Pelmeg

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
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/04/2024		Labelling	
WS/2614	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	14/03/2024	n/a		

[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).

	B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS				
R/0025	Renewal of the marketing authorisation.	14/09/2023	20/11/2023	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Pelmeg in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0026	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	20/10/2023	n/a		
IG/1593	A.1 - Administrative change - Change in the name and/or address of the MAH	24/02/2023	20/11/2023	SmPC, Labelling and PL	
IB/0023	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	31/01/2023	n/a		
IB/0021	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	05/10/2022	n/a		
IA/0022	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the	03/10/2022	n/a		

	finished product, including quality control sites (excluding manufacturer for batch release)				
PSUSA/2326/ 202201	Periodic Safety Update EU Single assessment - pegfilgrastim	29/09/2022	n/a		PRAC Recommendation - maintenance
IG/1526	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	23/06/2022	n/a		
IAIN/0019	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	23/06/2022	n/a		
IB/0017	B.II.f.1.a.1 - Stability of FP - Reduction of the shelf life of the finished product - As packaged for sale	15/10/2021	19/05/2022	SmPC	
IB/0012	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	08/07/2021	19/05/2022	SmPC and PL	
IB/0016	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	02/07/2021	19/05/2022	SmPC and PL	To update "Myelodysplastic syndrome and acute myeloid leukaemia in breast and lung cancer patients" section and product handling

WS/2084	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	24/06/2021	n/a		
IAIN/0015	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	03/06/2021	n/a		
IB/0013/G	This was an application for a group of variations. B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	28/04/2021	n/a		
IG/1363/G	This was an application for a group of variations. B.IV.1.b - Change of a measuring or administration device - Deletion of a device 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	10/03/2021	n/a		

IG/1295/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release 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) 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)	09/10/2020	19/05/2022	Annex II and PL	
WS/1916	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. 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	08/10/2020	19/05/2022	SmPC	
II/0006/G	This was an application for a group of variations. 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 B.I.a.4.c - Change to in-process tests or limits	03/09/2020	n/a		

	applied during the manufacture of the AS - Deletion of a non-significant in-process test B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP				
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/07/2020	19/05/2022	PL	
IB/0007	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	23/04/2020	n/a		
T/0005	Transfer of Marketing Authorisation	20/12/2019	09/03/2020	SmPC, Labelling and PL	
PSUSA/2326/201901	Periodic Safety Update EU Single assessment - pegfilgrastim	19/09/2019	11/11/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2326/201901.
IAIN/0004	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	05/09/2019	n/a		
IAIN/0003	A.1 - Administrative change - Change in the name and/or address of the MAH	29/08/2019	11/11/2019	SmPC, Labelling and PL	

IB/0001/G	This was an application for a group of variations. 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 B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	17/04/2019	n/a		