EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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
IAIN/0020/G	This was an application for a group of variations. 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 -	11/11/2022		Annex II and 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).

	Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site A.7 - Administrative change - Deletion of manufacturing sites				
PSUSA/10733 /202109	Periodic Safety Update EU Single assessment - galcanezumab	19/05/2022	15/07/2022	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10733/202109.
IA/0019	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	14/06/2022	n/a		
PSUSA/10733 /202103	Periodic Safety Update EU Single assessment - galcanezumab	28/10/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10733 /202009	Periodic Safety Update EU Single assessment - galcanezumab	20/05/2021	16/07/2021	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10733/202009.
PSUSA/10733 /202003	Periodic Safety Update EU Single assessment - galcanezumab	29/10/2020	n/a		PRAC Recommendation - maintenance
IAIN/0015	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	14/07/2020	n/a		
II/0013	B.II.b.4.c - Change in the batch size (including batch	18/06/2020	n/a		

	size ranges) of the finished product - The change requires assessment of the comparability of a biological/immunological medicinal product or a new bioequivalence study				
PSUSA/10733 /201909	Periodic Safety Update EU Single assessment - galcanezumab	17/04/2020	n/a		PRAC Recommendation - maintenance
II/0009	Update of sections 4.2 and 5.1 of the SmPC following final results from a CONQUER study (A Randomized, Double-Blind, Placebo-Controlled Study of Galcanezumab in Adults with Treatment-Resistant Migraine; the Package Leaflet is updated accordingly. In addition, the Marketing authorisation holder (MAH) took the opportunity correct to Slovakian contact information in the Package Leaflet. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/03/2020	07/01/2021	SmPC and PL	The SmPC section 4.2 and 5.1 has been updated to reflect the results of the study conducted in patients with treatment resistant migraine. The PL have been updated accordingly.
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/03/2020	07/01/2021	PL	
IA/0011	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	20/01/2020	07/01/2021	SmPC	
PSUSA/10733 /201903	Periodic Safety Update EU Single assessment - galcanezumab	17/10/2019	09/12/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10733/201903.

IB/0008	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	07/08/2019	n/a		
IB/0007/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	31/07/2019	n/a		
IA/0006	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	16/07/2019	n/a		
IAIN/0003	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	08/02/2019	n/a		
IAIN/0002	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	18/12/2018	09/12/2019	SmPC, Labelling and PL	
IAIN/0001	B.II.e.5.a.1 - Change in pack size of the finished	18/12/2018	09/12/2019	SmPC,	

	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			Labelling and PL	