

Librela

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/0003	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	18/02/2022		SPC and PL	To amend section 4.6 of the Summary of Product Characteristics (SPC) and the corresponding section 6 of the package leaflet following assessment of the 1st PSUR. In addition, the MAH has made some minor editorial changes for the national translations (DE, EL, ES, FI, FR, HR, HU, IT, MT, PL, PT, SK and SV) to better align with the English source and national QRD templates.
IB/0002	B.I.a.3.e - Change in batch size (including batch size ranges) of AS or intermediate - The scale for a biological/immunological AS is increased/decreased without process change (e.g. duplication of line)	17/12/2021	n/a		n/a
II/0001	B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS	15/07/2021	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