Previcox

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]
IB/0048/G	This was an application for a group of variations. B.II.a.1.b - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in scoring/break lines intended to divide into equal doses B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.d.1.i - Change in the specification parameters and/or limits of the finished product - Ph. Eur. 2.9.40 uniformity of dosage units is introduced to replace the currently registered method, either Ph. Eur. 2.9.5 or Ph. Eur. 2.9.6 B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data)	17/04/2020		SPC, Labelling and PL	The Agency accepted the group of variations to proceed to changes in scoring/break lines, changes in bossing, change in the specification parameters of the finished product and to extend the shelf life of the finished product. Furthermore, the MAH updated the product information according to the latest QRD template and made also some editorial changes.

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

IG/1203	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	20/03/2020		Annex II and PL	The Agency accepted the variation to change the name of the site responsible for batch release of the finished product. The address remains unchanged.
IB/0046	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	20/12/2019	n/a		n/a
T/0045	Transfer of Marketing Authorisation	26/11/2019	16/12/2019	SPC, Labelling and PL	The European Commission transferred the marketing authorisation for Previcox from 'MERIAL' to 'Boehringer Ingehleim Vetmetdica GmbH.
IA/0044/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition B.II.c.1.c - Change in the specification parameters and/or limits of an excipient - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	23/10/2019	n/a		n/a
IG/1127/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	10/07/2019	n/a		n/a
IA/0042	A.7 - Administrative change - Deletion of manufacturing sites	26/11/2018	n/a		n/a

IG/0756/G	This was an application for a group of variations. B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	03/03/2017	n/a		n/a
IB/0040	C.I.7.a - Deletion of - a pharmaceutical form	05/12/2014	10/06/2015	SPC, Labelling and PL	The Agency accepted a variation to delete the pharmaceutical form.
IAIN/0039	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	23/05/2014	10/06/2015	Annex II and PL	The Agency accepted the variation to change the address of the manufacturer responsible for batch release.
IB/0038	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)	10/04/2014	19/06/2014	SPC	The Agency accepted the variation on the extension of the current shelf life of the finished product from 36 months to 48 months based on real time data.
WS/0474/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.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method 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	13/03/2014	n/a		The Agency accepted a worksharing variation to add a new specification and test method for a starting material.
IB/0035	B.II.e.1.b.1 - Change in immediate packaging of the finished product - Type of container - Solid, semi-solid and non-sterile liquid pharmaceutical forms	28/06/2013	19/06/2014	SPC, Labelling and PL	The Agency accepted the variation on the addition of 60-count bottle presentations.
IAIN/0036	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	08/05/2013	19/06/2014	SPC, Labelling and PL	The Agency accepted a variation to add 60-count bottle presentations for 57 mg and 227 mg chewable tablets
IB/0034	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	27/03/2013	n/a		The Agency accepted a variation to register an alternative test procedure used in the synthesis of the active substance

WS/0318	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	13/12/2012	n/a		The Agency accepted the variation to register an alternative method used in the manufacturing process of the active substance.
IA/0031	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	24/10/2012	29/10/2012	SPC	The Agency accepted the variation on the replacement of the current blister by a new child-resistant blister.
IG/0185/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.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	02/08/2012	n/a		The Agency accepted the grouping of variations on minor changes in the manufacturing process.
WS/0002/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.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	09/06/2011	09/06/2011		The Agency accepted the variation on the extension of the re-test period of firocoxib from 48 months to 60 months.
II/0028	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	07/04/2011	18/05/2011	SPC, Annex II and PL	The European Commission amended the decision granting the marketing authorisation on the additional indication in the target species (dog) for Previcox chewable tablets for dogs for both strengths (57 mg and 227 mg): for the relief of the pain and inflammation associated with dental surgery.
II/0024	II - Other quality changes	13/01/2010	21/01/2010		The European Commission amended the decision granting the marketing authorisation to amend the specifications of one of the tablet excipients.
II/0023	II - New safety warning	09/12/2009	12/01/2010	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to include in the product literature additional information relating to the potential for the development of nervous system disorders in treated dogs.
IB/0026	1B-33 Minor change in the manufacture of the finished product	18/12/2009	18/12/2009		The Agency accepted the variation on a minor change in the manufacturing process of the finished product.

