Simparica

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]
R/0018	Renewal of the marketing authorisation.	18/06/2020	12/08/2020	SPC and PL	The European Commission renewed the marketing authorisation for Simparica.
IG/1249/G	This was an application for a group of variations. 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.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.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	26/05/2020	n/a		n/a
WS/1709	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	05/12/2019	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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IG/1164	B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	14/11/2019	n/a		n/a
WS/1611	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.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	22/05/2019	n/a		n/a
WS/1553	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	21/03/2019	29/10/2019	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. In addition, the applicant took the opportunity to delete the list of local representatives in the package leaflet of MiPet Easecto.
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	29/10/2019	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		The Agency accepted the variation to update the current detailed description of the pharmacovigilance system (DDPS).
IAIN/0010	B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	11/10/2017	n/a		The Agency accepted the variation to add a new primary packaging site.
II/0006	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	07/09/2017	10/10/2017	SPC and PL	The European Commission amended the Decision granting the marketing authorisation to add new indications for the treatment of ear mites and demodicosis in dogs.
IB/0009	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	11/08/2017	10/10/2017	SPC, Labelling and PL	The Agency accepted the variation to amend the SPC and package leaflet following assessment of a PSUR. The product information was simultaneously aligned with the latest QRD template, including minor editorial changes.
IA/0008	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)	14/07/2017	n/a		The Agency accepted the variation to amend the name of the secondary packaging site.
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	10/10/2017	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
IB/0005	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	16/03/2017	n/a		The Agency accepted the variation to extend the hold time of the bulk chewable tablets.
IB/0003	B.II.g.z - Design space and post approval change management control - Other variation	25/10/2016	n/a		The Agency accepted the variation to set the shelf life start date of the finished product to the day of the introduction of

					the intermediate into the finished product formulation.
IA/0002	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	15/06/2016	18/01/2017	SPC	The Agency accepted the variation to change the ATC Code of sarolaner from QP53BX06 to QP53BE03.
IB/0001	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)	08/01/2016	18/01/2017	SPC	The Agency accepted the variation to extend the shelf life to 30 months.