Leflunomide medac

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/0040	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	18/03/2024		PL	
N/0038	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	31/10/2023		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).

N/0037	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/03/2023	04/05/2023	PL	
N/0036	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	03/02/2023	04/05/2023	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	13/05/2022	04/05/2023	SmPC and PL	
PSUSA/1837/ 202009	Periodic Safety Update EU Single assessment - leflunomide	06/05/2021	n/a		PRAC Recommendation - maintenance
IAIN/0033	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)	22/12/2020	n/a		
IB/0032	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	08/07/2020	24/06/2021	SmPC, Annex II, Labelling and PL	
IA/0031	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	21/11/2019	n/a		

	from an already approved manufacturer				
IA/0030	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	14/06/2018	n/a		
PSUSA/1837/ 201709	Periodic Safety Update EU Single assessment - leflunomide	12/04/2018	n/a		PRAC Recommendation - maintenance
N/0029	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/01/2018	21/06/2018	PL	
IAIN/0027/G	This was an application for a group of variations. B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s) C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/07/2017	21/06/2018	SmPC, Labelling and PL	
PSUSA/1837/ 201609	Periodic Safety Update EU Single assessment - leflunomide	06/04/2017	n/a		PRAC Recommendation - maintenance
PSUSA/1837/ 201509	Periodic Safety Update EU Single assessment - leflunomide	14/04/2016	n/a		PRAC Recommendation - maintenance
IAIN/0025	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/12/2015	15/07/2016	SmPC and PL	
IA/0023	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	31/07/2015	15/07/2016	SmPC and PL	

IA/0022	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	08/07/2015	n/a		
IA/0021/G	This was an application for a group of variations. B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products 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	08/07/2015	n/a		
PSUSA/1837/ 201409	Periodic Safety Update EU Single assessment - leflunomide	10/04/2015	n/a		PRAC Recommendation - maintenance
R/0019	Renewal of the marketing authorisation.	22/01/2015	23/03/2015	SmPC, Annex II, Labelling and PL	Based on the review of data on quality, safety and efficacy, including all variations introduced since the marketing authorisation was granted, the CHMP considered that the benefit-risk balance of Leflunomide Medac in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0018	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	29/09/2014	23/03/2015	SmPC and PL	

IB/0017	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	09/09/2014	n/a		
IAIN/0016/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release	10/06/2014	23/03/2015	SmPC, Annex II, Labelling and PL	
PSUSA/1837/ 201309	Periodic Safety Update EU Single assessment - leflunomide	10/04/2014	n/a		PRAC Recommendation - maintenance
IB/0015	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/03/2014	23/03/2015	SmPC and PL	To add the patent protected indication 'psoriatic arthritis'. Subsequently the RMP was updated and adapted to the current format. In addition, the SmPC was brought in line with the latest QRD template.
X/0012/G	This was an application for a group of variations. - To add a new strength. - To extend the shelf life of the finished product. - To replace the DDPS with a summary of PhV system. - To make some editorial changes. C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation B.II.f.1.b.1 - Stability of FP - Extension of the shelf	30/05/2013	25/07/2013	SmPC, Annex II, Labelling and PL	Please refer to the assessment report Leflunomide medac-H-1227-X-12-G-AR-Extension.

	life of the finished product - As packaged for sale (supported by real time data) Annex I_2.(c) Change or addition of a new strength/potency				
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 are submitted by the MAH	28/01/2013	25/07/2013	SmPC and PL	Update of Sections 4.4 and 4.8 of the SmPC to add cutaneous lupus erythematosus, pustular psoriasis or worsening psoriasis and warn physicians about these skin reactions in accordance with the reference product. The Package Leaflet was updated accordingly.
N/0010	"Update of the local representatives contact details for France and Italy." Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/09/2012	29/10/2012	PL	
IB/0009	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	13/06/2012	29/10/2012	SmPC, Annex II, Labelling and PL	Implementation of changes approved in reference product – update of section 4.4 to add a warning for peripheral neuropathy and the frequency of this event has been changed to 'common' 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 Cyprus and Iceland.
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 product - Implementation of change(s) for which NO new additional data are submitted by the MAH	05/12/2011	30/01/2012	SmPC	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.

IB/0007	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	15/09/2011	n/a	SmPC and PL	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. The MAH also took the opportunity to make minor linguistic corrections to align with the reference product and made changes to the contact details of the local representatives in the package leaflets.
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 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	30/08/2011	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
IA/0006	B.III.1.a.2 - Submission of a new or updated Ph. Eur. Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	05/08/2011	n/a		
IA/0005	C.I.9.i - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) to a DDPS following the assessment of the same DDPS in relation to another medicinal product of the same MAH	30/06/2011	n/a		

IB/0004	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	23/06/2011	n/a	SmPC, Annex II, Labelling and PL	