
IA/0006	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	10/03/2010	26/08/2010	Annex II and PL	The Agency accepted the variation for the addition of a batch release site.
X/0004	X-4-I Addition or change of target species	17/06/2010	26/08/2010	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation of Meloxidyl to add a new strength 0.5 mg/ml oral suspension for cats.
X/0003	X-4-I Addition or change of target species X-3-III Extension to a new strength	13/01/2010	26/03/2010	SPC, Annex II and PL	The European Commission amended the decision granting the marketing authorisation of Meloxidyl to add new target species cattle, pigs and horses and a new strength 20 mg/ml solution for injection.
IA/0005	A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	10/03/2010	10/03/2010		The Agency accepted the variation on the addition of a batch release site.
X/0002	X-4-I Addition or change of target species X-3-III Extension to a new strength	15/07/2009	08/10/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation of Meloxidyl to add a new pharmaceutical form (solution for injection) for dogs and cats.
IB/0001	1B-02 Change in name of the medicinal product	26/01/2007	07/09/2007	SPC, Labelling and PL	The Agency accepted the variation on the change of the name of the product from "Meloxicam CEVA" to "Meloxidyl".