Aivlosin

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/0087	A.7 - Administrative change - Deletion of manufacturing sites	12/03/2021		Annex II and PL	The Agency approved the variation to delete the manufacturing sites responsible for batch release and batch control testing that are not located within the EU/EEA. Additionally, the MAH has corrected the local representatives and processed a few minor corrections in the Product Information.
II/0085/G	This was an application for a group of variations. B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range 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.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-	17/02/2021	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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	sterile medicinal products				
IA/0086	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	15/01/2021	n/a		n/a
IAIN/0084	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	12/11/2020		Annex II and PL	The Agency approved the variation to add an additional manufacturing site responsible for batch release. In addition some editorial changes to the Danish and Swedish PI have been made so that they are compliant with the QRD template, and the local representative in Belgium, The Netherlands and Luxembourg have been updated.
IB/0082/G	This was an application for a group of variations. 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) B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.e.1.a.1 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Solid pharmaceutical forms	21/08/2020	n/a		n/a
IAIN/0083/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.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	11/08/2020	n/a		n/a
II/0080/G	This was an application for a group of variations. B.II.b.1.d - Replacement or addition of a manufacturing site for the FP - Site which requires an initial or product specific inspection A.7 - Administrative change - Deletion of manufacturing sites	16/07/2020	n/a		n/a
II/0078	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	20/05/2020	24/06/2020	SPC and PL	The European Commission amended the marketing authorisation to include an additional indication for the granules for use in drinking water formulation: “treatment and metaphylaxis of swine enzootic pneumonia caused by susceptible strains of Mycoplasma hyopneumoniae in pigs”. As consequence, amendments to the dosage and withdrawal period sections of the product information have been made.

IAIN/0079/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	05/11/2019	n/a		n/a
T/0077	Transfer of Marketing Authorisation	30/01/2019	12/03/2019	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'ECO Animal Health Ltd' to 'ECO Animal Health Europe Limited'.
IB/0075/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.z - Changes in the manufacturing process of the AS - Other variation 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.z - Quality change - Active substance - Other variation	03/01/2019	n/a		The Agency accepted the group of variations relating to the active substance: change to the address of a manufacturer; increase in batch size and minor changes to manufacturing conditions.
IA/0076	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	12/12/2018	n/a		The Agency accepted the variation to make a change in the manufacturing equipment concerning Aivlosin 42.5 mg/g premix and oral powder.
II/0074/G	This was an application for a group of variations. B.II.c.1.d - Change in the specification parameters and/or limits of an excipient - Change outside the approved specifications limits range B.II.c.1.d - Change in the specification parameters and/or limits of an excipient - Change outside the approved specifications limits range B.II.c.1.z - Change in the specification parameters and/or limits of an excipient - Other variation	06/12/2018	n/a		The Agency accepted the group of variations relating to a change in the name of an excipient and to changes in the specification parameters for another excipient for Aivlosin 42.5 mg/g premix and oral powder.
II/0072	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	06/12/2018	12/03/2019	SPC and PL	The Agency accepted the variation to allow the use of Aivlosin in breeding chickens concerning Aivlosin 625 mg/g granules for use in drinking water for chickens and turkeys.
IB/0073/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	14/09/2018	n/a		The Agency accepted the group of variations to implement changes to the manufacturing process of the active substance.

	ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF 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.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality 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.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits				
IB/0071/G	This was an application for a group of variations. 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	10/01/2018	n/a		The Agency accepted the group of variations to change the specification of the active substance by widening the limits of one specification parameter and deleting another parameter.
IAIN/0070	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	13/12/2017	07/12/2018	SPC, Labelling and PL	The Agency accepted the variation to update the address of the local representative in Portugal; the product information was aligned with the latest QRD template version 8.1, including other minor editorial changes.
IAIN/0069/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	19/12/2016	19/07/2017	SPC, Annex II, Labelling and PL	The Agency accepted the group of variations to add presentations: 625 mg/g granules for use in drinking water for chickens and turkeys, 40 g & 400 g; to delete presentations 625 mg/g granules for use in drinking water for chickens, 40 g & 400 g; and to delete presentations 625 mg/g granules for use in drinking water turkeys, 40 g &

