LEUCOGEN

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
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		The Agency accepted the variation to update the detailed description of the pharmacovigilance system (DDPS).
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	n/a	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).
IG/0984	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	26/10/2018		PL	The Agency accepted the variation to update the local representatives in the package leaflet.
WS/1282	This was an application for a variation following a worksharing procedure according to Article 20 of	21/06/2018	20/08/2018	SPC, Labelling	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] 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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	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			and PL	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.
IG/0724	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	21/12/2016	20/12/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
IB/0004/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	14/12/2016	n/a		The Agency accepted the group of variations to increase the formulation titre of the vaccine and to adjust slightly the acceptance criteria at release for the titration control.
WS/0639	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	11/12/2014	27/11/2015	SPC and PL	The Agency accepted the variation to rank all the adverse reactions observed during the course of one treatment in "frequency groupings" with the most frequently occurring reactions listed first.
R/0002	Renewal of the marketing authorisation.	10/04/2014	12/06/2014	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation of the product.
WS/0440	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	07/11/2013	n/a		The Agency accepted the variation to adjust the pH specifications of Leucogen and Leucofeligen FeLV/RCP.