

Arti-Cell Forte

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/0004	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	26/08/2020		PL	The Agency accepted the variation to amend the list of local representatives.
IAIN/0002/G	This was an application for a group of variations. A.6 - Administrative change - Change in ATC Code/ATC Vet Code 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	17/07/2020		SPC and PL	The Agency accepted the group of variations to implement a change to section 5 of the SPC to add the ATC Vet Code assigned by WHO and change the name of the local representative in France on the package leaflet.
IAIN/0001/G	This was an application for a group of variations. B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the product information 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 B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the	26/04/2019	16/04/2020	SPC and PL	The Agency accepted the group of variations to make changes in the manufacturing process and to a part of the primary packaging material not in contact with the finished product formulation as well as to update the list of local representatives in the package leaflet. In addition, the MAH has taken the opportunity to make a number of editorial changes in the product information.

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

manufacturing process