	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.b - Change in pack size of the finished product - Deletion of a pack size(s) 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				400 g; and to change the name of the manufacturer responsible for batch release.
II/0067/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.b.z - Change in control of the AS - Other variation 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.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.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition	08/12/2016	n/a		The Agency accepted the group of variations relating to changes in the manufacturing of the active substance.
IAIN/0068/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	02/08/2016	n/a		The Agency accepted the group of variations to update the Detailed Description of the Pharmacovigilance System (DDPS) to include a change in the Qualified Person for Pharmacovigilance (QPPV) and to include administrative changes not impacting the operation of the pharmacovigilance system.
IB/0066/G	This was an application for a group of variations. B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (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	22/07/2016	19/07/2017	SPC, Labelling and PL	The Agency accepted the group of variations to extend the shelf-life of the finished product, Aivlosin 625 mg/g water soluble granule and for Aivlosin 42.5 mg/g Oral Powder after first opening; and to change the storage temperature of the finished product Aivlosin 625 mg/g water soluble granule 40 g pack size.
II/0064	C.II.3 - Changes to the withdrawal period for a veterinary medicinal product	21/04/2016	26/05/2016	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to change the withdrawal period for eggs (and include layers to the therapeutic indication) for the use of Aivlosin 625 mg/g Water Soluble Granules (WSG) to treat chickens with infections caused by

					Mycoplasma gallisepticum.
IB/0065	B.II.e.5.d - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products	17/03/2016	26/05/2016	SPC, Annex II, Labelling and PL	The Agency accepted the variation to add a pack size of 400 g Aivlosin granules for use in drinking water for pigs.
IAIN/0063	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	08/10/2015	n/a		The Agency accepted the variation to change the QPPV details and consequentially the DDPS.
II/0062/G	This was an application for a group of variations. B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS 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	10/09/2015	n/a		The Agency accepted the variation to increase the retest date and to amend release and stability specifications for the active pharmaceutical ingredient.
IAIN/0061	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	21/11/2014	15/10/2015	PL	The Agency accepted the variation to amend distributors listed on the package leaflet, other minor editorial changes.
IA/0060/G	This was an application for a group of variations. 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 B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	21/11/2014	n/a		The Agency accepted the group of variations to add a new batch size and consequential minor manufacturing change.
R/0059	Renewal of the marketing authorisation.	10/07/2014	09/09/2014	SPC, Annex II, Labelling and PL	The European Commission renewed the Community marketing authorisation for Aivlosin.
IAIN/0058	C.II.6.a - Changes to the labelling or the PL which are not connected with the SPC - Administrative information concerning the holder's representative	16/01/2014	09/09/2014	PL	The Agency accepted the variation to update distributors within Romania and Denmark.
X/0051	Annex I_3. Other changes specific to veterinary medicinal products to be administered to food-producing animals: change or addition of target species	10/10/2013	04/12/2013	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new target species, turkeys, to the existing product range for Aivlosin (granules for oral solution).
IB/0057	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	13/09/2013	n/a		The Agency accepted the variation to make a change in the machinery used during the manufacture of Aivlosin 625 mg/g water soluble granules.
IB/0056	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	03/05/2013	n/a		The Agency accepted the variation related to the manufacturing process.

