Nobivac Myxo-RHD

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
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		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	12/07/2012	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.

[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] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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