Cosentyx

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
II/0127	Update of section 4.4 of the SmPC to include recommendations on clinical management of cases of tuberculosis following the PSUSA (PSUSA/00010341/202312) procedure following which cumulative requests were requested to assess the safety topics of tuberculosis and hepatitis C virus	13/02/2025		SmPC and PL	Update of the warning on tuberculosis as follows: Tuberculosis (active and/or latent reactivation) has been reported in patients treated with secukinumab. Patients should be evaluated for tuberculosis infection prior to initiating treatment with secukinumab. Secukinumab should not be given to patients with active tuberculosis (see

[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).

	with secukinumab. The Package Leaflet is updated accordingly. C.I.3.b - 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 - Change(s) with new additional data submitted by the MAH				section 4.3). In patients with latent tuberculosis, anti tuberculosis therapy should be considered prior to initiation of secukinumab as per clinical guidelines. Patients receiving secukinumab should be monitored for signs and symptoms of active tuberculosis. For more information, please refer to the Summary of Product Characteristics.
II/0124	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	13/02/2025	n/a		
IB/0126/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.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	19/12/2024	n/a		
IB/0125/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a	19/12/2024		Annex II	

	biological/immunological medicinal product B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation				
PSUSA/10341 /202312	Periodic Safety Update EU Single assessment - secukinumab	19/09/2024	18/11/2024	SmPC and PL	Please refer to Cosentyx-EMEA/H/C/PSUSA/00010341/202312 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IB/0123/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.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	18/09/2024	n/a		
II/0120	Submission of the interim report for study CAIN457M2301E1. This is an ongoing four-year, multicenter, double-blind, randomised withdrawal extension study of two Phase III studies, CAIN457M2301 and CAIN457M2302, conducted to assess long-term efficacy and safety of two secukinumab 300 mg dose regimens (Q2W or Q4W), in adult subjects with moderate to severe hidradenitis suppurativa. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	05/09/2024	n/a		

IB/0122/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.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	13/08/2024	n/a		
IB/0121/G	This was an application for a group of variations. 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.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 B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	02/08/2024	n/a		
IB/0119	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	08/07/2024	n/a		

II/0116	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	20/06/2024	n/a		
IB/0118/G	This was an application for a group of variations. 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 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.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation	29/05/2024	n/a		
IB/0117	B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	23/05/2024	n/a		
IAIN/0115/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.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	27/03/2024	n/a		

IB/0113/G	This was an application for a group of variations. B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	25/03/2024	n/a		
IB/0112/G	This was an application for a group of variations. B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation B.II.b.2.z - Change to importer, batch release arrangements and quality control testing of the FP - Other variation	08/03/2024	n/a		

IB/0111/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.a.2.z - Changes in the manufacturing process of the AS - Other variation	06/02/2024	n/a		
II/0110	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	25/01/2024	n/a		
II/0107	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	14/12/2023	n/a		
IA/0109	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	20/10/2023	n/a		
IB/0108	B.II.g.4.z - Changes to an approved change management protocol - Other variation	22/09/2023	n/a		
IAIN/0106/G	This was an application for a group of variations. 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 A.5.b - Administrative change - Change in the name	29/08/2023	05/07/2024	Annex II and PL	

	and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) 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 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 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.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				
N/0105	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/08/2023	n/a		
IB/0104/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.2.a - Changes in the manufacturing process of	17/08/2023	n/a		

	the AS - Minor change in the manufacturing process of the AS				
II/0101	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	13/07/2023	n/a		
IAIN/0103/G	This was an application for a group of variations. 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.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	10/07/2023	05/07/2024	Annex II and PL	
IB/0102	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	23/06/2023	n/a		
II/0090	Extension of indication to include treatment of Hidradenitis Suppurativa (HS) for cosentyx, based on results from two Phase 3 studies CAIN457M2301 (SUNSHINE) and CAIN457M2302 (SUNRISE). These studies are multi-center, randomized, double-blind, placebo-controlled, parallel group Phase 3 studies	26/04/2023	26/05/2023	SmPC and PL	Please refer to Scientific Discussion 'Cosentyx-H-C-003729-II-0090'.

