Equioxx

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]
IAIN/0029/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH 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	20/01/2022		SPC, Labelling and PL	The Agency accepted the variation to change the address of the marketing authorisation holder and to process administrative changes in the DDPS.
IAIN/0028/G	This was an application for a group of variations. 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.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	13/09/2021		Annex II and PL	The Agency accepted the group of variations to add a manufacturing site responsible for batch release and primary packaging.
IA/0027	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)	18/03/2021	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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IB/0025/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation 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 arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	12/03/2021		Annex II and PL	The Agency accepted the group of variations to introduce changes to the sites responsible for primary packaging, quality control testing and batch release; and to extend the stability of the tablet bulk.
II/0024	C.II.7.a - Introduction of a new Pharmacovigilance system - Which has not been assessed by the relevant national competent authority/EMA for another product of the same MAH	17/02/2021	n/a		n/a
IB/0023/G	This was an application for a group of variations. 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 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)	05/02/2021	n/a		n/a
IA/0026	B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	04/01/2021	n/a		n/a
T/0022	Transfer of Marketing Authorisation	19/08/2020	14/10/2020	SPC, Labelling	The European Commission transferred the marketing authorisation from 'Ceva Santé Animale', France to

				and PL	'Audevard', France.
WS/1382	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.II.7.b - Introduction of a new Pharmacovigilance system - Which has been assessed by the relevant national competent authority/EMA for another product of the same MAH	21/06/2018	n/a		n/a
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		n/a
T/0019	Transfer of Marketing Authorisation	23/05/2017	29/06/2017	SPC, Annex II, Labelling and PL	The European Commission transferred the marketing authorisation from 'MERIAL' to 'CEVA Santé Animale'.
IA/0018	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	07/03/2017	n/a		The Agency accepted the variation for a minor change to the test procedure for the finished product.
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
X/0015	Annex I_2.(d) Change or addition of a new pharmaceutical form	08/12/2016	09/02/2017	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new pharmaceutical form, 57mg oral chewable tablet.
IA/0016	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	06/01/2017	n/a		The Agency accepted the variation to make a change to the dosing syringe.
IG/0592	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	04/09/2015	n/a		n/a

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.
IA/0013/G	This was an application for a group of variations. B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	07/02/2014	n/a		The European Medicines Agency accepted the group of type IA variations to register an additional supplier for the packaging components of the finished product containing firocoxib and to introduce a minor change in the dimensions of the packaging components of the new supplier.
R/0009	Renewal of the marketing authorisation.	11/04/2013	06/06/2013	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for EQUIOXX.
IB/0011	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 register an alternative test procedure for 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.
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.	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.

	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				
IB/0005/G	This was an application for a group of variations. 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 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	12/03/2010	11/10/2010	SPC, Labelling and PL	The European Medicines Agency accepted a grouped type IB variation to add two new pack sizes: 1 carton box of 7 syringes and 1 carton box of 14 syringes.
IB/0003	1B-33 Minor change in the manufacture of the finished product	18/12/2009	18/12/2009		The European Medicines Agency approved a type IB variation concerning minor changes in the manufacture of the finished product for the oral paste for horses.
X/0001	X-3-IV Change or addition of a new pharmaceutical form	14/10/2009	18/12/2009	SPC, Labelling and PL	The European Commission issued a positive decision for the extension of the marketing authorisation to include a new pharmaceutical form, which will be available as a 20 mg/ml solution for injection.
IA/0004	1A-32.b Change in the batch size of the finished product-Downscaling down to 10-fold	27/11/2009	27/11/2009		The European Medicines Agency approved a type IA variation to amend the batch size of the finished product for the oral paste for horses.
II/0002	II - Other quality changes	16/09/2009	21/09/2009		The European Commission issued a decision on a type II variation, concerning a change in the detailed description of the pharmacovigilance system (a change of Qualified Person for Pharmacovigilance and minor changes in the text of the description).