Lyumjev

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
PSUSA/1755/ 202404	Periodic Safety Update EU Single assessment - insulin lispro	16/01/2025	n/a		PRAC Recommendation - maintenance
R/0019	Renewal of the marketing authorisation.	14/11/2024	13/01/2025	SmPC and PL	
IB/0018	B.II.f.1.b.5 - Stability of FP - Extension of the shelf	24/04/2024	13/01/2025	SmPC	

[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).

	life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol				
IB/0017	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	13/02/2023	n/a		
II/0014	Extension of indication to include the treatment of diabetes mellitus in adolescents and children aged 1 year and above, based on final results from study I8B-MC-ITSB; this is a pivotal Phase 3 study designed to evaluate the safety and efficacy of Lyumjev compared to Humalog in combination with basal insulin in children and adolescent patients with T1D. The study was designed to compare change in HbA1c as the primary endpoint. As a consequence, sections 4.1, 4.2, 4.8, 5.1, and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to implement update minor editorial and linguistic changes in the SmPC and Package Leaflet. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	13/10/2022	18/11/2022	SmPC and PL	Please refer to Scientific Discussion 'Lyumjev-H-C-5037-II-0014'
II/0016	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	17/11/2022	n/a		

	biological AS				
IA/0015	A.7 - Administrative change - Deletion of manufacturing sites	23/05/2022	n/a		
X/0010	Annex I_1.(c) Replacement of a biological AS with one of a slightly different molecular structure	24/02/2022	25/04/2022		
PSUSA/1755/ 202104	Periodic Safety Update EU Single assessment - insulin lispro	02/12/2021	n/a		PRAC Recommendation - maintenance
IA/0013	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	25/08/2021	n/a		
IA/0012	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	25/08/2021	n/a		
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/06/2021	25/04/2022	PL	
II/0008/G	This was an application for a group of variations. Update of sections 4.8 and 5.1 of the SmPC in order to update clinical information based on final results from study Study I8B-MC-ITRO (PRONTO-Pump-2); this is a Phase 3 prospective, randomized, double-	11/02/2021	21/04/2021	SmPC and PL	The information regarding infusion site reactions in the SmPC and PL was updated in SmPC 4.8. The update in SmPC 5.1on efficacy of Lyumjev in study ITRO (aka PRONTO-Pump-2) reflects the non-inferiority of Lyumjev in overall glycaemic control and superiority in control of postprandial glucose excursions compared with Humalog,

	blind trial, which compared Lyumjev to Humalog in adults with Type 1 Diabetes using continuous subcutaneous insulin infusion. The Package Leaflet is updated accordingly. The MAH also provides a phase 2 study evaluating Lyumjev in a Medtronic Pump (Study I8B-MC-ITSM) as a grouped variation. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				also when used as CSII.
II/0006/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.IV.z - Quality change - Change in Medical Devices - Other variation	11/02/2021	21/04/2021	SmPC, Labelling and PL	Sections 1, 2, 4.2, 4.4, 6.4, 6.5, 6.6 and 8 of the SmPC were updated in order to add the new pre-filled pen presentations; the Package Leaflet and Labelling are updated accordingly.
II/0005	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	21/01/2021	21/04/2021	SmPC	
PSUSA/1755/ 202004	Periodic Safety Update EU Single assessment - insulin lispro	26/11/2020	n/a		PRAC Recommendation - maintenance
IB/0007	B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP -	19/10/2020	n/a		

	Replacement/addition of a site where batch control/testing takes place				
IB/0003	C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	26/08/2020	21/04/2021	SmPC and PL	
IB/0002	B.II.f.1.a.3 - Stability of FP - Reduction of the shelf life of the finished product - After dilution or reconstitution	30/06/2020	21/04/2021	SmPC and PL	
IAIN/0001	A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	10/04/2020	21/04/2021	SmPC, Labelling and PL	