Osurnia

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/0024	C.I.3.z - Change(s) in the SPC, Labelling or PL of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR: implementation of wording agreed by the competent authority that does not require additional assessment	16/07/2021		SPC and PL	The Agency accepted the variation to update section 4.6 of the SPC and the corresponding section 6 of the package leaflet following assessment of surveillance of adverse events for Osurnia.
IA/0023/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	12/03/2021	n/a		n/a
IAIN/0022/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	22/12/2020		Annex II and PL	The Agency accepted the group of variations to make changes to the manufacturers responsible for batch release and batch control testing.

[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

	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				
IB/0021	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	05/11/2020	n/a		n/a
T/0020	Transfer of Marketing Authorisation	27/08/2020	16/09/2020	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Elanco GmbH', Germany to 'Dechra Regulatory B.V.', Netherlands.
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.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	08/07/2020	n/a		n/a
IB/0018/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.3.z - Change in batch size (including batch size ranges) of AS or intermediate - Other variation	29/05/2020	n/a		n/a
IA/0017/G	This was an application for a group of variations. 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.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)	17/04/2020	n/a		n/a
IB/0016	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	21/02/2020	16/09/2020	SPC and PL	The Agency accepted the variation to update section 4.5 of the SPC and section 12 of the package leaflet to implement the changes requested following assessment of a PSUR.
IB/0015	B.II.c.1.f - Change in the specification parameters and/or limits of an excipient - Addition or replacement (excluding biological or immunological product) of a specification parameter with its corresponding test method as a result of a safety or quality issue	05/12/2019	n/a		n/a

R/0014	Renewal of the marketing authorisation.	16/04/2019	03/07/2019	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for OSURNIA.
IAIN/0013/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.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	20/12/2018	03/07/2019	Annex II and PL	The Agency accepted the group of variations to add new batch release and batch testing sites.
IB/0011/G	This was an application for a group of variations. B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/12/2018	n/a		The Agency accepted the variation to add a purification site for the starting material, to tighten the bulk density specification and to implement minor changes to the ASMF.
IG/1041/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	18/12/2018	n/a		n/a
II/0009/G	This was an application for a group of variations. B.I.a.1.c - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The	06/12/2018	n/a		The Agency accepted the grouped variation to add an alternative manufacturer for one of the active substances and to update the residual solvent testing methods for this

	proposed manufacturer uses a substantially different route of synthesis or manufacturing conditions 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				active substance.
T/0010	Transfer of Marketing Authorisation	19/10/2018	21/11/2018	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Elanco Europe Ltd' to 'Elanco GmbH'.
II/0008	B.I.a.1.c - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer uses a substantially different route of synthesis or manufacturing conditions	13/09/2018	n/a		The Agency accepted the variation to add an active substance manufacturer for florfenicol, supported by an ASMF.
IG/0794	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	03/07/2017	25/05/2018	SPC, Annex II, Labelling and PL	The Agency accepted the variation to change the name of the site responsible for batch release and add a minor amendment to the address.
IB/0006	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	12/05/2017	25/05/2018	SPC, Labelling and PL	The Agency accepted the variation to amend the product information following assessment of a PSUR.
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.
IB/0004/G	This was an application for a group of variations. 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 A.7 - Administrative change - Deletion of manufacturing sites B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place 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 B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	30/09/2016	n/a		The Agency accepted the group of variations relating to manufacturing activities and minor changes to the manufacturing process.

	B.I.a.4.c - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of a non-significant in-process test 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.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.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.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation				
T/0003	Transfer of Marketing Authorisation	29/06/2016	25/07/2016	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Novartis Sante Animale S.A.S.' to 'Elanco Europe Ltd'.
IB/0002	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)	17/07/2015	25/07/2016	SPC, Labelling and PL	The Agency accepted the variation to extend the shelf life of the finished product from 2 to 3 years based on available real time stability data.
IB/0001	B.II.e.1.a.2 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Semi-solid and non-sterile liquid pharmaceutical forms	02/10/2014	n/a		The Agency accepted the variation to make a minor change in the material used to manufacture the primary packaging.