IB/0054	B.II.e.5.d - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products	20/12/2012	04/12/2013	SPC, Labelling and PL	The Agency accepted the variation to add a pack size of 400 g Aivlosin granules for use in drinking water for pheasants and to update the local representatives for all presentations.
IB/0053	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	20/11/2012	04/12/2013	SPC, Labelling and PL	The Agency accepted the variation to reduce the shelf life from 36 months to 24 months for the 625 mg/g granules for use in drinking water for chicken-400 g sachet (EU/2/04/044/008) and reduce the maximum storage temperature from 30°C to 25°C. A reduction in shelf life for the 160 g sachet was also implemented (EU/2/04/044/010).
IA/0052/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	27/07/2012	n/a		The Agency accepted the group of variations to delete a site for the manufacture of the active substance and to remove three testing facilities.
IA/0049	B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)	29/02/2012	26/03/2012	SPC, Labelling and PL	The Agency accepted the variation to delete the 16g pack size of Aivlosin 625 mg/g granules for use in drinking water for pheasants.
IA/0050	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	16/03/2012	n/a		The Agency accepted the variation to add a testing facility for all authorised presentations.
IA/0048	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	16/12/2011	n/a		The Agency accepted the variation to change the batch size of the intermediate
IA/0047	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	16/12/2011	n/a		The Agency accepted the variation to change the batch size of the finished product
IB/0046	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	31/08/2011	31/08/2011	PL	The Agency accepted the variation for a change in local representatives for Belgium, Italy and Poland.
IB/0045/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.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	07/03/2011	18/05/2011	SPC and PL	The Agency accepted the group of variations for a change of shelf life from 2 years to 3 years, and a change of the current storage conditions statement from "Do not store above 25°C" to "Store below 30°C" for the 42.5 mg/g oral powder for pigs and 42.5 mg/g premix for medicated feeding stuff for pigs.
IB/0044/G	This was an application for a group of variations. B.II.f.1.b.1 - Stability of FP - Extension of the shelf	12/10/2010	18/05/2011	SPC, Labelling and PL	The Agency accepted the group of variations to extend the shelf life of oral powder for pigs to 2 years, to add a new specification parameter to the specification for 8.5 mg/g

	life of the finished product - As packaged for sale (supported by real time data) B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation				premix and oral powder and to increase the in-feed shelf life of 8.5 mg/g premix to 2 months in meal.
IB/0043	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	12/10/2010	12/10/2010		The Agency accepted the variation for the addition of a manufacturer of finished product for the 625 mg/g granules for use in drinking water for pheasants and 42.5 mg/g oral powder for pigs.
IB/0042	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	25/11/2009	15/03/2010	SPC, Labelling and PL	The Agency accepted the variation to extend the shelf life of the 42.5 mg/g premix for medicated feeding stuff for pigs from 18 to 24 months.
X/0037	X-3-III Extension to a new strength	14/10/2009	14/12/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new pharmaceutical strength (42.5 mg/g) oral powder for pigs.
X/0036	X-4-I Addition or change of target species	14/10/2009	14/12/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new target species, 625 mg/g Granules for use in drinking water for pheasants.
IB/0041	1B-07-c Replacement or addition of a manufacturing site for part or all of manufacturing process	25/11/2009	25/11/2009		The Agency accepted the variation for an additional manufacturer of the intermediate product for the 8.5 mg/g premix for medicated feeding stuff for pigs and 8.5 mg/g oral powder for pigs.
IB/0040	1B-07-c Replacement or addition of a manufacturing site for part or all of manufacturing process	25/11/2009	25/11/2009		The Agency accepted the variation for an additional manufacturer of the finished product for the 42.5 mg/g premix for medicated feeding stuff for pigs.
IB/0039	1B-07-c Replacement or addition of a manufacturing site for part or all of manufacturing process	07/09/2009	07/09/2009		The Agency accepted the variation for an additional manufacturer for the 625 mg/g Granules for use in drinking water for chickens and pigs.
R/0038	Renewal of the marketing authorisation.	17/06/2009	27/08/2009		The European Commission renewed the marketing authorisation for Aivlosin.
X/0032	X-3-IV Change or addition of a new pharmaceutical form	11/03/2009	11/05/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new pharmaceutical form (granules for use in drinking water) for pigs. The new presentations are intended for the treatment and prevention of Porcine Proliferative Enteropathy (ileitis) caused by Lawsonia intracellularis in pigs.
II/0034	II - New presentation	11/02/2009	18/03/2009	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation regarding an update to the quality part of the dossier for Aivlosin including an update

