Idacio

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/0023	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	23/10/2024		SmPC	

[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/0022	Renewal of the marketing authorisation.	14/09/2023	30/10/2023	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Idacio in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
PSUSA/10783 /202212	Periodic Safety Update EU Single assessment - adalimumab	31/08/2023	n/a		PRAC Recommendation - maintenance
II/0018/G	This was an application for a group of variations. B.I.b.2.d - Change in test procedure for AS or starting material/reagent/intermediate - Substantial change to or replacement of a biological/immunological/immunochemical test method or a method using a biological reagent for a biological AS 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	15/06/2023	n/a		
IB/0020	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	16/03/2023	n/a		
IB/0019/G	This was an application for a group of variations. B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a	22/02/2023	n/a		

	manufacturing site for the FP - Other variation				
II/0017	Submission of an updated RMP version 6 in order to propose a continuation of the observational registry (RABBIT) Study #1 (Study Identifier: FKS0-000-RAB) and the cancelation of the observational registry (IBD UK) (Study Identifier: FKS0-000-IBD). In addition, the MAH took the opportunity to align the RMP with the current approved RMP of the reference product. C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required	29/09/2022	n/a		
IB/0016	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	08/03/2022	n/a		
IB/0015	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	05/01/2022	n/a		
IAIN/0014	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	08/10/2021	n/a		
IB/0013	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	21/09/2021	22/10/2021	SmPC and PL	

	product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				
IB/0012	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	22/07/2021	n/a		
IB/0011/G	This was an application for a group of variations. B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation A.7 - Administrative change - Deletion of manufacturing sites	05/07/2021	22/10/2021	Annex II and PL	
IB/0009	B.II.f.z - Stability of FP - Other variation	09/06/2021	22/10/2021	SmPC and PL	Update of section 6.4 of the Summary of Product Characteristics and section 5 of the Package Leaflet.
IB/0010	C.I.3.a - 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 - Implementation of wording agreed by the competent authority	26/05/2021	22/10/2021	SmPC and PL	
II/0007	B.I.e.2.z - Design Space - Introduction of a post approval change management protocol related to the AS - Other variation	14/01/2021	n/a		
IB/0008	C.I.3.a - 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	21/10/2020	22/10/2021	SmPC and PL	

	assessment done under A 45/46 - Implementation of wording agreed by the competent authority				
II/0006/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.II.d.1.z - Change in the specification parameters and/or limits of the finished product - Other variation	03/09/2020	n/a		
PSUSA/10783 /201912	Periodic Safety Update EU Single assessment - adalimumab	03/09/2020	n/a		PRAC Recommendation - maintenance
IB/0004	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	19/12/2019	18/06/2020	SmPC	
WS/1651	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	03/10/2019	18/06/2020	Annex II	
WS/1652/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No	25/07/2019	18/06/2020	SmPC, Labelling and	

	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.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			PL	
IAIN/0001/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.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	12/06/2019	18/06/2020	Annex II and PL	