Zolvix

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]
IA/0028	A.7 - Administrative change - Deletion of manufacturing sites	12/03/2021		Annex II and PL	The Agency accepted the variation to delete a site responsible for batch release.
IA/0027	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	04/06/2019	n/a		The Agency accepted the variation to add a batch control testing site.
IA/0026	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	05/03/2019	n/a		The Agency accepted a variation to add a new batch control testing site.
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	18/12/2018	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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	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				
T/0024	Transfer of Marketing Authorisation	01/10/2018	30/10/2018	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Elanco Europe Ltd' to 'Elanco GmbH'.
II/0023/G	This was an application for a group of variations. B.I.a.2.b - Changes in the manufacturing process of the AS - Substantial change to the manufacturing process of the AS which may have a significant impact on the quality, safety or efficacy of the medicinal product B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits 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	15/03/2018	n/a		The Agency accepted the group of variations to include an additional route of synthesis of the active substance. Consequential changes to the in-process tests and limits as well as a new active substance specification were approved.
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	10/07/2018	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/0021/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.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.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	09/06/2017	n/a		The Agency accepted the group of variations to make minor changes in the manufacturing process of the active substance Monepantel AHC 2102225 B and to file an optimized analytical method for an intermediate product.
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	19/01/2017	n/a		The Agency accepted the variation to update the pharmacovigilance system.

	of the same MAH				
IB/0019/G	This was an application for a group of variations. C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release B.II.e.1.b.3 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Deletion of an immediate packaging container without a complete deletion of a strength or pharmaceutical form	15/07/2016	14/07/2017	SPC, Annex II, Labelling and PL	The Agency accepted a group of variations to update sections 4.4 and 5.1 of the SPC to update the safety information, to change the name of the site responsible for manufacturing and batch release of the finished product and to delete the immediate packaging container aluminium bags for Zolvix Oral solution 25 mg/ml.
T/0018	Transfer of Marketing Authorisation	16/10/2015	19/11/2015	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from "Novartis Healthcare A/S" to "Elanco Europe Ltd"
IA/0017	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	14/08/2015	n/a		The Agency accepted a variation to introduce an increased batch size of the finished product.
IA/0016/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.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.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)	04/06/2015	n/a		The Agency accepted the group of variations to implement minor changes in the manufacturing process of the active substance, to delete a non-significant in-process test during the manufacture of the active substance and to delete a non-significant specification parameter.
IB/0015	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)	05/12/2014	19/11/2015	SPC	The Agency accepted the variation to extend the shelf-life of the finished product for ZOLVIX 25 mg/ml Oral Solution - packaged in laminated aluminium bags- from 2 years to 3 years.
R/0013	Renewal of the marketing authorisation.	11/09/2014	07/11/2014	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Zolvix.
IB/0014/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new	23/10/2014	n/a		The Agency accepted the variation to add three alternative manufacturers for starting materials used in the synthesis of active substance and to add a new specificaiton parameter for the active substance.

	specification parameter to the specification with its corresponding test method B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation				
IAIN/0012/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 the variation to update the DDPS according to the latest version (ref version 2.3) including the change of QPPV.
IB/0011	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	11/12/2013	n/a		The Agency accepted the variation to add an alternative manufacturer of the starting material.
II/0009	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	07/11/2013	19/08/2014	SPC and PL	The Agency accepted a variation to modify pharmacodynamic properties by moving part of the text from indications and adding information regarding efficacy against 4th stage larvae of a strain of H. contortus where a combination of abamectin with derquantel was not effective.
IAIN/0010	A.1 - Administrative change - Change in the name and/or address of the MAH	10/07/2013	19/08/2014	SPC, Labelling and PL	The Agency accepted a variation to change the address of the Marketing Authorisation Holder
IB/0008/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation 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.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits 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	08/01/2013	n/a		The Agency accepted a group of variations to change the manufacturing process of the active substance, with 3 consequential variations to add a site for synthesis of the active substance, monepantel, to add a new in-process test and limits, and to add a new specification parameter with its corresponding test method.
IA/0006	B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling	23/02/2012	n/a		The Agency accepted the variation to change the batch size of the intermediate.

II/0004	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	14/07/2011	19/08/2011	SPC and PL	The European Commission approved a type II variation to extend the indication to Haemonchus contortus strains resistant to salicylanilides.
IG/0003/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 C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV C.I.9.h - 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 pharmacovigilance system	10/03/2011	10/03/2011		The Agency accepted the group of variations to change the QPPV, to change the contact details of the QPPV and to change the DDPS.
IB/0003/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.3.z - Change in batch size (including batch size ranges) of AS or intermediate - Other variation 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.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	18/02/2011	18/02/2011		The Agency accepted the group of variations to change the manufacturing process of the active substance; to change the batch size of an intermediate; to add a test procedure for an intermediate and to change the specification limits of a reagent used in the manufacturing process of the active substance.
II/0001/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 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	07/01/2011	17/01/2011	SPC and PL	The European Commission accepted the group of variations regarding changes to therapeutic indications to include inhibited fourth larvae of the following parasites: Haemonchus contortus, Teladorsagia circumcincta, Teladorsagia trifurcata, Teladorsagia davtiani, Trichostrongylus axei. There were also changes to the Summary of Product Characteristics in section "4.8 Interaction with other medicinal products and other forms of interaction" and section 12 of the package leaflet.
IA/0002	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the currently approved batch size	11/11/2010	11/11/2010		The Agency accepted the variation for the addition of a new batch size (3000 L) for the finished product.