EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Broadline

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]
IG/1203	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	20/03/2020		Annex II and PL	To change the name of the site responsible for batch release of the finished product from Merial SAS (4 Chemin du Calquet, 31000, Toulouse, France) to Boehringer Ingelheim Animal Health France SCS. The address remains unchanged.
T/0028	Transfer of Marketing Authorisation	19/11/2019	17/12/2019	SPC, Labelling and PL	The European Commission transferred the marketing authorisation for Broadline from 'MERIAL' to 'Boehringer Ingehleim Vetmetdica GmbH.
IA/0027	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	14/11/2019	n/a		n/a
IB/0026	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	11/10/2019	17/12/2019	SPC and PL	The Agency accepted the variation to update the Summary of Product Characteristics (SPC) and the package leaflet to implement an agreed wording following assessment of a PSUR.
II/0024	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or	18/07/2019	29/08/2019	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add a new therapeutic

[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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	modification of an approved one				indication: treatment of infections with Ancylostoma ceylanicum (L4 larvae and adults).
IG/1127/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	10/07/2019	n/a		n/a
II/0023	B.I.z - Quality change - Active substance - Other variation	17/04/2019	n/a		The Agency accepted the variation relating to register substantial changes in the updated version of the restricted part of the ASMF for the active substance (S)-methoprene, and editorial changes in the applicant's part with no impact on the part 2C1.
IAIN/0022/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 B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS	03/10/2018	n/a		The Agency accepted the group of variations to change some specifications and test procedures for the active substance in order to comply with the new Ph. Eur. Monograph; and to change the address of the ASMF holder and supplier of the active substance.
R/0020	Renewal of the marketing authorisation.	19/07/2018	24/09/2018		The European Commission renewed the marketing authorisation for Broadline.
IB/0021/G	This was an application for a group of variations. B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits 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 B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products B.II.e.7.b - Change in supplier of packaging	03/08/2018	n/a		The Agency accepted the group of variations to add an alternative supplier for the immediate packaging (applicator), and to implement consequential changes to composition and dimensions of the immediate packaging, as well as to update the specification for fill volume.

	components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
IB/0019/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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.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.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	14/06/2018	n/a		For the active substance eprinomectin, the Agency accepted the group of variations to register changes to the manufacturing process, changes to in-process tests/limits and to delete a manufacturing site.
IA/0018	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	19/01/2018	n/a		The Agency accepted the variation to register an updated certificate of suitability for the active substance praziquantel.
IA/0017	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	03/07/2017	n/a		The Agency accepted the variation to add a supplier of a packaging component.
II/0013	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	12/05/2017	13/06/2017	SPC and PL	The European Commission amended the decision granting the marketing authorisation to extend the spectrum of efficacy with the addition of three cestodes, one nematode lungworm, and the cat liver fluke.
IB/0016/G	This was an application for a group of variations. B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	09/06/2017	27/06/2018	SPC, Labelling and PL	The Agency accepted the group of variations to change the storage conditions of the finished product and to implement the agreed wording in the product information in accordance with the outcome of the assessment of a PSUR.
IA/0015/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	04/04/2017	n/a		The Agency accepted the variation to delete a secondary packaging site and to register minor changes to the manufacturing process of the finished product.
II/0011	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	08/12/2016	13/06/2017	SPC	The Agency has accepted a variation to change the release and shelf life specifications.
IA/0014	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	25/11/2016	n/a		The Agency accepted the variation to change the name of the manufacturer for the active substance fipronil.

IB/0012/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	05/08/2016	29/11/2016	SPC, Labelling and PL	The agency accepted the group of variations to add a new pack size of 15 applicators in spot-on applicator for Broadline 24.9 mg and for Broadline 74.7 mg spot-on solution. The new pack sizes are intended for use by veterinarians.
IA/0010	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	25/05/2016	n/a		The Agency accepted the variation to introduce minor changes to an approved test procedure of the active substance fipronil.
IAIN/0009	A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	20/11/2015	29/11/2016	Annex II and PL	The Agency accepted the variation to change the address of the manufacturer of the finished product and batch release.
IG/0592	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	04/09/2015	n/a		n/a
IB/0007	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	31/07/2015	n/a		The Agency accepted the variation to register an updated Ph. Eur. certificate of suitability of one of the active ingredients of Broadline, from an already approved manufacturer.
II/0001	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	12/03/2015	13/04/2015	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add the following indications in the target species (cats): - treatment of infestations with feline lungworms (L3, L4, immature adults and adults of Aelurostrongylus abstrusus) - treatment of notoedric mange (Notoedres Cati).
IB/0004/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.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	19/02/2015	n/a		The Agency accepted a variation to add a new manufacturing site for an intermediate used in the manufacture fipronil active substance and to increase the batch size as a consequence.
IB/0005	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	23/12/2014	n/a		The Agency accepted the variation to add an alternative manufacturer for the starting material.
IB/0003/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	12/12/2014	n/a		The Agency accepted a group of variations to add a new manufacturing site for one of the active substances with consequential changes to the manufacturing process and testing.

	of the AS 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.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture 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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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/0002	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	04/08/2014	n/a		The Agency accepted the variation to extend the re-test period of the active substance based on real time data.