

## Arti-Cell Forte

### Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued / amended on	Product Information affected <sup>2</sup>	Summary <sup>3</sup>
IAIN/0009/G	This was an application for a group of variations.  A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	22/10/2021		Annex II and PL	The Agency accepted the group of variations to change the name of a manufacturing site.
IB/0008	C.II.7.b - Introduction of a new Pharmacovigilance system - Which has been assessed by the relevant national competent authority/EMA for another product of the same MAH	22/10/2021	n/a		n/a
T/0007	Transfer of Marketing Authorisation	29/06/2021	26/07/2021	SPC, Labelling and PL	The European Commission transferred the marketing authorisation from 'Global Stem cell Technology NV' in Belgium to 'Boehringer Ingelheim Vetmedica GmbH' in Germany.
IB/0006/G	This was an application for a group of variations.	30/04/2021	n/a		n/a

<sup>1</sup> 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.

<sup>2</sup> SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

<sup>3</sup> Since October 2019 summary information is no longer published for variations that do not impact upon the product information

	B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data				
IAIN/0005	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	21/10/2020	20/07/2021	PL	The Agency accepted the variation to update the address of the local representative for Luxembourg in the package leaflet.
II/0003/G	This was an application for a group of variations.  B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits 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.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.c - Change in test procedure for the finished product - Substantial change to or replacement of a biol/immunol/immunochemical test method or a method using a biol. reagent or replacement of a biol. reference preparation not covered by an approved protocol B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	07/10/2020	n/a		n/a
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	20/07/2021	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	20/07/2021	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	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p> <p>B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process</p>	26/04/2019	16/04/2020	SPC and PL	<p>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.</p>
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