					on the method of analysis for tylvalosin and its impurities. In addition, the variation concerned some changes for the granules for use in drinking water for chickens only, i.e. an extension of the shelf-life from 2 years to 3 years, an additional pack size of 400 grams and a change in the wording of the SPC in relation to incompatibilities.
II/0031	II - Other quality changes	17/09/2008	20/10/2008	SPC	The European Commission amended the decision granting the marketing authorisation regarding an update to the quality part of the dossier including new packaging material for the finished product (aluminium foil laminated bags) and a change in the shelf life of the finished product, 42.5 mg/g premix for medicated feeding stuff (18 months).
N/0033	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/07/2008	16/07/2008	PL	A notification of a change in the local representatives was sent to the European Commission.
IB/0030	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	25/02/2008	05/06/2008	SPC	The Agency accepted the variation for an increase of the shelf life (from 2 to 3 years) of the finished product for the 8.5 mg/g oral powder and premix for medicated feeding stuff presentations.
X/0026	X-3-IV Change or addition of a new pharmaceutical form	16/04/2008	05/06/2008	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new target species (chicken) and a new pharmaceutical form, granules for use in drinking water. The new presentation is intended for the treatment and prevention of respiratory disease associated with Mycoplasma gallisepticum in chickens.
II/0029	II - Other quality changes	16/01/2008	05/02/2008	SPC	The European Commission amended the decision granting the marketing authorisation regarding a change in the shelf life of the 42.5 mg/g presentation from 24 to 12 months (as a result of the assessment of follow-up measures).
IA/0028	1A-03 Change in name of active substance	25/05/2007	19/12/2007	SPC, Annex II, Labelling and PL	The Agency accepted the variation for a change in the name of the active substance from "acetylisovaleryltylosin" to the new INN "tylvalosin".
II/0027	II - Other quality changes	11/07/2007	16/07/2007		The European Commission amended the decision granting the marketing authorisation regarding an update to the quality part of the dossier.
IB/0020	1B-41-b Change in pack size of finished product	11/08/2006	23/02/2007	SPC, Labelling and PL	The Agency accepted the variation for the addition of a new pack size (3 kg) for the 8.5 mg/g oral powder for pigs.
IB/0019	1A-43-b Addition or replacement or deletion of a measuring or administration device	08/09/2006	23/02/2007	SPC, Labelling and PL	The Agency accepted the variation for the addition of a measuring device (25 ml scoop) for the 8.5 mg/g oral powder for pigs.
IB/0018	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	03/08/2006	23/02/2007	SPC	The Agency accepted the variation for a change of shelf life of the finished product from 18 months to 24 months for the 8.5 mg/g oral powder for pigs.

