



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Levetiracetam Teva

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/0038/G	This was an application for a group of variations. 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	19/06/2023		SmPC and PL	

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).



	new additional data is required to be submitted by the MAH 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				
IA/0037	B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	31/10/2022	n/a		
IB/0036	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	06/07/2022		SmPC, Labelling and PL	
IB/0035	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	21/05/2021	17/06/2021	SmPC and PL	
IA/0034/G	This was an application for a group of variations. B.II.b.3.a - Change in the manufacturing process of	03/05/2021	n/a		

	the finished or intermediate product - Minor change in the manufacturing process B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation				
IA/0033	A.7 - Administrative change - Deletion of manufacturing sites	15/02/2021	17/06/2021	Annex II and PL	
IB/0032/G	This was an application for a group of variations. 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 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	11/01/2021	17/06/2021	SmPC and PL	
IB/0031/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	11/06/2020	n/a		

	and/or limits of an AS, starting material/intermediate/reagent - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)				
IB/0030	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	22/01/2020	10/08/2020	SmPC and PL	
IA/0029/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer B.III.1.a.2 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate	25/09/2019	n/a		

	from an already approved manufacturer				
IB/0028	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	03/09/2019	10/08/2020	SmPC and PL	
IAIN/0027	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	13/11/2018	n/a		
IB/0026	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	12/10/2018	29/10/2019	SmPC and PL	
N/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/01/2018	29/10/2019	PL	
IA/0024	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	21/12/2017	n/a		
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	03/02/2017	11/01/2018	SmPC and PL	

	new additional data is required to be submitted by the MAH				
R/0021	Renewal of the marketing authorisation.	26/05/2016	15/07/2016	SmPC, Annex II, Labelling and PL	
IA/0022	A.7 - Administrative change - Deletion of manufacturing sites	30/03/2016	15/07/2016	Annex II and PL	
IB/0020	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	13/11/2015	n/a		
IAIN/0019/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.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.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	14/10/2015	n/a		

	corresponding test method B.III.1.a.3 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition) B.III.2.z - Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - Other variation				
T/0018	Transfer of Marketing Authorisation	09/01/2015	03/02/2015	SmPC, Labelling and PL	
IB/0016	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	30/07/2014	n/a		
IAIN/0013/G	This was an application for a group of variations. B.III.1.a.1 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer 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.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting	25/07/2014	n/a		

	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 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				
IB/0017	B.I.b.z - Change in control of the AS - Other variation	22/07/2014	n/a		
IB/0015	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	22/07/2014	n/a		
IB/0014	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	22/07/2014	n/a		
IB/0012	To delete 'swallow tablets whole' from section 5 of labelling PARTICULAR TO APPEAR ON THE OUTER PACKAGING'. Furthermore the MAH took this	01/07/2014	27/01/2015	Labelling	

	opportunity to correct errors in Bulgarian, Italian, Danish, Hungarian, German and Swedish annexes. In addition the wording/orthography of the SmPC and/or PIL is being brought in line with the originator for BG, IT, HR, CZ, FI, DE, DK, EL, HU, LT, PT, SL, ES, NO. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation				
IB/0011/G	This was an application for a group of variations. 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 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	28/03/2014	27/01/2015	SmPC and PL	
IB/0010	C.I.2.z - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Other variation	03/01/2014	27/01/2015	SmPC and PL	
IAIN/0009/G	This was an application for a group of variations.	24/06/2013	n/a		

	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation B.II.e.7.a - Change in supplier of packaging components or devices (when mentioned in the dossier) - Deletion of a supplier A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)				
IB/0008/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.I.c.2.z - Change in the specification parameters and/or limits of the immediate packaging of the AS - Other variation B.I.c.2.z - Change in the specification parameters and/or limits of the immediate packaging of the AS - Other variation B.I.c.2.z - Change in the specification parameters and/or limits of the immediate packaging of the AS - Other variation B.I.c.2.z - Change in the specification parameters and/or limits of the immediate packaging of the AS - Other variation	30/10/2012	n/a		
IAIN/0007	B.II.b.2.b.1 - Change to batch release arrangements	23/08/2012	31/10/2012	Annex II and	

	and quality control testing of the FP - Not including batch control/testing			PL	
IB/0006	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 are submitted by the MAH	11/07/2012	31/10/2012	SmPC, Annex II, Labelling and PL	Update of the product information to be in line with the reference product (Keppra II-131), The SmPC was updated in order to add 'panic attack' as an undesirable effect following the cumulative review of the safety data for Keppra. The Package Leaflet was updated in accordance. In addition, the description of pancytopenia, erythema multiforme, Stevens-Johnsons syndrome and toxic epidermal necrolysis in section 4 of the Package Leaflet was updated. Furthermore, the product information was brought in line with the latest QRD template, version 8.
IA/0005	B.II.b.3.a - Change in the manufacturing process of the finished product - Minor change in the manufacturing process of an immediate release solid oral dosage form or oral solutions	12/06/2012	n/a		
IB/0004	B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products	13/04/2012	n/a		
IB/0003	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 are submitted by the MAH	05/03/2012	11/06/2012	SmPC and PL	On 5 January 2012, the MAH received a notification from the Agency requesting the submission of a variation for Levetiracetam Teva. This variation is to update section 4.8 of the SmPC and section 4 of the PIL as a consequence of the adoption by the CHMP of safety variations related to significant modifications of the Summary of Product

					Characteristics due in particular to new quality, pre-clinical, clinical or pharmacovigilance data to the reference medicinal product Keppra. In addition, the MAH has taken this opportunity to correct local representatives in the package leaflet for Austria, Germany, Estonia, Italy, Norway and Finland in all languages. Further corrections have been made in languages for Greece, Estonia, France, Iceland, Italy, Portugal, Romania and Slovenia in line with the reference medicinal product.
IAIN/0002	A.5.a - Administrative change - Change in the name and/or address of a manufacturer responsible for batch release	06/01/2012	11/06/2012	Annex II and PL	
IB/0001/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	28/11/2011	11/06/2012	SmPC, Labelling and PL	

	the range of the currently approved pack sizes				
--	--	--	--	--	--