Felisecto Plus

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/0004	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	11/06/2021		SPC, Labelling and PL	The Agency accepted the variation to update the product information following the assessment of a PSUR. In addition, the MAH took the opportunity to align the product information with QRD template v8.2 and to correct some minor editorial changes to correctly reflect the English text in some other language versions.
WS/1828	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/06/2020		SPC, Labelling and PL	The Agency accepted the variation to correct translation errors which have been identified in the Bulgarian, Czech, Dutch, Greek, Estonian, Finish, French, Croatian, Hungarian, Icelandic, Lithuanian, Maltese, Portuguese, Romanian, Slovakian, Slovenian and Spanish Product Information (PI) following the outcome of a Product Defect Notification.
IG/1249/G	This was an application for a group of variations. B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size	26/05/2020	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

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	ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size				
IB/0001	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	16/08/2019	n/a		n/a