Econor

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
IB/0057/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold	02/08/2019		SPC	The Agency accepted the group of variations to add a manufacturing and packaging site, increase the batch size, apply changes to the testing procedure and immediate packaging material for the 25kg bag, and reduce the shelf life from 60 to 24 months for Econor 10% Premix.

[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] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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

	compared to the originally approved batch size B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms				
IA/0056	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	29/05/2019	n/a		The Agency accepted the variation to include an additional quality 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 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		The Agency accepted the group of variations to update the detailed description of the pharmacovigilance system (DDPS).
T/0054	Transfer of Marketing Authorisation	24/10/2018	26/11/2018	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Elanco Europe Ltd' to 'Elanco GmbH'.
II/0052	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	13/09/2018	26/11/2018	SPC	The Agency accepted the variation to update section 5.1 of the SPC for Econor 10% premix for medicated feed due to new preclinical data (submitted in response to a recommendation arising from the extension of the target species to rabbits in 2013), and to include agreed editorial changes in the product information.
IAIN/0053	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	10/08/2018	n/a		The Agency accepted the variation to add a secondary packaging site.
IB/0051	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	12/07/2017	10/07/2018	SPC, Labelling and PL	The Agency accepted the variation to implement the changes requested as an outcome of the PSUR assessment and consequently update the product information for Econor 10% Premix and Econor 50% Premix.
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	19/01/2017	n/a		The Agency accepted the variation to update the pharmacovigilance system.

	national competent authority/EMA for another product of the same MAH				
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	07/06/2017	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/0048	Transfer of Marketing Authorisation	11/02/2016	26/02/2016	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Novartis Tiergesundheit GmbH' to 'Elanco Europe Ltd'.
T/0047	Transfer of Marketing Authorisation	23/05/2014	23/06/2014	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Novartis Animal Health GmbH' to 'Novartis Tiergesundheit GmbH'.
IA/0046	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	02/04/2014	n/a		The Agency accepted the variation to change the quality control testing site of the active substance.
IB/0045	C.I.7.b - Deletion of - a strength	13/03/2014	23/06/2014	SPC, Annex II, Labelling and PL	The Agency accepted the variation on deletion of strength of Econor 0.5% Premix.
IAIN/0044/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 on the update of the DDPS.
IB/0043/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.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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.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	13/12/2013	n/a		The Agency accepted the variation to register one manufacturing site responsible for the whole manufacturing process. This main change has triggered a number of consequential changes related to manufacturing process of the active substance, tightening of specification limits, addition of new specification parameter to the specification, change to a test procedure for active substance.

	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.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits 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				
X/0039	Annex I_3. Other changes specific to veterinary medicinal products to be administered to food-producing animals: change or addition of target species	13/06/2013	05/08/2013	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation of Econor 10% premix for medicated feedingstuff to add a new target species, rabbits.
IB/0042	C.I.7.b - Deletion of - a strength	08/05/2013	05/08/2013	SPC, Annex II, Labelling and PL	The Agency accepted the variation to delete Econor 1% premix.
IA/0041	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	27/07/2012	n/a		The Agency accepted the variation on changes to the DDPS that do not impact on the operation of the pharmacovigilance system.
II/0040	B.II.b.5.d - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of an in-process test which may have a significant effect on the overall quality of the finished product	13/10/2011	13/10/2011		The Agency accepted the variation on deletion of an in-process test during the manufacture of the finished product.
IB/0038/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products 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.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	31/05/2011	31/05/2011		The Agency accepted the group of variations on the change of the manufacturing site for the finished product, batch control site and to change the batch size from 1000 kg to 1800 kg.
IB/0037/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.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the	01/04/2011	01/04/2011		The Agency accepted the group of variations on the change of the spray drying site for the manufacture of the active substance and the change of the temperature at which the drying takes place

