Abasaglar

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/0033	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	23/07/2020		SmPC and PL	
WS/1587/G	This was an application for a group of variations	23/07/2020		SmPC, Annex	The SmPC sections 1, 4.2, 4.4, 6.2, 6.4, 6.5, 6.6, 8 of the

[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).

	following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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			II, Labelling and PL	SmPC were updated in order to add a new pre-filled pen presentation. The Labelling and the PL have been updated accordingly.
IB/0032	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	12/05/2020	n/a		
IA/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	23/01/2020	n/a		
PSUSA/1751/201904	Periodic Safety Update EU Single assessment - insulin glargine	14/11/2019	13/01/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/1751/201904.
IB/0029	B.II.b.4.f - Change in the batch size (including batch size ranges) of the finished product - The scale for a biological/immunological medicinal product is increased/decreased without process change (e.g. duplication of line)	20/12/2019	n/a		

N/0026	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/08/2019	13/01/2020	Labelling and PL	
R/0023	Renewal of the marketing authorisation.	29/05/2019	25/07/2019	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 Abasaglar in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
WS/1541	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	27/06/2019	n/a		
IB/0024	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	20/03/2019	n/a		
PSUSA/1751/ 201804	Periodic Safety Update EU Single assessment - insulin glargine	31/10/2018	n/a		PRAC Recommendation - maintenance
IA/0022	B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	09/08/2018	n/a		
PSUSA/1751/ 201710	Periodic Safety Update EU Single assessment - insulin glargine	17/05/2018	n/a		PRAC Recommendation - maintenance
IB/0020	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of	24/04/2018	n/a		

	the AS				
T/0018	Transfer of Marketing Authorisation	05/01/2018	27/02/2018	SmPC, Labelling and PL	
WS/1314	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e.1.a.3 - Change in immediate packaging of the finished product - Qualitative and quantitative composition - Sterile medicinal products and biological/immunological medicinal products	01/02/2018	27/02/2018	SmPC	
PSUSA/1751/ 201704	Periodic Safety Update EU Single assessment - insulin glargine	30/11/2017	n/a		PRAC Recommendation - maintenance
II/0014	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	01/09/2017	n/a		
IB/0015/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	04/07/2017	n/a		
PSUSA/1751/ 201610	Periodic Safety Update EU Single assessment - insulin glargine	05/05/2017	n/a		PRAC Recommendation - maintenance

II/0010/G	This was an application for a group of variations. C.I.Z (Type II): Update of section 4.4 and 4.6 of the SmPC of the cartridge presentations (EU/1/44/94/001-4,9) to only recommend the use of cartridges in Lilly reusable pens and to remove the suggestion to withdraw insulin from a syringe. C.I.2 (Type IB): Update of section 4.2 of the SmPC in order to align the wording on switching from 3000 U/ml to 100 U/ml with the reference product, Lantus. The Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity to replace U/ml by units/ml, to amend the details of the Polish affiliate, to correct the image of the KwikPen and to bring the PI in line with the latest QRD template version 10.0. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	19/01/2017	11/04/2017	SmPC, Labelling and PL	4.2 Posology and method of administration From other twice daily NPH insulin to ABASAGLAR To reduce the risk of nocturnal and early morning hypoglycaemia, patients who are changing their basal insulin regimen from a twice daily NPH insulin to a once daily regimen with ABASAGLAR should reduce their daily dose of basal insulin by 20-30 % during the first weeks of treatment. Switch from insulin glargine 300 units/ml to ABASAGLAR ABASAGLAR and Toujeo (insulin glargine 300 units/ml) are not bioequivalent and are not directly interchangeable. To reduce the risk of hypoglycemia, patients who are changing their basal insulin regimen from an insulin regimen with once daily insulin glargine 300 units/ml to a once daily regimen with ABASAGLAR should reduce their dose by approximately 20%. During the first weeks the reduction should, at least partially, be compensated by an increase in mealtime insulin, after this period the regimen should be adjusted individually. 4.4 Special warnings and precautions for use Pens to be used with ABASAGLAR cartridges The cartridges should only be used in conjunction with a Lilly reusable insulin pen and should not be used with any other reusable pen as the dosing accuracy has not been established with other pens.

					6.6 Special precautions for disposal and other handling Insulin pen The ABASAGLAR cartridges are to be used only in conjunction with a Lilly reusable insulin pen (see section 4.4). The pen should be used as recommended in the information provided with the device. The manufacturer's instructions for using the pen must be followed carefully for loading the cartridge, attaching the needle, and administering the insulin injection. If the insulin pen is damaged or not working properly (due to mechanical defects) it has to be discarded, and a new insulin pen has to be used.
IB/0012	B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	06/01/2017	n/a		
IB/0011	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	20/12/2016	n/a		
PSUSA/1751/ 201602	Periodic Safety Update EU Single assessment - insulin glargine	02/09/2016	n/a		PRAC Recommendation - maintenance
II/0008/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	28/04/2016	11/04/2017	Annex II and PL	

	site B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.2.c.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits				
II/0006/G	This was an application for a group of variations. B.II.b.1.c - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch release/control, and secondary packaging, for biol/immunol medicinal products or pharmaceutical forms manufactured by complex manufacturing processes B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product	25/02/2016	n/a		

	- Addition of a new test(s) and limits				
IB/0007/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.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits 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.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.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	03/02/2016	n/a		
IA/0005	A.7 - Administrative change - Deletion of manufacturing sites	03/12/2015	n/a		
IB/0004	B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS	24/06/2015	n/a		
II/0003/G	This was an application for a group of variations. B.IV.1.c - Change of a measuring or administration	21/05/2015	09/12/2015	SmPC, Labelling and	

	device - Addition or replacement of a device which is an integrated part of the primary packaging 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			PL	
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/02/2015	09/12/2015	PL	
IAIN/0001/G	This was an application for a group of variations. A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs 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	03/12/2014	09/12/2015	SmPC, Labelling and PL	