Nobivac LeuFel

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/1409	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	07/10/2021		PL	The Agency accepted the variation to update the list of local representatives.
IG/0808	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	29/05/2019	n/a		n/a
WS/1483	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	16/04/2019	01/04/2020	SPC, Labelling and PL	The Agency accepted the variation to mention in section 5 of the SPC and section 15 of the package leaflet that, for the leukaemia component, protection against persistent viraemia is observed in 73% of cats 3 weeks after their first vaccine injection. The Marketing Authorisation Holder also takes the opportunity to make some editorial corrections in the product information and to update the list of local representatives in the package leaflets (including deleting of the UK local representative).
WS/1282	This was an application for a variation following a worksharing procedure according to Article 20 of	21/06/2018	09/08/2018	SPC, Labelling and PL	The European Commission amended the Decision on granting the marketing authorisation to modify the duration

[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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	Commission Regulation (EC) No 1234/2008. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				of immunity of the feline leukemia component.
IG/0932	B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number	25/07/2018	n/a		The Agency accepted the variation to adjust the method of determination of the aluminium content in the vaccines to fully comply with the Ph. Eur. monograph.