Kyntheum

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/0021	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	23/11/2022		PL	
IB/0020	B.II.z - Quality change - Finished product - Other variation	07/11/2022	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).

R/0019	Renewal of the marketing authorisation.	24/02/2022	25/04/2022	SmPC, Labelling and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Kyntheum in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10616 /202107	Periodic Safety Update EU Single assessment - brodalumab	10/02/2022	n/a		PRAC Recommendation - maintenance
IB/0017/G	This was an application for a group of variations. 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 B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information B.II.e.6.b - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that does not affect the product information B.II.e.1.z - Change in immediate packaging of the finished product - Other variation	21/06/2021	n/a		
PSUSA/10616 /202007	Periodic Safety Update EU Single assessment - brodalumab	11/02/2021	n/a		PRAC Recommendation - maintenance
IB/0015	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/07/2020	30/09/2020	SmPC and PL	

II/0014	Update of section 4.4 and 4.8 of the SmPC and relevant sections of the PL to reflect a signal of anaphylactic reaction detected in the post marketing setting. Minor updates have also been included throughout the product information. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/06/2020	30/09/2020	SmPC and PL	After reviewing the available data including case reports from post-marketing sources, clinical trials and published literature, the MAH identified a signal with one case providing evidence for a causal relationship between anaphylactic reaction and brodalumab. Considering the positive rechallenge and the temporal relationship that suggests causality, the MAH included this event as new undesirable effect in section 4.8 with a "rare" frequency and a warning in section 4.4. In the event of an anaphylactic reaction, or any other serious allergic reaction, administration of Kyntheum should be discontinued and appropriate therapy initiated. In addition, other changes to the SmPC were approved mainly based on updated safety data of all pooled phase 2 and 3 clinical trials in the psoriasis development programme including a deletion of a warning on reduced absolute neutrophil count, changes to frequencies of ADRs and minor changes in section 5.1 and 5.2. The Package leaflet was updated accordingly
PSUSA/10616 /201907	Periodic Safety Update EU Single assessment - brodalumab	13/02/2020	n/a		PRAC Recommendation - maintenance
IA/0013	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)	09/12/2019	n/a		
II/0011	Update of section 5.1 of the SmPC "Mechanism of action" subsection with information about the inhibition of cytokine IL-17C.	26/09/2019	30/09/2020	SmPC	The mechanism of action subsection of the SmPC has been updated to include that brodalumab exerts its anti-inflammatory effects in psoriasis by inhibiting signaling

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				mediated by IL-17C in addition to IL-17A and IL-17F.
PSUSA/10616 /201901	Periodic Safety Update EU Single assessment - brodalumab	11/07/2019	n/a		PRAC Recommendation - maintenance
IB/0010	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	25/04/2019	n/a		
IA/0009/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	10/04/2019	n/a		
PSUSA/10616 /201807	Periodic Safety Update EU Single assessment - brodalumab	14/02/2019	n/a		PRAC Recommendation - maintenance
IB/0007	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	11/02/2019	n/a		
IB/0005/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	03/10/2018	13/09/2019	Labelling and PL	

	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.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 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				
II/0004/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.II.b.2.b - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place for a biol/immunol product and any of the test methods at the site is a biol/immunol method	13/09/2018	n/a		
PSUSA/10616 /201801	Periodic Safety Update EU Single assessment - brodalumab	12/07/2018	n/a		PRAC Recommendation - maintenance
IB/0001/G	This was an application for a group of variations.	12/09/2017	02/08/2018	SmPC, Annex	

	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 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			II, Labelling and PL	