Onsior

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/0029	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	06/01/2021		SPC and PL	The Agency accepted the variation to update the product information in order to implement the recommendation from the latest PSUR outcome.
IB/0031/G	This was an application for a group of variations. 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.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other 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.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	27/11/2020	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/0030	B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	30/10/2020	n/a		n/a
II/0024/G	This was an application for a group of variations. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	05/12/2019	20/01/2020	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add a new therapeutic indication for the treatment of pain and inflammation associated with soft tissue surgery in dogs (tablets) and to update the product information in order to: extend the period of administration for up to 2 days in dogs undergoing soft tissue surgery (solution for injection), reflect the interchangeable use of tablets and solution for injection in dogs (tablets and solution for injection), include information in case of accidental intravenous use in dogs (solution for injection) and address interactions in case of concurrent use of Onsior with furosemide and benazepril in dogs (tablets and solution for injection).
IB/0028/G	This was an application for a group of variations. B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.e.2.z - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Other variation B.II.e.3.c - Change in test procedure for the immediate packaging of the finished product - Deletion of a test procedure if an alternative test procedure is already authorised	20/12/2019	n/a		n/a
IAIN/0027/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.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 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 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 B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets,	16/12/2019	11/12/2020	SPC, Labelling and PL	The Agency accepted the group of variations to add eight new presentations, and to change the shape of the packaging.

	ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes 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 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 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 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				
IB/0026/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	11/12/2019	n/a		n/a
IA/0025	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	02/10/2019	n/a		n/a
IA/0023/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 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 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	28/06/2019	n/a		n/a
IG/1041/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance	18/12/2018	n/a		n/a

	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				
IA/0021	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	19/11/2018	n/a		n/a
IB/0020	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	31/10/2018	n/a		n/a
T/0019	Transfer of Marketing Authorisation	13/07/2018	03/08/2018	SPC, Annex II, Labelling and PL	The European Commission transferred the marketing authorisation from 'Elanco Europe Ltd' to 'Elanco GmbH'.
II/0018/G	This was an application for a group of variations. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	15/03/2018	26/04/2018	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add a new therapeutic indication - treatment of pain and inflammation associated with chronic musculo-skeletal disorders in cats (Onsior 6 mg tablets for cats); and for significant modifications of the Summary of Product Characteristics: interchangeable use of tablets and solution for injection - interchangeable use of Onsior 6 mg tablets and Onsior 20 mg/ml solution for injection for cats; drug interaction robenacoxib and benazepril - concurrent use with furosemide and benazepril (Onsior 6 mg tablets and Onsior 20 mg/ml solution for injection in cats); Intravenous use of Onsior 20 mg/ml solution for injection in cats - overdose advice in case of accidental intravenous use.
WS/1074	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	19/01/2017	n/a		The Agency accepted the variation to update the pharmacovigilance system.
IG/0681	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	07/06/2016	10/07/2017	Annex II and PL	The Agency accepted the variation to change the name of the site responsible for manufacturing and batch release of the finished product
T/0015	Transfer of Marketing Authorisation	24/08/2015	18/09/2015	SPC, Labelling	The European Commission amended the decision granting the marketing authorisation to transfer the marketing

				and PL	authorisation from 'Novartis Animal Health Ltd' to 'Elanco Europe Ltd'.
IAIN/0014/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.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	01/04/2015	18/09/2015	SPC, Annex II, Labelling and PL	The Agency accepted a group of variations relating to manufacturing site changes.
IAIN/0013/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	26/02/2014	n/a		The Agency accepted a group of variations to update the detailed description pharmacovigilance system (DDPS) and qualified person for pharmacovigilance (QPPV).
IB/0012	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)	20/12/2013	n/a		The Agency accepted type IB variation to delete a non-significant specification parameter.
R/0010	Renewal of the marketing authorisation.	12/09/2013	08/11/2013	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Onsior.
IAIN/0011/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	27/09/2013	n/a		The European Medicines Agency accepted a grouped type IA variation to replace an older version of the DDPS for Onsior (version 1.3) with version 2.2, which was assessed for Prac-tic (EMEA/V/C/ 000103/IA/0012), to amend the name and contact details of the QPPV for Onsior and to introduce minor changes which do not impact on the operation of the pharmacovigilance system.
II/0006/G	This was an application for a group of variations. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or	08/11/2012	13/02/2013	SPC and PL	The European Commission amended the decision granting the marketing authorisation to change the following: - New indication – solution for injection ("treatment of pain and inflammation associated with orthopaedic surgery in cats", (including the repeated use of the solution for injection post surgery)) - Additional warnings following PSUR assessment

	modification of an approved one C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a 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				- New indication – tablet ("For the reduction of moderate pain and inflammation associated with orthopaedic surgery in cats").
IA/0009/G	This was an application for a group of variations. 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.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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 currently approved batch size B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits	04/10/2012	n/a		The Agency accepted a grouping of type IA variations to make quality changes.
IB/0008/G	This was an application for a group of variations. 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.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions	07/09/2012	n/a		The Agency accepted a grouping of variations to add a manufacturer as an additional/alternative site and to slighly change the description of the seal on the vial.

	B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions 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				
IB/0005/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.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.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	09/11/2011	25/05/2012	SPC, Labelling and PL	The Agency accepted a grouping of type IB variations to extend the shelf-life of Onsior 6mg tablets for cats from 3 to 4 years; to extend the shelf-life of Onsior tablets for dogs (all four strengths) from 30 months to 4 years and to change the storage instructions from "Store below 30°C" to "Store below 25°C" for Onsior 6mg tablets for cats.
IB/0004/G	This was an application for a group of variations. 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.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site 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.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions 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	22/07/2011	22/07/2011		The Agency accepted the grouping of variations consisting of 6 type IB variations and 6 type IA variations as a result of a change of manufacturing site for Onsior solution for injection.

	product information B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging 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)				
IA/0002	1A-41-a-1 Change in pack size of finished product- change in number of units in a pack	15/06/2009	22/12/2009	SPC, Labelling and PL	The Agency accepted the variation to add a new pack size with 30 tablets (5 blisters with 6 tablets each) for Onsior 6 mg tablets for cats.
IA/0003	1A-07-b-01 Replacement or addition of manufacturing site for part or all of manufacturing process	13/10/2009	13/10/2009		The Agency accepted the variation to add a manufacturing site for part or all of the manufacturing process of the finished product (tablets).
II/0001	II - Other quality changes	16/04/2009	19/05/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to update the quality part of the dossier.