EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Draxxin

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/0049	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 implement changes to section 4.5 of the SPC and section 12 of the product leaflet following assessment of a PSUR. The applicant also took the opportunity to correct the translations errors and to amend a minor error in section 1 of the product leaflet of Draxxin 25 mg/ml.
IB/0048	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	19/02/2021		SPC and PL	The Agency accepted the variation to amend the wording of certain SPC and package leaflet sections and to align the product information with the latest QRD template.
IB/0047/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.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing	04/06/2020	09/02/2021	Annex II and PL	The Agency accepted the group of variations, for the 25 mg/ml strength, including the change to add an alternative as manufacturing site responsible for batch release, including batch testing. The MAH took the opportunity to align the PI according to the latest QRD template and to correct the IT, ES, PL and DE translations in line with the EN text.

[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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	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.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation 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.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
IB/0046	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/02/2020	09/02/2021	SPC and PL	The Agency accepted the variation to add a standard sentence to Section 4.5 of the SPC and to Section 12 of the package leaflet.
IB/0045	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	19/07/2019	23/10/2019	SPC and PL	The Agency accepted the variation to process the changes in the product information following the outcome of a procedure concerning PSUR.
IB/0044	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/06/2019	23/10/2019	SPC, Labelling and PL	The Agency accepted the variation to correct translation errors in the product information in several language versions (BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IT, LT, LV, MT, NO, PL, PT, RO, SE, SI and SK).
IB/0043	B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	20/12/2018	n/a		The Agency accepted the variation to introduce a new batch size range.
IG/0976	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	26/10/2018	23/10/2019	PL	The Agency accepted the variation to delete the list of local representatives from the product information.
IG/0951	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	05/07/2018	n/a		n/a
IG/0936	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	13/06/2018	n/a		The Agency accepted the group of variations to make a change in the legal entity name of the manufacturing site used to manufacture the finished products.
IG/0851	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	15/11/2017	n/a		The Agency accepted the variation to change the name of the secondary packaging site.

IB/0038/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.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.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 B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	27/10/2017	22/03/2018	Annex II and PL	The Agency accepted the group of variations to add alternate manufacturing sites for the finished product, to change the in-process tests and the batch size.
IG/0812	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	15/06/2017	n/a		The Agency accepted the variation to change the legal entity name of the manufacturing site used to manufacture the finished products Cerenia 10 mg/ml Solution for Injection and Draxxin 100 mg/ml and 25 mg/ml Solution for Injection.
IG/0747	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	23/03/2017	22/03/2018	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
X/0029	Annex I_3. Other changes specific to veterinary medicinal products to be administered to food-producing animals: change or addition of target species	08/09/2016	09/11/2016	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add sheep as a target species for the 100 mg/ml strength.
II/0035	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	08/09/2016	09/11/2016	SPC and PL	The European Commission amended the decision granting the marketing authorisation for the addition of wording to the SPC, Section 5.1 Pharmacodynamic properties regarding the anti-inflammatory and immune-modulating properties that have been observed in cattle and pigs.

II/0031	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	18/02/2016	27/04/2016	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add a new therapeutic indication for use in swine respiratory disease (SRD) associated with Bordetella bronchiseptica.
II/0034	C.II.3 - Changes to the withdrawal period for a veterinary medicinal product	12/03/2015	13/04/2015	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to change the withdrawal periods for cattle and pigs affecting all registered Draxxin presentations, following the revision of MRLs for tulathromycin.
IAIN/0033	B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	14/01/2015	13/04/2015	Annex II and PL	The Agency accepted the variation to change the manufacturer responsible for importation and batch release, including batch control/testing for Draxxin 25 mg/ml solution for injection for pigs.
IG/0445	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	20/11/2014	13/04/2015	Annex II and PL	The Agency accepted the variation to change the name of the manufacturing site of the finished product responsible for batch release.
IA/0030	A.7 - Administrative change - Deletion of manufacturing sites	03/09/2014	n/a		The Agency accepted the variation to remove a manufacturing site for the active substance of Draxxin 100mg/ml solution for injection for cattle and pigs.
X/0026	Annex I_2.(c) Change or addition of a new strength/potency	08/05/2014	08/07/2014	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for a line extension-addition of 25 mg/ml solution for injection for pigs only.
IG/0357/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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	31/10/2013	n/a		The Agency accepted the variation to add two manufacturing sites for secondary packaging.
IAIN/0027	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	05/09/2013	08/07/2014	SPC, Annex II, Labelling and PL	The Agency accepted the variation to add an additional manufacturer responsible for batch release.
T/0025	Transfer of Marketing Authorisation	30/04/2013	22/05/2013	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Pfizer Ltd' to 'Zoetis Belgium SA'.
IB/0024/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.b.1.h - Change in the specification parameters and/or limits of an AS, starting	31/10/2012	n/a		The Agency accepted the group of variations relating to the manufacturing process of the active substance.

