Suvaxyn Circo+MH RTU

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/0018	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	14/10/2021		SPC	The Agency accepted the variation to extend the shelf life of the finished product from 18 months to 24 months.
WS/2010	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	18/03/2021	n/a		n/a
R/0015	Renewal of the marketing authorisation.	16/07/2020	16/09/2020	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Suvaxyn Circo+MH RTU.
WS/1852/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. B.I.a.1.e - Change in the manufacturer of AS or of a	10/09/2020	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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS				
WS/1668	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.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	10/10/2019	n/a		n/a
WS/1606	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	20/06/2019	n/a		n/a
IAIN/0012	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	18/03/2019	18/10/2019	SPC, Labelling and PL	The Agency accepted the variation to add a standard warning in the SPC and package leaflet, following the last PSUR assessment.
IG/1035	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	28/02/2019	n/a		The Agency accepted the variation to introduce a minor change in the test procedure for the active substance.
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	18/10/2019	PL	The Agency accepted the variation to delete the list of local representatives from the product information.
IG/0945	B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer	10/08/2018	n/a		The Agency accepted the variation to add two new TSE certificates of suitability for suppliers of starting material.
IB/0007	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	03/08/2018	n/a		The Agency accepted the variation for a change in a test procedure for the active substance.
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
II/0005/G	This was an application for a group of variations.	15/06/2017	n/a		The Agency accepted the group of variations to amend the

	B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation				manufacturing process.
II/0004/G	This was an application for a group of variations. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	12/04/2017	17/05/2017	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to increase the duration of immunity for the Mycoplasma Hyopneumoniae component and to increase the upper limit for finished product potency for the PCV2 component.
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	17/05/2017	SPC, Labelling and PL	The Agency accepted the variation to update the list of local representatives in the product information.
II/0002	B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product	14/07/2016	17/05/2017	SPC	The Agency accepted the variation to change the manufacturing process.
IB/0003	C.II.6.b - Changes to the labelling or the PL which are not connected with the SPC - Other changes	01/07/2016	17/05/2017	Labelling	The Agency accepted the variation to update the labelling to reduce the label text registered for the 50 dose presentation to align it to the approved 25 dose reduced label text requirements.
IB/0001	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	11/03/2016	n/a		The Agency accepted the variation for a change in the manufacturing process of the active substance.