	conducted to assess the short (16 weeks) and long-term (up to 52 weeks) efficacy and safety of two secukinumab dose regimens (Q2W or Q4W) compared to placebo in adult subjects with moderate to severe HS. As a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 11.1 of the RMP has also been approved. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0100	B.II.g.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	23/05/2023	n/a		
IB/0099/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.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.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	28/04/2023	n/a		

II/0097	Update of section 4.8 of the SmPC in order to add 'pyoderma gangrenosum' to the list of adverse drug reactions (ADRs) with frequency 'not known' based on a systematic review of the MAH safety database, clinical trial data, literature search and epidemiological evaluation. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to update the Instructions for Use (IFU) of the pre-filled syringes (PFS) and to update the Additional Information (IFU videos) for PFS to the Cosentyx EU website. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	26/04/2023	26/05/2023	SmPC and PL	Following a systematic review of the MAH safety database, clinical trial data, literature search and epidemiological evaluation, there is sufficient evidence for confirmation of a causal association between secukinumab and Pyoderma gangrenosum. Therefore Pyoderma gangrenosum is added to the list of adverse drug reactions with a frequency not known in section 4.8 of the SmPC. For more information, please refer to the Summary of Product Characteristics.
IB/0098/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.a.2.z - Changes in the manufacturing process 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	23/03/2023	n/a		
II/0096	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	23/02/2023	n/a		
II/0095/G	This was an application for a group of variations.	19/01/2023	26/05/2023	SmPC	The SmPC section 6.3 has been updated as follows: shelf

	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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 B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range				life extended from 18 months to 2 years.
IB/0094/G	This was an application for a group of variations. B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.I.b.2.z - Change in test procedure for AS or	10/01/2023	n/a		

	starting material/reagent/intermediate - Other variation				
IB/0093/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	07/11/2022	n/a		
II/0092/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.z - Change in control of the AS - Other variation 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	27/10/2022	n/a		
N/0091	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/08/2022	n/a		
II/0079	C.I.6 (Extension of indication) Extension of indication to include treatment of	19/05/2022	20/06/2022	SmPC and PL	Please refer to Scientific Discussion "Cosentyx

	Juvenile Idiopathic Arthritis (Enthesitis-Related Arthritis and Juvenile Psoriatic Arthritis) in patients 6 years and older whose disease has responded inadequately to, or who cannot tolerate, conventional therapy for Cosentyx alone or in combination with methotrexate; as a consequence, sections 4.1, 4.2, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 10.2 of the RMP has been approved. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				EMEA/H/C/003729/II/0079”.
IB/0089/G	This was an application for a group of variations. B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	08/06/2022	n/a		
IB/0088/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.5.b - Change to in-process tests or limits	31/05/2022	n/a		

	applied during the manufacture of the finished product - Addition of a new test(s) and limits B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation				
IB/0087	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	25/05/2022	n/a		
IB/0086	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	13/04/2022	n/a		
IB/0085/G	This was an application for a group of variations. 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 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)	11/04/2022	n/a		
II/0084	Update of section 4.8 of the SmPC in order to add the new ADR "dyshidrotic eczema" with the frequency Uncommon based on post-marketing data. The section 4 of Package Leaflet is updated	31/03/2022	20/06/2022	SmPC and PL	With this submission, the section 4.8 of the SmPC (as well as section 4 of the Package Leaflet) has been updated to include 'dyshidrotic eczema' as a new adverse reaction, with the frequency of 'uncommon'. The rationale for the

	accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				addition of this adverse reaction is based on plausible mechanism, disproportionality across multiple databases, and relevant individual case safety reports (literature and post-marketing). For more information, please refer to the Summary of Product Characteristics.
N/0083	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/02/2022	20/06/2022	Labelling and PL	
II/0076	C.I.4 - Update of sections 4.2 and 5.1 of the SmPC for Cosentyx 150mg and 300mg in order to introduce a new posology regimen for adult plaque psoriasis patients and psoriatic arthritis patients with concomitant moderate to severe plaque psoriasis with a body weight of 90 kg or higher based on the final results of Study CAIN457A2324 and exposure-response modeling; this is a randomized, double-blind, multicenter study assessing short (16 weeks) and long-term efficacy (up to 1 year), safety, and tolerability of sub-cutaneous secukinumab in subjects of body weight 90 kg or higher with moderate to severe chronic plaque-type psoriasis; the Package Leaflet is updated accordingly. The RMP version 9.3 has also been adopted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/12/2021	20/01/2022	SmPC and PL	Study CAIN457A2324 was a randomised double-blind, multicentre study evaluating a new dosing regimen of secukinumab every two weeks (Q2W) and the standard dosing regimen of secukinumab every four weeks (Q4W) in adult plaque psoriasis patients and psoriatic arthritis patients with concomitant moderate to severe plaque psoriasis with a body weight of 90 kg or higher. The more frequent Q2W maintenance regimen of secukinumab was associated with higher responses rate in patients with a body weight of 90kg or higher and the rates for adverse event were similar between the two treatment groups. Therefore, section 4.2 of the SmPC has been updated for the adult plaque psoriasis indication as follows "Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher." The same is applicable for patients with psoriatic arthritis and concomitant moderate to severe plaque psoriasis. Section 5.1 of the SmPC has also been updated with the results of the study. For more information, please refer to the Summary of Product Characteristics.

IB/0082/G	This was an application for a group of variations. B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	03/11/2021	n/a		
IAIN/0081	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	03/08/2021	20/01/2022	SmPC and PL	
X/0067	Annex I_2.(c) Change or addition of a new strength/potency	20/05/2021	16/07/2021	SmPC, Labelling and PL	
PSUSA/10341 /202012	Periodic Safety Update EU Single assessment - secukinumab	08/07/2021	n/a		PRAC Recommendation - maintenance
IB/0080	B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation	02/07/2021	n/a		
II/0073	Update of section 5.1 of the SmPC in order to include the 52 weeks results from study A2311; a multicentre, randomised, open-label study in paediatric patients aged 6 years to less than 18 years with moderate to severe chronic plaque psoriasis. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance	01/07/2021	20/01/2022	SmPC	Please refer to Scientific Discussion 'Cosentyx EMEA/H/C/003729/II/0073'.

	data				
IB/0078/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.a.2.z - Changes in the manufacturing process of the AS - Other variation	29/06/2021	n/a		
IB/0077	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	21/06/2021	n/a		
IB/0074/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.a.2.z - Changes in the manufacturing process of the AS - Other variation	17/05/2021	n/a		
IA/0075/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.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished product - Tightening of in-process limits B.II.b.5.c - Change to in-process tests or limits	26/04/2021	n/a		

	applied during the manufacture of the finished product - Deletion of a non-significant in-process test				
IB/0072/G	This was an application for a group of variations. B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number B.II.d.2.z - Change in test procedure for the finished product - Other variation B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits B.II.d.2.z - Change in test procedure for the finished product - Other variation B.II.d.2.z - Change in test procedure for the finished product - Other variation B.II.d.2.z - Change in test procedure for the finished product - Other variation	06/04/2021	n/a		

IB/0071	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)	31/03/2021	n/a		
II/0069	Update of section 5.1 of the SmPC based on final results from study CAIN457F3302 ; this is a randomised, double-blind, placebo-controlled study (MAXIMISE) assessed the efficacy of secukinumab in 485 PsA patients with axial manifestations who were naive to biologic treatment and responded inadequately to NSAIDs; the MAH took this opportunity to introduce minor editorial changes in Section 5.1 of the SmPC. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	18/02/2021	16/07/2021	SmPC	Study CAIN457F3302 (MAXIMISE) is a randomised double-blind placebo-controlled study in 485 psoriatic arthritis (PsA) patients with axial symptoms. The CHMP considered that the study has adequately demonstrated clinically relevant effects of secukinumab on axial symptoms in PsA patients. Apart from the specific manifestations required for eligibility, the general characteristics of enrolled patients were consistent with those in the original registration studies for secukinumab in PsA, and the doses and posologies were generally aligned with those previously authorised. The reported safety information is consistent with the extensive experience gained with secukinumab in earlier clinical studies as well as in the post-marketing setting. Section 5.1 of the SmPC has been updated as follows: "A randomised, double-blind, placebo-controlled study (MAXIMISE) assessed the efficacy of secukinumab in 485 PsA patients with axial manifestations who were naive to biologic treatment and responded inadequately to NSAIDs. The primary variable of at least a 20% improvement in Assessment of SpondyloArthritis International Society (ASAS 20) criteria at week 12 was met. Treatment with secukinumab 300 mg and 150 mg compared to placebo also resulted in greater improvement in signs and symptoms (including decreases from baseline in spinal pain) and improvement in physical function. (…)

