

Bovela

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/0010	C.I.4.z - Change(s) in the SPC, Labelling or package leaflet further to a veterinary PSUR	08/12/2017		SPC and PL	The Agency accepted the variation to update the Summary of Product Characteristics (SPC) and the package leaflet to implement an agreed wording following assessment of a PSUR. The product information was also updated in accordance with the latest version of the QRD template.
IAIN/0009	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/11/2017	n/a		The Agency accepted the variation to replace the secondary packaging site.
IG/0831	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	01/09/2017	19/10/2017	PL	The Agency accepted the variation to delete the list of local representatives from the package leaflet.
IB/0007/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an	17/01/2017	n/a		The Agency accepted the variation to introduce minor adaptations to the test procedures 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).

	approved test procedure				
IG/0722	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	27/09/2016	20/10/2017	PL	The Agency accepted the variation to update the list of local representatives in the package leaflet.
II/0005/G	This was an application for a group of variations. B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorised B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorised B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorised	08/09/2016	n/a		The European Commission amended the decision granting the marketing authorisation to update the test procedures.
IA/0004	B.II.e.3.a - Change in test procedure for the immediate packaging of the finished product - Minor changes to an approved test procedure	27/05/2016	n/a		The Agency accepted the variation to revise the primary packaging documentation.
IA/0003	B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)	25/02/2016	n/a		The Agency accepted the variation to delete the non-significant specification parameter for the filling material for the reagent.
IB/0002/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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 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	13/08/2015	n/a		The Agency accepted the group of variations to make minor changes to a test method.

IAIN/0001	method and test method number B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	03/06/2015	n/a		The Agency accepted the variation to add an alternative site for secondary packaging of the finished product.
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