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/2058	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	07/10/2021		SPC and PL	The variation is to introduce the associated non-mixed use (at the same time but not mixed) of Nobivac L4 with Nobivac Respira Bb. In addition, an editorial change is made in SPC sections 4.8, 4.9 and relevant leaflet sections.
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	16/09/2021	SPC, Labelling and PL	The Agency accepted the group of variations 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.	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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	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 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 procedure	20/08/2014	n/a		The Agency accepted the variation to change the qualified person for pharmacovigilance (QPPV).
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.