Matever

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/0031/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	24/10/2018		SmPC, Labelling 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).

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	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				
N/0030	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/07/2018		PL	
N/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/05/2017	25/01/2018	PL	
N/0028	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/03/2017	25/01/2018	PL	
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	16/01/2017	25/01/2018	SmPC and PL	
IB/0026	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	05/12/2016	n/a		

IAIN/0025	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)	10/10/2016	n/a		
N/0024	Update of the package leaflet with revised contact details of the local representatives for Lithuania, Estonia and Latvia, for the film-coated tablets presentations (EU/1/11/711/001-029). Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/07/2016	25/01/2018	PL	
R/0023	Renewal of the marketing authorisation.	28/04/2016	29/06/2016	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 Matever in the approved indications remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IAIN/0022	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	13/01/2016	n/a		
IAIN/0021	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	12/05/2015	n/a		
II/0018	B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range	26/03/2015	n/a		

N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/02/2015	29/06/2016	PL	
IB/0019/G	This was an application for a group of variations. B.II.b.1.f - Replacement or addition of a manufacturing site for part or all of the manufacturing process of the FP - Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for sterile medicinal products (including those that are aseptically manufactured) excluding biological/ immunological medicinal products 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.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	12/01/2015	n/a		
N/0017	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/10/2014	15/01/2015	PL	
IB/0016/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	05/05/2014	15/01/2015	SmPC, Annex II 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				
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	01/04/2014	15/01/2015	PL	
IB/0013	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	19/12/2013	15/01/2015	SmPC and PL	
IAIN/0011	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	21/10/2013	n/a		
N/0010	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/08/2013	15/01/2015	PL	
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	21/05/2013	15/01/2015	PL	

N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	06/02/2013	15/01/2015	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	24/08/2012	28/09/2012	SmPC, Labelling and PL	Section 4.8 of the SmPC was updated in order to add 'panic attack' as an undesirable effect following the cumulative review of the safety data for Keppra (II-131). The Package Leaflet was updated in accordance. In addition, editorial changes were made to sections 2 and 4.1 of the SmPC. Section 2 of the Package Leaflet was updated in order to change the description of the quantity of the sodium excipient in Matever concentrate for solution for infusion. 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 and details for local representatives in IT and NL were updated in Annex III B.
N/0004	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/05/2012	28/09/2012	PL	
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	04/04/2012	28/09/2012	SmPC and PL	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 (SmPC) due in particular to new quality, pre-clinical, clinical or pharmacovigilance data to Matever's reference medicinal product Keppra. Additional minor editorial changes were made to the Portuguese and Slovakian SmPCs.
IAIN/0002	C.I.9.i - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a	06/01/2012	n/a		

	DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH				
N/0001	The Marketing Authorisation Holder (MAH) took the opportunity to update details of local representatives in Annex IIIB. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/11/2011	28/09/2012	PL	