					Improvement in ASAS 20 and ASAS 40 for both secukinumab doses were observed by week 4 and were maintained up to 52 weeks." For more information, please refer to the Summary of Product Characteristics.
X/0059	Extension application to add a new strength of 300mg (in 2ml) solution for injection (in pre-filled syringe and pre-filled pen). The RMP (version 7.1) is updated in accordance. Annex I_2.(c) Change or addition of a new strength/potency	17/09/2020	20/11/2020	SmPC, Annex II, Labelling and PL	
IB/0068	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	05/11/2020	n/a		
PSUSA/10341 /201912	Periodic Safety Update EU Single assessment - secukinumab	23/07/2020	17/09/2020	SmPC and PL	Please refer to Cosentyx EMEA/H/C/PSUSA/00010341/201912 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IA/0065/G	This was an application for a group of variations. B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	28/08/2020	n/a		

II/0057	Extension of Indication to include the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years who are candidates for systemic therapy; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, 5.2, 5.3 of the SmPC are updated. Section 6.6 of the SmPC for the solution for injection is also updated. The Package Leaflet is updated in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Netherlands in the Package Leaflet. The RMP was updated to version 6.1. Furthermore, the Annex II is brought in line with the latest QRD template version 10.1. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	25/06/2020	31/07/2020	SmPC, Annex II and PL	Please refer to Scientific Discussion "Cosentyx EMEA/H/C/003729/II/0057".
IB/0064/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place 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	24/07/2020	n/a		

IB/0062	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/07/2020	17/09/2020	SmPC and PL	
IA/0063	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	17/07/2020	n/a		
IB/0061/G	This was an application for a group of variations. 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.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.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.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.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.3.z - Change in the manufacturing process of	26/06/2020	n/a		

	the finished or intermediate product - Other variation B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation 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.g.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product				
II/0053/G	This was an application for a group of variations. Grouping of two variations: One type II variation II C.I.6.a: Extension of indication to include the treatment of active non-radiographic axial spondyloarthritis for Cosentyx. As a consequence, sections 4.1, 4.2, 4.5, 4.8, 5.1 of the SmPC are amended. The package leaflet is amended in accordance. The RMP has been updated to version 5.1. Minor editorial change was made in the Annex II. One type IB C.I.11.z to change the due date of the Psoriasis Registry (category 3 study) within the RMP. The group of variations leads to amendments to the Summary of Product Characteristics, Annex II and Package Leaflet and to the Risk Management Plan (RMP).	26/03/2020	28/04/2020	SmPC, Annex II and PL	Please refer to Scientific Discussion Cosentyx-EMEA-H-C-003729-II-0053-G

	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation				
IB/0058/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.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.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.d.1.d - Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition) B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test	17/02/2020	n/a		

	method and test method number B.II.d.2.f - Change in test procedure for the finished product - To reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number B.II.d.2.z - Change in test procedure for the finished product - Other variation B.II.d.2.z - Change in test procedure for the finished product - Other variation B.II.d.2.z - Change in test procedure for the finished product - Other variation B.II.d.2.z - Change in test procedure for the finished product - Other variation B.II.d.2.z - Change in test procedure for the finished product - Other variation				
IB/0055/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	25/10/2019	n/a		
II/0051	Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to include additional dosing information for AS patients based on final results from study CAIN457F2314; this is a randomized, double-blind, double dummy, placebo controlled, parallel-group, Phase 3 multicentre study of secukinumab versus placebo to demonstrate efficacy at 16 weeks and to	19/09/2019	21/10/2019	SmPC and PL	Study CAIN457F2314 evaluated 226 patients, of whom 13.3% and 23.5% used concomitant MTX or sulfasalazine, respectively. Patients randomised to secukinumab received 10 mg/kg intravenously at weeks 0, 2, and 4, followed by either 150 mg or 300 mg subcutaneously every month. At week 16, patients who were randomised to placebo at baseline were re-randomised to receive secukinumab