	AS				
X/0033	X-3-IV Change or addition of a new pharmaceutical form	13/10/2010	06/01/2011	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new pharmaceutical form (oral powder).
IB/0036/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products 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.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	12/11/2010	12/11/2010		The Agency accepted the group of variations on the change of the manufacturing site for the finished product and the batch control site and also to increase the batch size.
IB/0035	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	28/07/2010	28/07/2010		The Agency accepted the group of variations including one type IB and one type IA variations. The variations concerned the change of the spray drying site for the finished product.
II/0032	II - New safety warning	16/04/2009	08/05/2009	SPC and PL	The European Commission amended the decision granting the marketing authorisation on the deletion of a contraindication in the SPC and package leaflet ("valnemulin should not be administered to rabbits because of its toxicity in this species").
R/0031	Renewal of the marketing authorisation.	14/01/2009	06/03/2009	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Econor. This decision was based on the favourable opinion and an assessment report adopted by the CVMP on 14 January 2009.
IA/0030	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	15/08/2008	15/08/2008		The Agency accepted the variation on minor changes to the approved test procedure of the finished product.
IA/0029	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	15/08/2008	15/08/2008		The Agency accepted the variation on minor changes to the approved test procedure of the finished product.
IA/0028	1A-04 Change in name and/or address of a manufacturer of the active substance	15/08/2008	15/08/2008		The Agency accepted the variation on a change in the name of a manufacturer of the active substance where no Ph.Eur. Certificate of suitability is available.
IA/0027	1A-32-a Change in the batch size of the finished product	15/08/2008	15/08/2008		The Agency accepted the variation on a change in batch size of a finished product - up to 10-fold compared to the original batch size approved at the granting of the marketing authorisation.
IA/0026	1A-11-a Change in batch size of active substance or intermediate	15/08/2008	15/08/2008		The Agency accepted the variation on a change in batch size of an intermediate - up to 10-fold compared to the original batch size approved at the grant of the marketing

					authorisation.
IB/0025	1B-19-b Change in specification of an excipient-addition of new test parameter to the specification	30/07/2008	30/07/2008		The Agency accepted the variation on a change in the specification of an excipient (addition of new test parameter to the specification).
IA/0024	1A-19-a Change in specification of an excipient-tightening of specification limits	30/07/2008	30/07/2008		The Agency accepted the variation on a change in the specification of an excipient (tightening of specification limits).
II/0023	II - Other quality changes	11/07/2007	04/09/2007	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on the quality part of the dossier.
IA/0022	1A-05 Change in name and/or address of a manufacturer of the finished product	29/06/2005	03/02/2006	SPC, Labelling and PL	The Agency accepted the variation on a change in the name of the manufacturer of the finished product.
S/0021		09/02/2005	26/05/2005	Annex II	The European Commission amended the decision granting the marketing authorisation and approved a change of Annex II lifting the specific conditions of the marketing authorisation in relation to pharmacovigilance.
IB/0020	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	15/12/2004	26/05/2005	SPC, Labelling and PL	The Agency accepted the variation on the extension of the shelf life of the 1%, 10% and 50% presentation from 3 to 5 years.
IA/0019	1A-47-c Deletion of a pack-size(s)	06/10/2004	26/05/2005	SPC, Annex II, Labelling and PL	The Agency accepted the variation on the deletion of all presentations in polyethylene bags packed in cardboard cartons. The remaining presentations are packed in aluminium-lined plastic bags.
R/0018	Renewal of the marketing authorisation.	14/01/2004	31/03/2004	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Econor.
II/0013	II - New Indication (same therapeutic area)	15/10/2003	27/01/2004	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on the addition of a new indication, "prevention of clinical signs of porcine colonic spirochaetosis (colitis)".
II/0012	II - New Indication (same therapeutic area)	15/10/2003	27/01/2004	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation on the addition of a new indication, "treatment of clinical signs of porcine proliferative enteropathy (ileitis)".
II/0014	II - Other quality changes	12/11/2003	13/11/2003		The European Commission amended the decision granting the marketing authorisation on the change of the quality of the product (alteration of the particle size distribution of the finished product for Econor 50%).
I/0015	01_Change in the name of a manufacturer of the medicinal product	16/10/2003	05/11/2003	Annex II, Labelling and	The EMEA approved a Type I Variation for Econor 50 %, changing the name and address of the manufacturer of the finished product. Amendments have been incorporated in the

