NEXGARD SPECTRA

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
WS/1338/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	13/09/2018	18/10/2018	SPC and PL	The European Commission amended the decision granting the marketing authorisation to add new therapeutic indications: for the treatment of demodicosis (caused by *Demodex canis*) and sarcoptic mange (caused by *Sarcoptes scabiei* var. *canis*).
IB/0016	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	17/08/2018	n/a		The Agency accepted the variation to register an alternative HPLC testing method for the determination of the related substances in the active substance milbemycin oxime.
IG/0961	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)	31/07/2018	n/a		The Agency accepted the variation to change the name of a manufacturer and to correct an error in the address of another manufacturing site.
IG/0876	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase	05/01/2018	n/a		The Agency accepted the variation to register an alternative

[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).

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	compared to the originally approved batch size				increased batch size of the intermediate substance.
IB/0013/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.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 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 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.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	30/11/2017	18/10/2018	SPC, Labelling and PL	The Agency accepted the grouped variation: - to make available a new pack size of 15 chewable tablets, for NEXGARD SPECTRA for all strengths currently registered; - to change the weight of the secondary packaging paperboard carton; - to add a new secondary packaging site for the finished product.
IA/0012/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.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	17/10/2017	n/a		The Agency accepted the variation to add alternative suppliers for the primary packaging, and consequently, to register a change in the composition and specification of the primary packaging.
II/0011	B.I.a.1.b - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a manufacturer of the AS supported by an ASMF	07/09/2017	n/a		The Agency approved the variation to introduce a new manufacturer for the active substance milbemycin oxime.
II/0008	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	16/03/2017	15/05/2017	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to add new indications: Prevention of angiostrongylosis (by reduction of the level of infection with immature adult (L5) and adult stages of

					Angiostrongylus vasorum) with monthly administration, Treatment of Ancylostoma ceylanicum.
IA/0010/G	This was an application for a group of variations. 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 B.I.c.2.b - Change in the specification parameters and/or limits of the immediate packaging of the AS - Addition of a new specification parameter to the specification with its corresponding test method	20/03/2017	n/a		The Agency accepted the group of variations for changes to the test method.
IA/0009	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	16/01/2017	n/a		The Agency accepted the variation to register a minor change to a test procedure.
IA/0007	B.II.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter	09/06/2016	n/a		The Agency accepted the variation to delete an obsolete specification parameter, test of uniformity of dosage units, from the shelf-life specifications of the finished product.
IA/0006	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	22/04/2016	n/a		The Agency accepted the variation relating to minor changes to the manufacturing process of the finished product.
IG/0610	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	25/09/2015	n/a		The Agency accepted a variation to register an increased batch size for the intermediate substance obtained during the manufacturing process of afoxolaner.
WS/0756	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.g - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Introduction of a new manufacturer of the AS that is not supported by an ASMF and requires significant update to the relevant AS section in the dossier	10/09/2015	n/a		The European Commission amended the Decision granting the marketing authorisation to introduce a new manufacturing site for the active substance.
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		The Agency accepted the variation to change the QPPV.
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	03/07/2015	n/a		The Agency accepted the variation to extend the retest period of afoxolaner used by Merial in the manufacture of afoxolaner-based chewable tablets for dogs.
IG/0548	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	30/04/2015	n/a		The Agency accepted a variation to introduce a minor change in an approved test procedure.