Ruconest

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
II/0088/G	This was an application for a group of variations. Submission of an updated RMP version 20.0 in order to request the early termination of the EU registry study C1 1412, as well as to update safety information based on cumulative data from clinical trials, the EU registry	16/01/2025	n/a		

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	data, post-marketing data and literature. A request for the extension of the due date for the European survey of educational materials for Ruconest is also included. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
IB/0091	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	09/12/2024	n/a		
PSUSA/873/202404	Periodic Safety Update EU Single assessment - conestat alfa	28/11/2024	n/a		PRAC Recommendation - maintenance
IB/0090/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	29/08/2024		Annex II	

	or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.z - Quality change - Active substance - Other variation B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place				
IA/0087	B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number	04/07/2024	n/a		
PSUSA/873/202310	Periodic Safety Update EU Single assessment - conestat alfa	16/05/2024	n/a		PRAC Recommendation - maintenance
IAIN/0086	B.II.d.1.h - Change in the specification parameters and/or limits of the finished product - Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product	19/03/2024	n/a		

PSUSA/873/202304	Periodic Safety Update EU Single assessment - conestat alfa	30/11/2023	n/a		PRAC Recommendation - maintenance
IA/0084/G	This was an application for a group of variations. B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number 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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/11/2023	n/a		
IB/0083	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	05/10/2023	n/a		
PSUSA/873/202210	Periodic Safety Update EU Single assessment - conestat alfa	25/05/2023	26/07/2023	SmPC and PL	Please refer to Ruconest-EMEA/H/C/PSUSA/00000873/202210 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IB/0081	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	20/04/2023	n/a		
IB/0080	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other	12/04/2023	n/a		

	variation				
IB/0078	B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB	07/03/2023	n/a		
IA/0079	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	13/02/2023	n/a		
PSUSA/873/202204	Periodic Safety Update EU Single assessment - conestat alfa	01/12/2022	n/a		PRAC Recommendation - maintenance
IB/0076	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	16/11/2022	n/a		
PSUSA/873/202110	Periodic Safety Update EU Single assessment - conestat alfa	10/06/2022	n/a		PRAC Recommendation - maintenance
IB/0073/G	This was an application for a group of variations. B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation	30/05/2022	n/a		
II/0071	n/a B.I.b.1.f - Change in the specification parameters	12/05/2022	n/a		n/a

	and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS				
IB/0072/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	30/03/2022	n/a		
IB/0068/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	03/12/2021	n/a		
IA/0069	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	02/12/2021	n/a		

PSUSA/873/202104	Periodic Safety Update EU Single assessment - conestat alfa	02/12/2021	n/a		PRAC Recommendation - maintenance
IB/0066	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	05/10/2021	n/a		
IB/0067	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/08/2021	n/a		
PSUSA/873/202010	Periodic Safety Update EU Single assessment - conestat alfa	10/06/2021	n/a		PRAC Recommendation - maintenance
IB/0064/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation A.7 - Administrative change - Deletion of manufacturing sites	02/06/2021	n/a		
II/0063	B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS	20/05/2021	n/a		
II/0058	B.I.b.z - Change in control of the AS - Other variation	04/02/2021	n/a		

N/0060	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/02/2021	26/07/2023	Labelling and PL	
IAIN/0061	B.IV.1.a.1 - Change of a measuring or administration device - Addition or replacement of a device which is not an integrated part of the primary packaging - Device with CE marking	06/01/2021	n/a		
IB/0059	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	05/01/2021	n/a		
IA/0057/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	04/11/2020	n/a		
II/0056	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	01/10/2020	n/a		
IB/0055	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	18/05/2020	n/a		

PSUSA/873/201910	Periodic Safety Update EU Single assessment - conestat alfa	14/05/2020	n/a		PRAC Recommendation - maintenance
II/0053/G	This was an application for a group of variations. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	26/03/2020	28/04/2020	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion Ruconest-H-C-001223-II-0053-G.
II/0052	B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	16/01/2020	n/a		
PSUSA/873/201810	Periodic Safety Update EU Single assessment - conestat alfa	16/05/2019	n/a		PRAC Recommendation - maintenance
IA/0051	A.7 - Administrative change - Deletion of manufacturing sites	25/02/2019	n/a		
IB/0048/G	This was an application for a group of variations. B.IV.z - Quality change - Change in Medical Devices - Other variation B.II.e.7.b - Change in supplier of packaging	20/12/2018	n/a		

	components or devices (when mentioned in the dossier) - Replacement or addition of a supplier				
PSUSA/873/201710	Periodic Safety Update EU Single assessment - conestat alfa	17/05/2018	n/a		PRAC Recommendation - maintenance
IB/0047	B.I.a.3.b - Change in batch size (including batch size ranges) of AS or intermediate - Downscaling down to 10-fold	14/05/2018	n/a		
N/0046	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/04/2018	08/11/2018	Labelling and PL	
IB/0045	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	05/03/2018	n/a		
IB/0043	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	20/12/2017	n/a		
IA/0042	A.7 - Administrative change - Deletion of manufacturing sites	30/11/2017	08/11/2018	Annex II	
IB/0041/G	This was an application for a group of variations. B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	31/08/2017	n/a		

	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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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				
PSUSA/873/201610	Periodic Safety Update EU Single assessment - conestat alfa	22/06/2017	24/08/2017	SmPC and	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