	material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue B.I.b.1.h - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition or replacement (excl. Biol. or immunol. substance) of a specification parameter as a result of a safety or quality issue 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.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				
IB/0022	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	02/12/2011	n/a		The Agency accepted the variation to replace a current test method for release and stability testing of the active substance.
IB/0021/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.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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	23/11/2011	n/a		The Agency accepted the group of variations to add an alternate finished product manufacturer, make a minor change in the test procedure for the finished product and to change the batch size of the finished product.
II/0020	X-4-I Addition or change of target species	10/02/2010	15/03/2010	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for the addition of pigs to the 250 ml presentation of Draxxin 100 mg/ml solution for injection. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.
R/0019	Renewal of the marketing authorisation.	16/07/2008	19/09/2008		The European Commission renewed the marketing authorisation for Draxxin.
II/0017	II - New Indication (same therapeutic area)	14/05/2008	20/06/2008	SPC and PL	The European Commission amended the decision granting the marketing authorisation for the addition of the

					pathogen Haemophilus parasuis to the indication for the treatment and prevention of respiratory disease in pigs. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.
IB/0018	1B-14-b Change in manufacturer active substance or starting material-new manufacturer	10/01/2008	10/01/2008		The Agency accepted the variation to add an alternate manufacturing source for the active substance.
IB/0015	1B-13-b Change in test procedure for active substance or starting material-other changes test procedure	14/11/2007	14/11/2007		The Agency accepted the variation to replace a test method with an alternate test method.
IA/0016	1A-13-a Change in test procedure for active substance or starting material-minor changes test procedure	18/10/2007	18/10/2007		The Agency accepted the variation to make a minor change in a test procedure.
IB/0014	1B-10 Minor change in the manufacturing process of the active substance	15/05/2007	15/05/2007		The Agency accepted the variation to change the manufacturing process of the active substance.
IB/0009	1B-13-b Change in test procedure for active substance or starting material-other changes test procedure 1B-12-b2 Addition new test parameter to specification of starting material/intermediate/	23/03/2007	23/03/2007		The Agency accepted the variation to add an alternate test procedure (ultraviolet detection) and a consequential change in the specification due to the addition of this alternate test procedure.
IA/0013	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	02/03/2007	02/03/2007		The Agency accepted the variation to clarify the operational details of approved test procedures.
IA/0012	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	02/03/2007	02/03/2007		The Agency accepted the variation to clarify the operational details of approved test procedures.
IA/0011	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	02/03/2007	02/03/2007		The Agency accepted the variation to clarify the operational details of approved test procedures.
IA/0010	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	02/03/2007	02/03/2007		The Agency accepted the variation to clarify the operational details of approved test procedures.
II/0007	II - New Indication (same therapeutic area)	17/01/2007	20/02/2007	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for the addition of an indication for the treatment of infectious bovine keratoconjunctivitis (IBK). Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.
II/0006	II - New Indication (same therapeutic area)	17/01/2007	20/02/2007	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for the addition of an indication for the prevention of respiratory disease in pigs. The proposed pathogens are identical to those already approved under the indication for the treatment of respiratory disease in pigs. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.
IA/0005	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	07/03/2006	07/03/2006		The Agency accepted the variation to update the methods

					of procedure related to the finished product specification.
II/0004	II - New Indication (same therapeutic area)	17/05/2005	24/06/2005	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for an additional indication for the treatment and prevention of bovine respiratory disease associated with Mycoplasma bovis sensitive to tulathromycin. Amendments have been incorporated into the relevant sections of the Commission Decision and of the EPAR.
N/0003	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/04/2004	31/08/2004	PL	The EMEA accepted a notification to update the package insert with regard to the list of local representatives to include those from the ten new EU Member States.
IB/0002	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	08/01/2004	31/08/2004	SPC, Labelling and PL	The Agency accepted the variation to extend the shelf-life of the product from 18 to 36 months.
IB/0001	1B-17-a Change in the re-test period of the active substance	08/01/2004	31/08/2004		The Agency accepted the variation to extend the re-test period of the active substance from 24 to 36 months.