	assess long-term efficacy up to Week 156 in patients with active AS; the PL is updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				(either 150 mg or 300 mg subcutaneously) every month. The primary endpoint was ASAS20 at week 16. Patients were blinded to the treatment regimen up to week 52, and the study continued to week 156. Patients treated with secukinumab (150 mg and 300 mg) demonstrated improved signs and symptoms, and had comparable efficacy responses regardless of dose that were superior to placebo at week 16 for the primary endpoint (ASAS20). Overall, the efficacy response rates for the 300 mg group were consistently greater compared to the 150 mg group for the secondary endpoints. During the blinded period, the ASAS20 and ASAS40 responses were 69.7% and 47.6% for 150 mg and 74.3% and 57.4% for 300 mg at week 52, respectively. The ASAS20 and ASAS40 responses were maintained up to week 156 (69.5% and 47.6% for 150 mg versus 74.8% and 55.6% for 300 mg). Greater response rates favouring 300 mg were also observed for ASAS partial remission (ASAS PR) response at week 16 and were maintained up to week 156. Larger differences in response rates, favouring 300 mg over 150 mg, were observed in anti TNFα IR patients (n=36) compared to anti TNFα-naïve patients (n=114). Based on these results the following underlined additional dosing recommendation for AS patients is added: The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Based on clinical response, the dose can be increased to 300 mg. Each 300 mg dose is given as two subcutaneous injections of 150 mg.
IAIN/0056	B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP -	14/10/2019	28/04/2020	Annex II and PL	

	Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing				
PSUSA/10341 /201812	Periodic Safety Update EU Single assessment - secukinumab	25/07/2019	16/09/2019	SmPC and PL	Please refer to Cosentyx EMEA/H/C/PSUSA/000010341/201812 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
R/0050	Renewal of the marketing authorisation.	27/06/2019	03/09/2019	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 Cosentyx in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0052/G	This was an application for a group of variations. 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.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.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.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	23/08/2019	n/a		

	B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product				
IAIN/0054	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/08/2019	21/10/2019	SmPC and PL	
IB/0046	B.II.g.4.b - Changes to an approved change management protocol - Minor changes that do not change the strategy defined in the protocol	17/04/2019	n/a		
IA/0049	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)	20/03/2019	n/a		
IB/0047/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.a.2.z - Changes in the manufacturing process of the AS - Other variation 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.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	14/03/2019	n/a		

IB/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.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	20/02/2019	n/a		
IB/0044	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	07/02/2019	n/a		
IB/0043	B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	20/12/2018	n/a		
IB/0041/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for 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.1.z - Change in the specification parameters and/or limits of an AS, starting	06/11/2018	n/a		

	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 B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material				
IB/0042	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	31/10/2018	n/a		
II/0033/G	This was an application for a group of variations. Update of sections 4.2, 4.8, 5.1 and 5.2 of the SmPC in order to include information on dose up-titration for Psoriatic Arthritis (PsA) and update of the radiographic sub-section for Psoriatic Arthritis (PsA) based on results from the 24-week data from study CAIN457F2342, the pooled data from PsA Phase 3 studies, the pooled data from patients who up-titrated their secukinumab dose in studies CAIN457F2306E1, CAIN457F2312 and CAIN457F2318, and long-term study observations which demonstrate higher rates of discontinuation for patients on secukinumab 150 mg compared to patients on secukinumab 300 mg. The Package leaflet is updated accordingly. In addition, the	20/09/2018	23/10/2018	SmPC and PL	In psoriatic arthritis patients, the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Based on clinical response, the dose can be increased to 300 mg. For information from study CAIN457F2342 and from pooled analyses, please refer to the Summary of Product Characteristics.

	Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives for Bulgaria, Estonia, Lithuania, Latvia and Hungary in the Package Leaflet and to bring the Package leaflet in line with the latest approved SmPC as per procedure (EMEA/H/C/003729/IB/0028). The RMP (v.3.1) has also been updated including suicidal ideation and behaviour as an important potential risk in the RMP and including minor administrative/editorial changes (LEG 005.2). C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/10341 /201712	Periodic Safety Update EU Single assessment - secukinumab	26/07/2018	20/09/2018	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10341/201712.
IA/0040/G	This was an application for a group of variations. B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) B.I.b.1.d - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-	10/08/2018	n/a		

	significant specification parameter (e.g. deletion of an obsolete parameter)				
IA/0039	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	07/08/2018	n/a		
IA/0038	B.III.2.a.2 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	26/07/2018	n/a		
II/0031/G	This was an application for a group of variations. 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 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	07/06/2018	20/09/2018	Annex II	The Annex II has been updated to include the following additional manufacturer of the active substance: Sandoz GmbH, Business Unit Biologics Technical Development and Manufacturing Drug Substance Schaftenau (BTDM DSS), Biochemiestrasse 10, 6336 Langkampfen, Austria
II/0034	B.II.g.2 - Introduction of a post approval change management protocol related to the finished product	17/05/2018	n/a		
T/0036	Transfer of Marketing Authorisation	20/03/2018	26/04/2018	SmPC, Labelling and PL	

IA/0037	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	24/04/2018	n/a		
IB/0030/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation B.II.b.4.z - Change in the batch size (including batch size ranges) of the finished product - Other variation	14/11/2017	n/a		
II/0026	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	14/09/2017	n/a		
IB/0027/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	16/08/2017	n/a		
IB/0028	B.II.f.1.d - Stability of FP - Change in storage conditions of the finished product or the diluted/reconstituted product	15/08/2017	26/04/2018	SmPC and PL	

IAIN/0029	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	03/08/2017	n/a		
II/0020	Update of section 4.5 of the SmPC in order to revise general information on CYP450/CYP3A4 as a result of data provided by the clinical drug-drug interaction study A2110. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	20/07/2017	26/04/2018	SmPC	In a study in subjects with plaque psoriasis, no interaction was observed between secukinumab and midazolam (CYP3A4 substrate).
II/0024	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	06/07/2017	n/a		
PSUSA/10341 /201612	Periodic Safety Update EU Single assessment - secukinumab	06/07/2017	n/a		PRAC Recommendation - maintenance
IB/0025/G	This was an application for a group of variations. 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.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	29/06/2017	n/a		
II/0021/G	This was an application for a group of variations.	01/06/2017	26/04/2018	SmPC, Annex II, Labelling	Statistically significant improvements at Week 4 from baseline in patients treated with secukinumab compared to

	Update of section 5.1 of the SmPC in order to add long term (52 week) data from the CLEAR study (CAIN457A2317) and to add new data from a scalp psoriasis study (CAIN457US01). In addition the MAH has taken the occasion to include a correction in section 4.2 of the SmPC to avoid medication errors - the Package Leaflet has been updated accordingly- and in section 5.1 of the SmPC to align the Psoriatic Arthritis Response Criteria (PsARC) definition to the relevant EMA guideline. The MAH has also implemented the latest QRD template version 10.0. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data			and PL	patients treated with ustekinumab (CLEAR) were demonstrated in the DLQI and these improvements were maintained for up to 52 weeks. Statistically significant improvements in patient-reported signs and symptoms of itching, pain and scaling at Week 16 and Week 52 (CLEAR) were demonstrated in the Psoriasis Symptom Diary© in patients treated with secukinumab compared to patients treated with ustekinumab. Statistically significant improvements (decreases) at Week 12 from baseline in the scalp psoriasis study were demonstrated in patient reported signs and symptoms of scalp itching, pain and scaling compared to placebo. A placebo-controlled study evaluated 102 patients with moderate to severe scalp psoriasis, defined as having a Psoriasis Scalp Severity Index (PSSI) score of ≥12, an IGA mod 2011 scalp only score of 3 or greater and at least 30% of the scalp surface area affected. Secukinumab 300 mg was superior to placebo at Week 12 as assessed by significant improvement from baseline in both the PSSI 90 response (52.9% versus 2.0%) and IGA mod 2011 0 or 1 scalp only response (56.9% versus 5.9%). Improvement in both endpoints was sustained for secukinumab patients who continued treatment through to Week 24.
IAIN/0023	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	24/04/2017	n/a		