IB/0017	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	17/07/2006	23/02/2007	SPC	The Agency accepted the variation for a change of shelf life of the finished product from 18 months to 24 months for the 8.5 mg/g Premix for medicated feeding stuff for pigs.
IA/0025	1A-08-a Change to batch release arrangements and quality control testing of the finished product	17/01/2007	17/01/2007		The Agency accepted the variation (No. 8a) for a change to batch release arrangements and quality control testing of the finished product (change of address/relocation of an approved laboratory for batch control/testing).
IA/0024	1A-08-a Change to batch release arrangements and quality control testing of the finished product	07/11/2006	07/11/2006		The Agency accepted the variation (No. 8a) for an additional site where batch control/testing takes place.
1A/0023	1A-08-a Change to batch release arrangements and quality control testing of the finished product	13/09/2006	13/09/2006		The Agency accepted the variation for an additional site where batch control/testing takes place.
II/0005	II - New Indication (same therapeutic area)	19/04/2006	22/05/2006	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new indication, the treatment of clinical outbreaks of swine dysentery caused by Brachyspira hyodysenteriae in herds where the disease has been diagnosed, and prevention of further clinical cases.
II/0004	II - New Indication (same therapeutic area)	19/04/2006	22/05/2006	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new indication, the treatment of porcine proliferative enteropathy (ileitis) caused by Lawsonia intracellularis in herds where there is a diagnosis based on clinical history, post-mortem findings and clinical pathology results.
IA/0014	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	17/05/2006	17/05/2006		The Agency accepted the variation concerning a minor change in the HPLC analytical test method for release of the finished product and shelf life testing for the 42.5 mg/g Premix.
IB/0012	1B-41-b Change in pack size of finished product	12/07/2005	02/02/2006	SPC, Labelling and PL	The Agency accepted the variation introducing a new pack size of 5 kg.
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/07/2005	02/02/2006	PL	The EMEA notified the European Commission about an update in the package insert and changes in the list of local representatives. Amendments have been incorporated in Annex IIIB of the Commission Decision and the relevant sections of the EPAR.
X/0008	X-3-IV Change or addition of a new pharmaceutical form	08/11/2005	02/02/2006	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new pharmaceutical form, oral powder. The new presentation is intended for the use in individual pigs on farms where only a small number of pigs are to receive the medicine. Larger groups should be treated with medicated feeding stuff containing the premix. The product is to be thoroughly mixed into the daily feed ration for each individual pig.

X/0007	X-3-III Extension to a new strength	08/11/2005	02/02/2006	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add a new lower strength (8.5 mg/g) of the premix for medicated feeding stuff. The inclusion rate of the new strength in pig feed (daily dose of 2.125 mg acetylisovaleryltylosin per kg bodyweight) corresponds to 5 kg Aivlosin per tonne feed i.e. 0.5%. This inclusion rate, therefore, is in accordance with the recommendations given in the European Pharmacopoeia monograph for premixes for medicated feeding stuffs.
IB/0013	1B-14-b Change in manufacturer active substance or starting material-new manufacturer	10/11/2005	10/11/2005		The Agency accepted the variation regarding an additional manufacturing site of the active substance in Japan.
II/0010	II - Other quality changes	07/09/2005	12/09/2005		The European Commission amended the decision granting the marketing authorisation to change in the manufacturing site of the active substance from Japan to China.
II/0003	II - Other quality changes	13/04/2005	16/06/2005	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to modify the wording in Sections 4.1 and 4.2 of the SPC (pharmacodynamic and pharmacokinetic properties). The proposed changes concerned mycoplasmacidal activity, resistance development, accumulation in certain cells and plasma distribution. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
II/0006	II - Other quality changes	17/05/2005	19/05/2005		The European Commission amended the decision granting the marketing authorisation to change the manufacturing site of the intermediate product from Japan to the United Kingdom.
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	24/02/2005	15/04/2005	PL	The EMEA notified the European Commission about an update in the package insert and changes in the list of local representatives. Amendments have been incorporated in Annex IIIB of the Commission Decision and the relevant sections of the EPAR.
II/0002	II - Other quality changes	09/03/2005	15/04/2005	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to modify the wording in the SPC and product literature in relation to the compatibility of the product with other products. The applicant had provided compatibility studies involving four different classes of veterinary medicinal products. The CVMP considered the diversity in the different types of feeding stuffs used in pigs and the large number of different premixes authorised for use in pigs and agreed that the compatibility studies provided were sufficient to support the proposed changes. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.

N/0001	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/10/2004	15/04/2005	PL	The EMEA notified the European Commission about changes to aspects of the package insert not connected to the Summary of Product Characteristics. The marketing authorisation holder has introduced a package insert in the form of an A5 booklet with all EU languages including the local representatives. Amendments have been incorporated in Annex IIIB of the Commission Decision and the relevant sections of the EPAR.