Kevzara

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
X/0043/G	This was an application for a group of variations. Extension application to add a new strength of 175 mg/ml solution for injection in vial, grouped with an extension of indication to include treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older for KEVZARA, based on results from study DRI13925; this is a	14/11/2024	13/01/2025	SmPC, Annex II, Labelling and PL	Refer to the scientific discussion: Kevzara EMEA/H/C/004254/X/0043/G

[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).

	multinational, multi-center, open-label, 2 phase, 3 portions study to describe the PK profile as well as safety and efficacy of sarilumab. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3, 6.5 and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP has also been approved. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one Annex I_2.(c) Change or addition of a new strength/potency				
IA/0047	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	11/12/2024		Annex II	
II/0044	Extension application to add a new strength of 175 mg/ml solution for injection in vial, grouped with an extension of indication to include treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older for KEVZARA, based on results from study DRI13925; this is a multinational, multi-center, open-label, 2 phase, 3 portions study to describe the PK profile as well as safety and efficacy of sarilumab. As a consequence, sections 1, 2, 3, 4.1, 4.2, 4.4, 4.8, 5.1, 5.2, 6.3, 6.5	17/10/2024	25/11/2024	SmPC, Labelling and PL	Please refer to Scientific Discussion: Kevzara-H-C-004254-II-0044

	and 6.6 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 5.0 of the RMP has also been approved. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
N/0046	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/08/2024	25/11/2024	PL	
IA/0045/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation	09/01/2024	n/a		
IB/0041	B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process	07/11/2023	n/a		

	of the AS				
IB/0040/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	07/09/2023	n/a		
PSUSA/10609 /202301	Periodic Safety Update EU Single assessment - sarilumab	31/08/2023	n/a		PRAC Recommendation - maintenance
II/0036/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.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS 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 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 B.I.b.2.e - Change in test procedure for AS or	20/07/2023	n/a		

	starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS 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 B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation				
N/0039	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/06/2023	25/11/2024	PL	
IB/0038/G	This was an application for a group of variations. B.II.e.z - Change in container closure system of the Finished Product - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation B.II.e.3.b - Change in test procedure for the	24/05/2023	n/a		

	immediate packaging of the finished product - Other changes to a test procedure (including replacement or addition) A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites				
IB/0035	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	15/02/2023	n/a		
T/0034	Transfer of Marketing Authorisation	31/10/2022	18/11/2022	SmPC, Labelling and PL	
IB/0033	B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation	24/05/2022	n/a		
R/0029	Renewal of the marketing authorisation.	24/02/2022	25/04/2022	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 Kevzara in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0032	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	06/01/2022	n/a		
IB/0030/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	08/12/2021	n/a		

	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 manufacturing site for the FP - Other variation 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 manufacturing site for the FP - Other variation B.II.b.1.z - Replacement or addition of a manufacturing site for the FP - Other variation				
N/0031	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/11/2021	25/04/2022	PL	
II/0028/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.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.c.3.b - Change in test procedure for the immediate packaging of the AS - Other changes to a test procedure (including replacement or addition) B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	14/10/2021	25/04/2022	Annex II	

	B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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 B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS				
PSUSA/10609 /202101	Periodic Safety Update EU Single assessment - sarilumab	16/09/2021	15/11/2021	SmPC and PL	Please refer to Kevzara EMEA/H/C/PSUSA/00010609/202101 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
II/0024/G	This was an application for a group of variations. B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.b.1.e - Change in the specification parameters	21/01/2021	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Deletion of a specification parameter which may have a significant effect on the overall quality of the AS and/or the FP				
N/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/01/2021	15/11/2021	PL	
IAIN/0026	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	12/01/2021	n/a		
PSUSA/10609 /202001	Periodic Safety Update EU Single assessment - sarilumab	17/09/2020	19/11/2020	SmPC and PL	Please refer to EMEA/H/C/PSUSA/00010609/202001 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
II/0022/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.4.e - Change to in-process tests or limits applied during the manufacture of the AS - Deletion of an in-process test which may have a significant effect on the overall quality of the AS B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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	07/05/2020	n/a		

	material/intermediate 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 B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation				
IB/0023	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)	30/03/2020	n/a		
PSUSA/10609 /201907	Periodic Safety Update EU Single assessment - sarilumab	27/02/2020	28/04/2020	SmPC and PL	Please refer to Kevzara EMEA/H/C/PSUSA/00010609/201907 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IB/0020	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	17/02/2020	28/04/2020	SmPC	
IB/0019/G	This was an application for a group of variations. 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	13/12/2019	n/a		

	B.IV.1.z - Change of a measuring or administration device - Other variation				
IA/0018/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.b - Change in test procedure for the finished product - Deletion of a test procedure if an alternative method is already authorised	27/11/2019	n/a		
IB/0017/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.2 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing	17/11/2019	28/04/2020	Annex II and PL	
II/0015/G	This was an application for a group of variations. 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 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.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	17/10/2019	n/a		

	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation 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.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure				
PSUSA/10609 /201901	Periodic Safety Update EU Single assessment - sarilumab	11/07/2019	n/a		PRAC Recommendation - maintenance
IB/0014	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	03/07/2019	n/a		
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/04/2019	28/04/2020	PL	
PSUSA/10609 /201807	Periodic Safety Update EU Single assessment - sarilumab	14/02/2019	n/a		PRAC Recommendation - maintenance
II/0011/G	This was an application for a group of variations. B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method	24/01/2019	n/a		

	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.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS B.I.b.1.f - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Change outside the approved specifications limits range for the AS				
II/0010/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.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 B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test	13/12/2018	n/a		

	procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure				
IA/0009	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	18/10/2018	n/a		
IB/0007	B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	10/08/2018	n/a		
PSUSA/10609 /201712	Periodic Safety Update EU Single assessment - sarilumab	12/07/2018	n/a		PRAC Recommendation - maintenance
II/0006/G	This was an application for a group of variations. 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.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	21/06/2018	n/a		

II/0004	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	07/12/2017	n/a		
II/0003/G	This was an application for a group of variations. B.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	23/11/2017	n/a		
IB/0002/G	This was an application for a group of variations. 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 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 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 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	24/08/2017	12/12/2018	SmPC, Labelling and PL	

IB/0001/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.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure 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.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	20/07/2017	n/a		