EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Semintra

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
IB/0004/G	This was an application for a group of variations. B.II.e.5.d - Change in pack size of the finished product - Change in the fill weight/fill volume of nonparenteral multi-dose (or single-dose, partial use) products C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	06/11/2015		SPC, Labelling and PL	The Agency accepted a group of variations to add a 100 ml presentation and to amend a sentence in SPC section "4.9 Amounts to be administered and administration route".
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/09/2014	n/a		The Agency accepted a variation to add an alternative site for secondary packaging and labelling.
IA/0002	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	12/09/2014	n/a		The Agency accepted a variation to change the name of the manufacturing site responsible for EU batch testing.
IAIN/0001	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	12/12/2013	28/11/2014	PL	The Agency accepted the variation to add the address of the Croatian representative in the package leaflet.

[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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