



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	09/04/2019		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	24/01/2019	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).



	<p>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</p> <p>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</p> <p>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</p> <p>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</p>				
II/0010/G	<p>This was an application for a group of variations.</p> <p>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</p> <p>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</p>	13/12/2018	n/a		

	<p>biol/immunol method</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure</p>				
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	<p>This was an application for a group of variations.</p> <p>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</p> <p>B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range</p> <p>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test</p>	21/06/2018	n/a		

	procedure				
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,	24/08/2017	12/12/2018	SmPC, Labelling and PL	

	ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes				
IB/0001/G	<p>This was an application for a group of variations.</p> <p>B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure</p> <p>B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product</p>	20/07/2017	n/a		