Vectormune ND

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]
WS/1892	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.5.c - Change in pack size of the finished product - Change in the fill weight/fill volume of sterile multidose (or single-dose, partial use) parenteral medicinal products, including biological/immunological medicinal products	17/02/2021		SPC, Labelling and PL	The Agency accepted a worksharing variation to add new, larger presentations of the solvent: 1000, 1200, and 1600 ml, in the same container closure system, beside the approved 200, 400, and 800 ml. This change concerns Vectormune ND and five nationally authorised veterinary medicinal products.
R/0013	Renewal of the marketing authorisation.	20/05/2020	20/07/2020	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Vectormune ND.
IAIN/0012/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets,	10/01/2020	20/07/2020	SPC and PL	The Agency accepted the group of variations to add three new presentations and to delete the existing presentations.

[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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	ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
WS/1597/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.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.e.4.c - Change in shape or dimensions of the container or closure (immediate packaging) - Sterile medicinal products B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	07/11/2019	20/07/2020	SPC	The Agency accepted the group of quality variations, including the one to reduce the shelf life of the solvent from 3 years to 30 months.
IAIN/0010	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	24/07/2018	09/08/2019	SPC, Labelling and PL	The Agency accepted the variation to change the name of the solvent, and to update the labelling for the solvent.
II/0009/G	This was an application for a group of variations. B.I.a.1.e - Change in the manufacturer of AS or of a 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.2.z - Changes in the manufacturing process of the AS - Other variation	19/04/2018	n/a		The Agency accepted the group of variations to add a new supplier for a starting material, and to implement changes in the antigen production process.
II/0007	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	18/01/2018	20/02/2018	SPC and PL	The Agency accepted the variation to add a new category of target species -layer chickens- and to precise the current indication.
WS/1082	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	09/11/2017	20/02/2018	SPC and PL	The Agency accepted the variation to add mixed, associated use for Vectormune ND and Cevac Transmune by subcutaneous and in-ovo use, in day-old broiler chickens and 18-day-old embryonated broiler chicken eggs. The applicant also took the opportunity to remove the list of local representatives from the package leaflet.
IG/0827/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	17/07/2017	n/a		n/a

	QPPV and/or QPPV contact details and/or back-up procedure 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				
II/0004	B.II.d.3 - Variations related to the introduction of real-time release or parametric release in the manufacture of the finished product	14/07/2016	n/a		The Agency accepted a variation to change the test method of the solvent
IA/0005	A.7 - Administrative change - Deletion of manufacturing sites	28/06/2016	n/a		The Agency accepted the variation to delete a manufacturing site.
IB/0003/G	This was an application for a group of variations. 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) 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	18/02/2016	10/02/2017	SPC and Labelling	The Agency accepted a variation to extend the shelf-life of the solvent, to modify the text of the vaccine and solvent labels.
II/0001	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	06/11/2015	n/a		The Agency accepted the variation to add a manufacturing site.
IG/0620	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	06/11/2015	n/a		The Agency accepted the variation to update the detailed description of pharmacovigilance system (DDPS).