				PL	relevant sections of the Commission Decision and of this EPAR.
I/0017	26_Changes to comply with supplements to pharmacopoeias	23/10/2003	23/10/2003		The EMEA approved a Type I variation concerning changes to comply with supplements to the European Pharmacopoeia in the manufacture of the finished product and consequentially a new site of batch release.
I/0016	11a_Change in the name of a manufacturer of the active substance	23/10/2003	23/10/2003	SPC, Labelling and PL	The EMEA approved a Type I variation to change the name of the manufacturer of the active substance.
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	29/11/2002	29/11/2002	SPC, Labelling and PL	The EMEA notified the Commission about corrections to be made in the Portuguese SPC and package insert (storage conditions) and the Greek SPC, labelling and package insert. Amendments have been incorporated in the relevant sections of the Commission Decision and of this EPAR.
Z/0010		05/12/2001	22/04/2002	SPC, Annex II, Labelling and PL	In September 2001, the Marketing Authorisation Holder applied for a lift of the suspension of the marketing authorisation for Econor and submitted the results of studies investigating the cause of the adverse reactions. Based on the data submitted the CVMP concluded on 5 December 2001 that the overall benefits outweigh the risks for Econor and recommended to the Commission to revoke the suspension of the marketing authorisation for Econor subject to changes to the product literature and further conditions. Consequently, on 29 April 2002 the Commission lifted the suspension of the marketing authorisation for Econor.
Z/0009		11/10/2000	20/12/2000	SPC, Annex II, Labelling and PL	In 2000, severe adverse reactions in a significant number of pigs were reported from several Member States. On the basis of the reported reactions and their impact on target animal safety, Denmark, Sweden and Finland suspended the use of Econor on their territories on 28 August, 4 September and 20 September 2000, respectively. On 12 October 2000, the CVMP recommended to the Commission to suspend the use of Econor in all EU Member States and the Commission on 20 December 2000 suspended the marketing authorisation for Econor in the European Union and the Marketing Authorisation Holder was asked to provide 3-monthly Periodic Safety Update Reports.
I/0007	11b_Change in supplier of an intermediate compound used in manufacture of the active substance	27/10/2000	29/11/2000		The EMEA approved a Type I variation for Econor 0.5 % to introduce a change in the manufacturer of the active substance (Type I No 11.b),
I/0008	01a-Modification of manufacturing authorisation	27/10/2000	27/10/2000	Annex II, Labelling and PL	The EMEA approved a Type I variation for Econor 0.5 % to introduce a change in the manufacturer of the finished product and consequentially a new site of batch release (Type I No 1). The amendments have been incorporated into Annex II, section A and Annex III, section 18 of the Community Decision and the relevant sections of the EPAR

X/0005	X-4-II Shortening of the withdrawal period	08/03/2000	17/09/2000	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for Econor 10% to shorten the withdrawal period from 4 days to 1 day. As a consequence, the existing Marketing Authorisations for Econor 10% (EU/2/98/010/007-010) have been replaced by the new extensions (EU/2/98/010/015-018). The amendments have been incorporated into the Community Decision and the relevant sections of this EPAR.
X/0006	X-4-II Shortening of the withdrawal period	08/03/2000	15/09/2000	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for Econor 50% to shorten the withdrawal period from 4 days to 1 day. As a consequence, the existing Marketing Authorisations for Econor 50% (EU/2/98/010/011-014) have been replaced by the new extensions (EU/2/98/010/019-022). The amendments have been incorporated into the Community Decision and the relevant sections of this EPAR.
X/0003	X-3-III Extension to a new strength	19/04/2000	15/09/2000	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for Econor 0.5%, introducing a new strength. Amendments have been incorporated into the Community Decision and the relevant sections of this EPAR.
II/0002	II - New Indication (same therapeutic area)	14/07/1999	31/01/2000	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for Econor 50% to reduce the dilution rate at which the product can be mixed into feed. As a consequence, the indications "For the prevention and treatment of swine dysentery" have been added. The amendments have been incorporated into Annex I, section 5.8 and Annex III, section 9 of the Community Decision and the relevant sections of this EPAR.
I/0001	01a-Modification of manufacturing authorisation	23/08/1999	16/11/1999	Annex II, Labelling and PL	The European Commission approved a variation (Type I No 1 following a Type II procedure) for a new manufacturer of the dosage form and a new site of batch release for Econor 1% and Econor 10%. The amendments have been incorporated into Annex II, section A and Annex III, section 19 of the Community Decision and the relevant sections of the EPAR.
I/0004	11_Change in or addition of manufacturer(s) of active substance	13/10/1999	13/10/1999		The EMEA approved a type I No. 11 variation for a new manufacturer and a new batch release site of the active ingredient. No amendments to the Commission Decision are required.