



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Semglee

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
IAIN/0047	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	30/11/2023		Annex II and PL	

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



T/0046	Transfer of Marketing Authorisation	03/08/2023	25/08/2023	SmPC, Labelling and PL	
IAIN/0045	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/06/2023	n/a		
N/0044	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/05/2023		Labelling and PL	
IB/0043/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 (including replacement or addition)	10/03/2023	n/a		
R/0040	Renewal of the marketing authorisation.	15/12/2022	15/02/2023	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Semglee in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/1751/202204	Periodic Safety Update EU Single assessment - insulin glargine	01/12/2022	n/a		PRAC Recommendation - maintenance
IA/0042	B.I.a.4.b - Change to in-process tests or limits	29/11/2022	n/a		

	applied during the manufacture of the AS - Addition of a new in-process test and limits				
IB/0039/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p>	27/06/2022	n/a		
IA/0038/G	<p>This was an application for a group of variations.</p> <p>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)</p> <p>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</p>	07/06/2022	n/a		
IB/0037	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	25/05/2022	n/a		
IA/0036/G	This was an application for a group of variations.	14/03/2022	n/a		

	<p>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)</p> <p>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</p>				
IB/0035	B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits	31/01/2022	n/a		
IAIN/0034/G	<p>This was an application for a group of variations.</p> <p>B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p> <p>B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site</p>	10/01/2022	15/02/2023	Annex II and PL	
IB/0032	B.II.z - Quality change - Finished product - Other variation	06/01/2022	n/a		

IA/0033	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	07/12/2021	n/a		
T/0031	Transfer of Marketing Authorisation	11/09/2021	19/10/2021	SmPC, Labelling and PL	
IB/0027/G	<p>This was an application for a group of variations.</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p> <p>B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation</p>	07/04/2021	n/a		

	<p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p>				
IB/0028/G	<p>This was an application for a group of variations.</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p> <p>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</p> <p>B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation</p>	26/03/2021	n/a		
IA/0029	A.7 - Administrative change - Deletion of manufacturing sites	09/03/2021	n/a		
IB/0026	B.IV.1.z - Change of a measuring or administration device - Other variation	21/12/2020	n/a		
PSUSA/1751/202004	Periodic Safety Update EU Single assessment - insulin glargine	26/11/2020	n/a		PRAC Recommendation - maintenance
IA/0025	B.II.d.2.a - Change in test procedure for the finished	23/10/2020	n/a		

	product - Minor changes to an approved test procedure				
IB/0024	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	09/10/2020	n/a		
IB/0023	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/10/2020	22/03/2021	SmPC and PL	
IB/0021/G	This was an application for a group of variations.  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  B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	01/04/2020	22/03/2021	SmPC, Annex II, Labelling and PL	
IB/0020	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	19/03/2020	n/a		
IA/0019/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	27/02/2020	n/a		

	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) B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
PSUSA/1751/201904	Periodic Safety Update EU Single assessment - insulin glargine	14/11/2019	16/01/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s) for PSUSA/1751/201904.
II/0009	B.II.b.1.d - Replacement or addition of a manufacturing site for the FP - Site which requires an initial or product specific inspection	26/09/2019	n/a		
IB/0018	B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale	16/08/2019	16/01/2020	SmPC	
IAIN/0015/G	This was an application for a group of variations.  A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing	17/05/2019	n/a		



IB/0016	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	16/05/2019	n/a		
IB/0014	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	03/05/2019	n/a		
IB/0013/G	This was an application for a group of variations.  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  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	08/03/2019	n/a		
IAIN/0012	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	29/01/2019	17/04/2019	SmPC, Labelling and PL	
IB/0011	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/12/2018	17/04/2019	SmPC, Annex II, Labelling and PL	
IB/0010	B.IV.1.z - Change of a measuring or administration device - Other variation	13/11/2018	n/a		

PSUSA/1751/ 201804	Periodic Safety Update EU Single assessment - insulin glargine	31/10/2018	n/a		PRAC Recommendation - maintenance
IB/0008/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.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	23/08/2018	n/a		
IB/0007/G	This was an application for a group of variations.  B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site 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	07/08/2018	n/a		
IB/0006/G	This was an application for a group of variations.  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.d.1.z - Stability of AS - Change in the re-test	26/07/2018	n/a		

	period/storage period or storage conditions - Other variation				
IB/0004/G	This was an application for a group of variations.  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  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	24/07/2018	n/a		
IB/0003	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	21/06/2018	n/a		
IB/0002	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	23/05/2018	17/04/2019	SmPC	
IB/0001	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	16/05/2018	17/04/2019	SmPC, Labelling and PL	