				Annex II	PSUSA/873/201610.
IB/0040	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	30/06/2017	n/a		
IB/0038	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	30/01/2017	n/a		
X/0034	Addition of a new pharmaceutical form "powder and solvent for solution for injection" to the existing Marketing Authorization i.e. Ruconest 2100 U powder for solution for injection. The proposed presentation for the a new pharmaceutical form is a complete kit package including solvent and administration devices and is intended to facilitate administration by the patient or the caregiver in the home care setting (home-treatment/self-administration). Annex I_2.(d) Change or addition of a new pharmaceutical form	10/11/2016	11/01/2017	SmPC, Labelling and PL	Addition of a new pharmaceutical form "powder and solvent for solution for injection" to the existing Marketing Authorization i.e. Ruconest 2100 U powder for solution for injection. The proposed presentation for the a new pharmaceutical form is a complete kit package including solvent and administration devices and is intended to facilitate administration by the patient or the caregiver in the home care setting (home-treatment/self-administration).
IA/0037	A.7 - Administrative change - Deletion of manufacturing sites	10/10/2016	n/a		
IA/0036	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	23/09/2016	n/a		

IB/0035/G	This was an application for a group of variations. 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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	20/06/2016	n/a		
II/0031	Extension of Indication to include adolescents in the treatment of acute angioedema attacks in patients with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency. As a consequence sections 4.1, 4.2, and 5.1 of the SmPC have been updated. The Package Leaflet is updated in accordance. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	25/02/2016	31/03/2016	SmPC and PL	Please refer to the scientific discussion Ruconest EMEA/H/C/001223/II/31 for further information.
II/0032	Update of sections 4.2 and 4.4 of the SmPC in order to remove the requirement for testing all new patients for IgE antibodies against rabbit epithelium (dander) prior to initiation of treatment and the requirement for repeat testing of IgE antibodies to rabbit dander. The	25/02/2016	31/03/2016	SmPC, Annex II and PL	Before initiating treatment with Ruconest, patients should be queried about prior exposure to rabbits and signs and symptoms suggestive of an allergic reaction. There is no requirement for patients who have not previously received Ruconest to be tested for the presence of IgE

	Package Leaflet is updated accordingly. The Annex II is updated to reflect changes to the educational materials. Consequentially, the RMP is updated (finally agreed version 13). In addition, the Marketing authorisation holder (MAH) took the opportunity to bring the PI in line with the latest QRD template version 9.1. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				antibodies against rabbit epithelium (dander) prior to initiation of Ruconest or for such testing to be repeated periodically in previously tested patients.
IB/0033	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	10/11/2015	n/a		
PSUSA/873/201504	Periodic Safety Update EU Single assessment - conestat alfa	06/11/2015	n/a		PRAC Recommendation - maintenance
R/0023	Renewal of the marketing authorisation.	23/07/2015	18/09/2015	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, the CHMP considered that the benefit-risk balance of Ruconest in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0030	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	26/08/2015	n/a		

IA/0028/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	24/07/2015	n/a		
IB/0027	To include QM Diagnostics UMC St Radboud-Nijmegen The Netherlands, as an additional facility for the health monitoring and pathogen screening of rabbits. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	24/06/2015	n/a		
II/0026	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	21/05/2015	n/a		
IB/0025/G	This was an application for a group of variations.	27/03/2015	n/a		

	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				
II/0021/G	This was an application for a group of variations. To implement changes in the specification limits of the Active Substance B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS	26/03/2015	n/a		To implement changes in the specification limits of the Active Substance
IB/0022	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	05/02/2015	n/a		
PSUV/0020	Periodic Safety Update	04/12/2014	n/a		PRAC Recommendation - maintenance
PSUV/0014	Periodic Safety Update	13/06/2014	n/a		PRAC Recommendation - maintenance
IB/0017	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	08/05/2014	n/a		

IA/0018/G	This was an application for a group of variations. 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.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	15/04/2014	n/a		
IB/0016	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	04/04/2014	n/a		
IB/0015	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	03/03/2014	n/a		
IA/0013	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	25/09/2013	10/03/2014	SmPC	
IB/0012	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	05/09/2013	n/a		
II/0010/G	This was an application for a group of variations. To add Sanofi-Chimie, Route d'Avignon, Aramon 30390, France, as a second Drug Substance manufacturer. As a consequence of the new site,	21/03/2013	10/03/2014	Annex II	

	minor changes are introduced in the manufacturing process of the Drug Substance. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place				
IAIN/0011	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	08/10/2012	n/a		
IAIN/0009/G	This was an application for a group of variations. C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV	07/09/2012	n/a		

IB/0008	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	02/08/2012	n/a		
IB/0006	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	19/04/2012	n/a		
IAIN/0007/G	This was an application for a group of variations. C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	17/04/2012	n/a		
IB/0005/G	This was an application for a group of variations. B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.II.d.1.c - Change in the specification parameters and/or limits of the finished product - Addition of a new specification parameter to the specification with its corresponding test method	05/01/2012	n/a		

	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				
IA/0004/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	16/12/2011	n/a		
IB/0003	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	19/10/2011	n/a		
IB/0002	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Extension of storage period of a biological/immunological medicinal product in accordance with an approved stability protocol	08/08/2011	n/a	SmPC and Annex II	- to extend the shelf life of medicinal product from 36 to 48 months at the approved storage condition 5°C ± 3 to 25°C ± 2 / 60% RH ± 5% - to update Annex II.b with regard to a removal of DDPS version and to introduce some editorial changes in DE and LV product information
IB/0001/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	22/02/2011	n/a		Changes to the specification for the active substance and for the skimmed rabbit milk.

	B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation 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				