IB/0025	1B-07-c Replacement or addition of a manufacturing site for part or all of manufacturing process	18/12/2009	18/12/2009		The Agency accepted the variation on the replacement of a manufacturing site for all of the manufacturing processes.
IA/0027	1A-32.b Change in the batch size of the finished product-Downscaling down to 10-fold	27/11/2009	27/11/2009		The Agency accepted the variation to amend the batch size of the finished product for the oral paste for horses.
IB/0021	1B-33 Minor change in the manufacture of the finished product	26/06/2009	26/06/2009		The Agency accepted the variation on minor changes in the manufacturing process of the finished product further to the addition of the alternative manufacturing site.
IB/0020	1B-07-c Replacement or addition of a manufacturing site for part or all of manufacturing process	26/06/2009	26/06/2009		The Agency accepted the variation on the addition of the alternative manufacturing and primary packaging site.
IA/0022	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	12/06/2009	12/06/2009		The Agency accepted the variation on a minor change to an approved test procedure.
IA/0019	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	12/06/2009	12/06/2009		The Agency accepted the variation on minor change in a test procedure of the finished product.
R/0018	Renewal of the marketing authorisation.	16/04/2009	29/05/2009		The European Commission renewed indefinitely the marketing authorisation for Previcox.
IA/0017	1A-08-a Change to batch release arrangements and quality control testing of the finished product	06/01/2009	06/01/2009		The Agency accepted the variation on a change to batch release arrangements and quality control testing of the finished product.
II/0016	II - Other quality changes	10/12/2008	15/12/2008		The European Commission amended the decision granting the marketing authorisation to change the in-process control specification for tablet thickness of the chewable tablets for dogs.
II/0014	II - New Indication (same therapeutic area)	17/09/2008	17/10/2008	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisationto add the new indication for the relief of post-operative pain and inflammation associated with soft tissue and orthopaedic surgery in dogs.
IA/0015	1A-07-b-01 Replacement or addition of manufacturing site for part or all of manufacturing process 1A-07-a Replacement or addition manufacturing site for part or all of manufacturing process	18/07/2008	18/07/2008		The Agency accepted the variation on the addition of an additional primary and secondary packaging site.
II/0012	II - New Indication (same therapeutic area)	12/03/2008	10/04/2008	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisationto add a new indication for the relief of post-operative pain and inflammation associated with soft-tissue surgery in dogs and which also included the deletion of a specification (test for heavy metals) for the caramel excipient.
IA/0011	04_Replacement of an excipient with a comparable excipient	07/08/2007	07/08/2007		The Agency accepted the variation on the change of the source of the excipient.
IB/0010	1B-17-a Change in the re-test period of the active substance	28/06/2007	28/06/2007		The Agency accepted the variation on the change in the re-test period of the active substance from 24 to 48 months.

X/0004	X-3-IV Change or addition of a new pharmaceutical form	17/01/2007	14/03/2007	SPC, Labelling and PL	The European Commission granted an extension to add a new target species, pharmaceutical form and indication (oral paste for horses).
IA/0009	1A-07-a Replacement or addition manufacturing site for part or all of manufacturing process	07/02/2007	07/02/2007		The Agency accepted the variation on the addition of a new secondary packaging site.
II/0007	II - Other quality changes	13/12/2006	04/01/2007	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on a quality change related to the storage conditions.
IB/0008	1B-41-a-2 Change in pack size of finished product-change in number of units in pack	24/08/2006	24/08/2006	SPC, Labelling and PL	The Agency accepted the variation on the addition of two new pack sizes to the finished product - a 180 tablet pack (18 blisters of 10 tablets) for both the 57 mg and 227 mg tablets for dogs.
IA/0006	1A-07-a Replacement or addition manufacturing site for part or all of manufacturing process 1A-07-b-01 Replacement or addition of manufacturing site for part or all of manufacturing process	07/04/2006	07/04/2006		The Agency accepted the variation on the addition of primary and secondary packaging sites.
IA/0005	1A-39 Change or addition of imprints, bossing or other markings on tablets or capsules	07/04/2006	07/04/2006		The Agency accepted the variation ona change in the embossing on Previcox chewable 57 mg and 227 mg tablets for dogs.
IB/0003	1B-33 Minor change in the manufacture of the finished product	16/02/2005	16/02/2005		The Agency accepted the variation on a minor change in the manufacture of the finished product.
IA/0001	1A-11-a Change in batch size of active substance or intermediate	12/11/2004	12/11/2004		The Agency accepted the variation on a change in batch size of the active substance.