IDELVION

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
IB/0068	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	12/09/2023		SmPC	
IB/0066	B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other	12/07/2023	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).

	changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
IB/0065	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	22/06/2023	n/a		
IA/0063	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	08/03/2023	n/a		
II/0059	Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update information and amend the frequencies of adverse drug reactions (ADRs) based on the final results from study CSL654_3003 listed as a category 3 study in the RMP; this is an open-label, multicentre, uncontrolled study to evaluate the safety, pharmacokinetics and clinical response of rIX-FP with regard to the prevention and treatment of bleeding in previously un-treated patients (PUPs) with Haemophilia B. The Package Leaflet is updated accordingly. The RMP version 4.1 has also been submitted (response to 2nd RSI) and can be accepted. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI and update the list of local representatives in the Package Leaflet. In addition, this application relates to paediatric studies submitted according to Article 46 of the	23/02/2023		SmPC and PL	Please refer to Scientific Discussion 'Idelvion-H-C-3955-II-59' Submission of the final results from study CSL654_3003 which is an open-label, multicentre, uncon-trolled study to evaluate the safety, pharmacokinetics and clinical response of rIX-FP with regard to the prevention and treatment of bleeding in previously untreated patients (PUPs) with Haemophilia B (listed as category 3 RMP study). Consequently, sections 4.2, 4.8 and 5.1 of the SmPC have been updated to update the information and amend the frequencies of adverse drug reactions (ADRs).

	paediatric Regulation. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IAIN/0062	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	01/12/2022	n/a		
IAIN/0060	B.IV.1.b - Change of a measuring or administration device - Deletion of a device	24/05/2022	n/a		
IB/0058/G	This was an application for a group of variations. B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) 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	15/03/2022	n/a		
IB/0057	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	04/03/2022	n/a		

IB/0054/G	This was an application for a group of variations. B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	04/02/2022	n/a		
IB/0053	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	15/12/2021	n/a		
N/0056	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/12/2021		PL	
IB/0055	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	08/12/2021	n/a		
PSUSA/10497 /202101	Periodic Safety Update EU Single assessment - albutrepenonacog alfa	02/09/2021	n/a		PRAC Recommendation - maintenance
IB/0052	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	05/07/2021	n/a		

IA/0051/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.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier 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	07/06/2021	n/a		
R/0047	Renewal of the marketing authorisation.	10/12/2020	04/02/2021	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of IDELVION in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0041/G	This was an application for a group of variations. B.II.b.3.e - Change in the manufacturing process of the finished or intermediate product - Introduction or increase in the overage that is used for the AS B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	10/12/2020	n/a		

	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IB/0049/G	This was an application for a group of variations. 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	25/11/2020	n/a		
IB/0048	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	05/11/2020	n/a		
II/0044/G	This was an application for a group of variations. 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 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	03/09/2020	n/a		

PSUSA/10497 /202001	Periodic Safety Update EU Single assessment - albutrepenonacog alfa	03/09/2020	n/a		PRAC Recommendation - maintenance
IB/0045	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	21/08/2020	n/a		
X/0035	Annex I_2.(c) Change or addition of a new strength/potency	25/06/2020	19/08/2020	SmPC, Labelling and PL	
IA/0046/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.2.z - Changes in the manufacturing process of the AS - 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.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	29/07/2020	n/a		
IB/0040	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	29/06/2020	n/a		
IB/0043	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	22/06/2020	n/a		

II/0038	B.II.e.1.b.2 - Change in immediate packaging of the finished product - Change in type/addition of a new container - Sterile medicinal products and biological/immunological medicinal products	05/06/2020	n/a		
II/0034	Submission of a variation to update sections 4.2, 4.4, 4.8, 5.1, and 5.2 of the SmPC to reflect data from the extension Study 3003 and to include adaptations to the Core SmPC of factor IX products. Updates of the PIL have been made accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	28/05/2020	19/08/2020	SmPC and PL	Data from the extension Study 3003 have been reflected in section 5.1. of the SmPC. In addition, sec-tion 4.2 of the SmPC has been updated to include that for patients >18 years under prophylaxis, fur-ther extension of the treatment interval may be considered. Additional minor changes have been made to align with the FIX core SmPC.
II/0037	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	14/05/2020	n/a		
IB/0032/G	This was an application for a group of variations. 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.d - Change in test procedure for the finished product - Other changes to a test procedure	25/10/2019	n/a		

