Canigen 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]
IB/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/07/2021		SPC and PL	The Agency accepted the variation to remove the mixed use claims.
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		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.
R/0007	Renewal of the marketing authorisation.	20/02/2020	24/04/2020	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Canigen L4.
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. 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	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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

	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
IAIN/0004	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	21/09/2017	23/10/2018	Annex II, Labelling and PL	The Agency accepted the variation to add the addresses of local representatives to the package leaflet. In addition the applicant took the opportunity to correct a few typographical errors in the annexes.
IB/0003/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	10/08/2017	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.
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/0001/G	This was an application for a group of variations. C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	12/08/2016	10/08/2017	SPC and PL	The Agency accepted the variation to include a mixed use claim with vaccines containing the live canine parainfluenza virus component and also to amend the frequency of adverse reactions in the SPC and package leaflet.

	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR				