



Kriptazen

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
IAIN/0005	C.I.3.z - Change(s) in the SPC, Labelling or PL of veterinary medicinal products intended to implement the outcome of a procedure concerning PSUR: implementation of wording agreed by the competent authority that does not require additional assessment	07/10/2021		SPC and PL	The Agency approved a variation to process the changes in the section "Adverse reactions" in the SPC and package leaflet, in accordance with the outcome of the CVMP discussion.
IB/0004/G	This was an application for a group of variations. B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer	24/09/2021	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



IB/0002/G	<p>This was an application for a group of variations.</p> <p>B.IV.2.b - Change in specification parameters and/or limits of a measuring or administration device for veterinary medicinal products - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.IV.2.b - Change in specification parameters and/or limits of a measuring or administration device for veterinary medicinal products - Addition of a new specification parameter to the specification with its corresponding test method</p> <p>B.IV.3.b - Change in test procedure of a measuring or administration device for veterinary medicinal products - Other changes to a test procedure (including replacement or addition)</p> <p>B.IV.2.z - Change in specification parameters and/or limits of a measuring or administration device for veterinary medicinal products - Other variation</p>	19/05/2021	n/a		n/a
IB/0003/G	<p>This was an application for a group of variations.</p> <p>B.II.e.1.z - Change in immediate packaging of the finished product - Other variation</p> <p>B.II.e.1.z - Change in immediate packaging of the finished product - Other variation</p>	19/03/2021		SPC, Labelling and PL	The Agency accepted the group of variations to update the storage conditions and correct use of the pump.
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