PSUSA/10341 /201606	Periodic Safety Update EU Single assessment - secukinumab	26/01/2017	22/03/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10341/201606.
II/0017	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	16/02/2017	n/a		
IB/0016	B.I.e.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	09/11/2016	n/a		
II/0011	B.I.e.2.z - Design Space - Introduction of a post approval change management protocol related to the AS - Other variation	13/10/2016	n/a		
IA/0014	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	15/08/2016	n/a		
II/0012	B.I.e.2 - Introduction of a post approval change management protocol related to the AS	28/07/2016	n/a		
PSUSA/10341 /201512	Periodic Safety Update EU Single assessment - secukinumab	07/07/2016	n/a		PRAC Recommendation - maintenance
IA/0013	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	24/06/2016	n/a		

II/0008/G	This was an application for a group of variations. Update of section 5.1 of the SmPC in order to add new data from the "CLEAR" study CAIN457A2317 (head-to-head versus Stelara) in moderate to severe plaque psoriasis. Update of section 5.1 of the SmPC in order to add new data from the "TRANSFIGURE" study CAIN457A2312 in moderate to severe palmoplantar plaque psoriasis. Update of section 5.1 of the SmPC in order to add new data from the "GESTURE" study CAIN457A2313 in moderate to severe plaque psoriasis with nail involvement. In addition, section 4.8 of the SmPC was amended with updated exposure data from the 3 studies. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	01/04/2016	22/03/2017	SmPC	The results of study A2317 confirmed the efficacy of secukinumab 300 mg in patients with moderate to severe plaque psoriasis. Superiority to ustekinumab was shown with respect to the results of the primary endpoint at Week 16 and the secondary endpoints available. The results of studies A2312, A2313 at Week 16 showed superior efficacy of secukinumab 300 mg compared to placebo in the treatment of moderate to severe plaque palmoplantar psoriasis and psoriasis with nail involvement, respectively. Disease-related quality of life was also improved in the secukinumab treated patients. The results from study A2313 relate mainly to disease of the fingernails as significant fingernail involvement was among the inclusion criteria and efficacy assessment at Week 16 was too early for toenails. Safety findings in studies A2317, A2312 and A2313 were consistent with the known safety profile of secukinumab.
II/0006	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	25/02/2016	n/a		

	product and is not related to a protocol				
IB/0009	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	18/01/2016	n/a		
PSUSA/10341 /201506	Periodic Safety Update EU Single assessment - secukinumab	14/01/2016	n/a		PRAC Recommendation - maintenance
IB/0007	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	21/12/2015	n/a		
II/0002	Extension of indication to add new indication for Cosentyx in the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; consequently, SmPC sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, and 5.2 have been revised to include new efficacy and safety information. The Package Leaflet and RMP have been updated accordingly. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	22/10/2015	19/11/2015	SmPC and PL	Please refer to the scientific discussion Cosentyx EMEA/H/C/003729/II/0002
II/0001/G	This was an application for a group of variations. Extension of Indication to include new indication for	22/10/2015	19/11/2015	SmPC and PL	Please refer to the Scientific Discussion Cosentyx-H-C-3729-II-01 G

	Cosentyx in the treatment alone or in combination with methotrexate (MTX) of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate; as a consequence, sections 4.1, 4.2, 4.4, 4.5, 4.8, 5.1, and 5.2 of the SmPC are updated in order to update the safety and efficacy information. The Package Leaflet and RMP have been updated accordingly. Furthermore, the due of the final report for the psoriasis registry in the RMP has been amended and minor editorial changes have been introduced throughout the PI. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation				
IB/0004/G	This was an application for a group of variations. B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	04/08/2015	n/a		

IB/0003/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	17/04/2015	19/11/2015	SmPC, Labelling and PL	