Levetiracetam Accord

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/0042	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	21/02/2024	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).

IB/0041/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	20/06/2023	27/06/2024	SmPC and PL	
IA/0040/G	This was an application for a group of variations. 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	07/03/2023	n/a		
IB/0039	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	20/06/2022	03/02/2023	SmPC and PL	Section 4.8 of the SmPC has been updated to include the adverse reaction neuroleptic malignant syndrome (NMS). The PL has been updated accordingly.

IA/0038	B.II.e.7.b - Change in supplier of packaging components or devices (when mentioned in the dossier) - Replacement or addition of a supplier	29/04/2022	n/a		
IA/0037	A.7 - Administrative change - Deletion of manufacturing sites	10/01/2022	03/02/2023	Annex II and PL	
IA/0036	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	29/06/2021	n/a		
IB/0034	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	08/06/2021	21/06/2021	SmPC and PL	
IAIN/0035	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	26/05/2021	n/a		
IA/0033	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	01/02/2021	n/a		
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	19/01/2021	21/06/2021	SmPC and PL	

	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				
IB/0031	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	11/01/2021	n/a		
IB/0030	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	04/12/2020	n/a		
IA/0029/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	02/07/2020	n/a		

IA/0028/G	This was an application for a group of variations. 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	18/03/2020	n/a		
IB/0027	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	04/02/2020	15/09/2020	SmPC and PL	
IAIN/0026	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	17/09/2019	n/a		
IB/0025	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	10/09/2019	15/09/2020	SmPC and PL	

	the MAH				
IAIN/0024	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)	14/08/2019	n/a		
IA/0023	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	08/03/2019	n/a		
T/0022	Transfer of Marketing Authorisation	01/02/2019	01/03/2019	SmPC, Labelling and PL	
IB/0021	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	23/10/2018	01/03/2019	SmPC and PL	
IAIN/0020/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.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.2.a - Change to importer, batch release	27/09/2018	n/a		

	arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place				
IA/0019	B.III.1.a.4 - Submission of a new/updated or deletion of Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Deletion of certificates (in case multiple certificates exist per material)	31/07/2018	n/a		
IAIN/0018	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	29/06/2018	01/03/2019	Annex II and PL	
IAIN/0017	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	16/11/2017	n/a		
IAIN/0016/G	This was an application for a group of variations. 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.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)	31/08/2017	n/a		
IB/0015	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following	08/12/2016	16/11/2017	SmPC and PL	

	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				
IAIN/0014/G	This was an application for a group of variations. 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.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)	25/10/2016	n/a		
R/0012	Renewal of the marketing authorisation.	26/05/2016	22/07/2016	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 Levetiracetam Accord in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0013	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	14/03/2016	n/a		
IB/0011/G	This was an application for a group of variations. To update the SmPC and package leaflet with the tabulated list of adverse reactions in section 4.8 with "hyponatraemia" and in section 4 of the PIL including	08/05/2014	27/05/2015	SmPC and PL	

	"decreased blood sodium concentration". To update 4.8 of the SmPC to include 'drug reaction with eosinophilia and systematic symptoms (DRESS)' as a rare adverse drug reaction. The package leaflet was updated accordingly. In addition Annex II was brought in line with the latest QRD version. Furthermore minor changes in the FR, FI, LV, PT, PL and SV PIL to be in line with the originator product. 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				
IB/0010	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	10/12/2013	29/01/2014	SmPC and PL	

IAIN/0009	C.I.8.a - Introduction of or changes to a summary of Pharmacovigilance system - Changes in QPPV (including contact details) and/or changes in the PSMF location	30/08/2013	n/a		
IAIN/0008	A.1 - Administrative change - Change in the name and/or address of the MAH	29/01/2013	29/01/2014	SmPC, Labelling and PL	
IAIN/0007	B.III.1.a.1 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from an already approved manufacturer	14/11/2012	n/a		
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	11/09/2012	31/10/2012	SmPC, Annex II, Labelling and PL	Following the CHMP adoption of a variation to the Marketing Authorisation of Keppra EMEA/H/C/000277/II/0131 on 19 April 2012 section 4.8 of the SmPC was updated in order to add 'panick attack' as an undesirable effect following the cumulative review of the safety data for Keppra. The package Leaflet was updated in accordance. In addition, editorial changes were made to section 2 and 4.1 of the SmPC. Moreover, the description of pancytopenia, erythema multiforme, Stevens-Johnsons syndrome and toxic epidermal necrolysis in section 4 of the Package Leaflet was updated. The PI was brought in line with the latest QRD template, version 8. As requested by EMA minor linguistic amendments for languages Estonian, Finnish, French, Hungarian, Icelandic, Italian, Lithuanian, Latvian, Maltese, Dutch, Norwegian, Polish, Portuguese, Romanian, Slovenian, Slovakian and

					Swedish were corrected in PI in line with the originato PI.
IAIN/0004/G	This was an application for a group of variations. B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	18/04/2012	17/09/2012	SmPC, Labelling and PL	

	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes				
IAIN/0003	B.II.e.5.a.1 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	18/04/2012	17/09/2012	SmPC, Labelling and PL	
IB/0002	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 or pharmacovigilance data to the reference medicinal product Keppra. In addition, the MAH has taken this opportunity to correct the layout in Annex I and IIIB. C.I.2.a - Change in the SPC, Labelling or PL of a	19/03/2012	17/09/2012	SmPC and PL	

	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				