	(including replacement or addition)				
IG/1160/G	This was an application for a group of variations. B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)	24/10/2019	18/06/2020	SmPC, Labelling and PL	
II/0027	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	12/09/2019	18/06/2020	SmPC and PL	
PSUSA/10497 /201901	Periodic Safety Update EU Single assessment - albutrepenonacog alfa	05/09/2019	n/a		PRAC Recommendation - maintenance
IB/0033	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	23/08/2019	n/a		
IB/0031	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	05/07/2019	n/a		
IB/0029/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	05/07/2019	n/a		

IB/0024/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes 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	21/06/2019	18/06/2020	SmPC, Labelling and PL	
IA/0030/G	This was an application for a group of variations. B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation	12/06/2019	n/a		
IA/0026	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor	26/04/2019	n/a		

	changes to an approved test procedure				
IA/0025	B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier	03/04/2019	n/a		
IAIN/0023/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 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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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	15/03/2019	n/a		
IB/0022	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	08/03/2019	n/a		
PSUSA/10497 /201807	Periodic Safety Update EU Single assessment - albutrepenonacog alfa	14/02/2019	n/a		PRAC Recommendation - maintenance
IB/0020/G	This was an application for a group of variations. B.I.e.5.c - Implementation of changes foreseen in an	06/02/2019	n/a		

	approved change management protocol - For a biological/immunological medicinal product B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product				
N/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/11/2018	18/06/2020	PL	
PSUSA/10497 /201801	Periodic Safety Update EU Single assessment - albutrepenonacog alfa	06/09/2018	n/a		PRAC Recommendation - maintenance
IB/0017/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	01/06/2018	n/a		
IB/0016	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	23/03/2018	n/a		
PSUSA/10497 /201707	Periodic Safety Update EU Single assessment - albutrepenonacog alfa	08/02/2018	n/a		PRAC Recommendation - maintenance
IB/0015	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	21/12/2017	01/03/2018	SmPC, Labelling and	

				PL	
IB/0013/G	This was an application for a group of variations. B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	13/12/2017	n/a		
IB/0010	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	26/07/2017	n/a		
IB/0012	B.II.g.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	13/07/2017	n/a		
IB/0011	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	07/07/2017	n/a		
PSUSA/10497 /201611	Periodic Safety Update EU Single assessment - albutrepenonacog alfa	09/06/2017	n/a		PRAC Recommendation - maintenance
II/0005	Update of section 4.8 of the SmPC in order to change a previous report of low titre inhibitor to the correct high titre inhibitor development in a previously untreated patient (PUP) in the ongoing extension study CSL654-3003. The Package Leaflet is updated accordingly.	21/04/2017	01/03/2018	SmPC and PL	One previously untreated patient (PUP) from the ongoing clinical trial developed high titre inhibitor against factor IX. There are insufficient data to provide information on inhibitor incidence in PUPs.

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0009/G	This was an application for a group of variations. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.a - Change to in-process tests or limits applied during the manufacture of the AS - Tightening of in-process limits B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change	20/04/2017	n/a		

	in the manufacturing process B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits				
IA/0008/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.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 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.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information	18/04/2017	n/a		
II/0003/G	This was an application for a group of variations. B.I.e.2 - Introduction of a post approval change management protocol related to the AS B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	06/04/2017	n/a		

IB/0007	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	04/04/2017	n/a		
IB/0006	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	29/03/2017	01/03/2018	SmPC	
II/0001/G	This was an application for a group of variations. B.I.e.2 - Introduction of a post approval change management protocol related to the AS B.I.e.3 - Deletion of an approved change management protocol related to the AS	10/11/2016	n/a		
N/0002	Update of the package leaflet with revised contact details of the local representatives for Cyprus, Greece, Belgium and Luxembourg. In addition, the MAH took the opportunity to correct the Polish local representative’s contact details in the Czech and Slovakian package leaflets. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/09/2016	01/03/2018	PL	