Nobivac L4

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/1871/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.a.3.b.3 - Changes in the composition (excipients) of the finished product - Other excipients - Change that relates to a biological/immunological product B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)	09/09/2020		SPC, Labelling and PL	The Agency accepted the variation to delete the multi-dose presentation (10 ml) and consequently remove the excipient - thiomersal from the finished product.
WS/1439/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.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 B.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires	06/12/2018	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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	assessment of the comparability of a biological/immunological AS B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)				
IG/0967/G	This was an application for a group of variations. 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	26/07/2018	n/a		n/a
IB/0008/G	This was an application for a group of variations. C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale	13/07/2017	23/07/2018	SPC, Labelling and PL	The Agency accepted the variation to update the product information following assessment of a PSUR and to reduce the shelf life of the finished product as packaged for sale.
R/0007	Renewal of the marketing authorisation.	19/01/2017	13/03/2017	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Nobivac L4.
IG/0718/G	This was an application for a group of variations. 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	22/09/2016	n/a		n/a
IB/0005	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	12/08/2016	13/03/2017	SPC and PL	The Agency accepted the variation to update section 4.6 of the SPC following the outcome of the assessments of a PSUR. The package leaflet is updated accordingly.
IAIN/0004	C.II.8 - Change in the frequency and/or date of submission of PSURs	20/01/2016	n/a		The Agency accepted the variation to amend the PSUR cycle for Nobivac L4.
II/0003	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	07/05/2015	03/06/2016	SPC, Annex II, Labelling and PL	The Agency accepted the variation to update the SPC and the package leaflet of Nobivac L4 to include a mixed use claim with Nobivac vaccines containing the live canine parainfluenza virus component for subcutaneous use.
IG/0465	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	20/08/2014	n/a		The Agency accepted the variation to change the qualified person for pharmacovigilance (QPPV).

	procedure				
II/0001	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	18/07/2013	n/a		The Agency accepted the variation to change the in-process pre-inactivation limits used during the manufacturing of the Leptospira antigens for Nobivac L4.