EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Nobivac Myxo-RHD

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]
IG/1348	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	18/03/2021		Annex II	The Agency accepted the variation to change the address of the active substance manufacturer.
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
IG/0718/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(s) in the	22/09/2016	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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	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				
IAIN/0006	B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information	05/08/2016	14/09/2017	SPC, Labelling and PL	The Agency accepted the variation to change the secondary packaging material from cardboard to plastic.
R/0005	Renewal of the marketing authorisation.	21/04/2016	21/06/2016	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Nobivac Myxo-RHD.
IB/0004	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	13/02/2015	26/03/2015	SPC and PL	The Agency accepted the variation to introduce changes to the SPC and package leaflet following PSUR assessments.
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).
IB/0002	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	14/02/2014	19/02/2015	SPC and PL	The Agency accepted the variation on the changes to the SPC due to the outcome of PSUR assessments.
II/0001	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	12/07/2013	n/a		The Agency accepted the variation on the addition of an additional manufacturing site with a minor change in the manufacturing process of the active substance.