Insulin aspart Sanofi

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
IA/0019	A.7 - Administrative change - Deletion of manufacturing sites	20/09/2024		Annex II and PL	
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/08/2024		PL	

[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).

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PSUSA/1749/ 202309	Periodic Safety Update EU Single assessment - insulin aspart	16/05/2024	n/a		PRAC Recommendation - maintenance
IB/0016	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	24/01/2024	n/a		
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/07/2023		PL	
II/0013/G	This was an application for a group of variations. Please refer to the Recommendations section B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method 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.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.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.1.b - Change in the specification parameters and/or limits of an AS, starting	12/05/2023	n/a		Not applicable

	material/intermediate/reagent - Tightening of specification limits B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol				
PSUSA/1749/ 202209	Periodic Safety Update EU Single assessment - insulin aspart	14/04/2023	n/a		PRAC Recommendation - maintenance
T/0011	Transfer of Marketing Authorisation	15/11/2022	09/12/2022		
II/0010/G	This was an application for a group of variations. Please refer to the Recommendations section B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change relates to all other pharmaceutical forms manufactured by complex manufacturing processes	17/11/2022	n/a		Not applicable
PSUSA/1749/ 202109	Periodic Safety Update EU Single assessment - insulin aspart	05/05/2022	n/a		PRAC Recommendation - maintenance
IA/0009/G	This was an application for a group of variations.	23/02/2022	n/a		

	B.I.b.2.b - Change in test procedure for AS or starting material/reagent/intermediate - Deletion of a test procedure for the AS or a starting material/reagent/intermediate, if an alternative test procedure is already authorised B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/11/2021	09/12/2022	PL	
PSUSA/1749/ 202009	Periodic Safety Update EU Single assessment - insulin aspart	06/05/2021	n/a		PRAC Recommendation - maintenance
X/0003	Addition of a new route of administration; intravenous use (100 units/ml solution for injection in 10 mL vial). Annex I_2.(e) Change or addition of a new route of administration	25/02/2021	21/04/2021	SmPC, Labelling and PL	Based on the CHMP review of data on quality, safety and efficacy the CHMP considers that the benefit-risk balance of Insulin aspart Sanofi for the new route of administration; intravenous use (100 units/ml solution for injection in 10 mL vial) is favourable in the following indication: Treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/10/2020	21/04/2021	PL	
IG/1282	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	15/09/2020	n/a		
IB/0002	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale	10/08/2020	21/04/2021	SmPC	

	(supported by real time data)				
IAIN/0001	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/08/2020	21/04/2021	SmPC and PL	