EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Leflunomide 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
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	15/01/2014		PL	
IAIN/0009	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	28/06/2013	n/a		
IB/0008	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	28/01/2013		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).

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	product - Implementation of change(s) for which NO new additional data are submitted by the MAH				
IA/0007/G	This was an application for a group of variations. B.II.b.4.b - Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold 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	29/11/2012	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	11/06/2012	n/a	SmPC, Annex II, Labelling and PL	Implementation of changes approved in the reference product – upate of section 4.4 to add a warning for peripheral neuropathy and the frequency of this event has been changed to 'commom' in section 4.8 as requested by CHMP. The PIL has been updated accordingly. Further updates concern the implementation of the latest QRD template. In addition, the MAH updated the list of local representatives for Austria, Germany, Finland, Ireland, Malta and Norway.
IB/0005	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	05/12/2011	n/a	SmPC and Labelling	Update of section 4.4 of the SmPC regarding the risk of leflunomide use in combination with biologicals following the CHMP assessment of the COLEBI study (FU2 038.1) as implemented in the originator product Arava II-49. The MAH also took the opportunity to update sections 8 and 9 of the SmPC and section 12 in the labelling with the EU numbers and the date of authorisation.
IA/0004	A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding	26/09/2011	n/a		

	manufacturer for batch release)				
IB/0003	Update of sections 4.2 and 5.1 of the SmPC to reflect the outcome of the clinical study R01143 (LEADER) regarding the use of a loading dose, as requested by CHMP. 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	06/09/2011	n/a	SmPC	Update of sections 4.2 and 5.1 of the SmPC to reflect the outcome of the clinical study R01143 (LEADER) regarding the use of a loading dose, as requested by CHMP.
IB/0002	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	04/08/2011	n/a	SmPC, Annex II and PL	Implementation of changes approved in reference product - update of section 4.4 to amend the warning for interstitial lung disease (ILD) as requested by CHMP. The PIL was revised accordingly. In addition the description of the risk of teratogenicity in the PIL was strengthened. Further updates concern the Annex IIB and the implementation of the latest QRD template.
IB/0001/G	This was an application for a group of variations. 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 B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	08/06/2011	n/a		

	B.II.b.2.a - Change to batch release arrangements and quality control testing of the FP - Replacement or addition of a site where batch control/testing takes place				