Dasselta

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
PSUSA/962/ 202107	Periodic Safety Update EU Single assessment - desloratadine	24/03/2022	30/05/2022	SmPC and PL	Please refer to Aerius-Azomyr-Neoclarityn-Desloratadine Teva-Dasselta-Desloratadine Actavis-Desloratadine ratiopharm-EMEA/H/C/PSUSA/00000962/202107 EPAR: Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IA/0020/G	This was an application for a group of variations.	05/10/2021	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).

	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.I.c.1.a - Change in immediate packaging of the AS - Qualitative and/or quantitative composition 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				
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/05/2021	30/05/2022	PL	
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	07/05/2020	30/04/2021	SmPC, Annex II, Labelling and PL	
IB/0017	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	12/03/2018	07/02/2019	SmPC	
IB/0016	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	07/02/2018	07/02/2019	SmPC, Labelling and PL	
PSUSA/962/201607	Periodic Safety Update EU Single assessment - desloratadine	23/03/2017	18/05/2017	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

					PSUSA/962/201607.
IA/0015/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	05/04/2017	n/a		
IAIN/0014	B.III.2.a.1 - Change of specification(s) of a former non EU Pharmacopoeial substance to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - AS	15/03/2017	n/a		
R/0012	Renewal of the marketing authorisation.	23/06/2016	16/08/2016	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 Dasselta in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0010	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	15/02/2016	n/a		
IA/0011	A.7 - Administrative change - Deletion of manufacturing sites	12/02/2016	n/a		

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 is required to be submitted by the MAH	07/10/2015	21/04/2016	SmPC and PL	
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 is required to be submitted by the MAH	11/06/2015	21/04/2016	SmPC and PL	
IB/0007/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	28/04/2015	21/04/2016	SmPC and PL	
IB/0005/G	This was an application for a group of variations.	05/03/2015	n/a		

	B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size 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				
IAIN/0006	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	26/02/2015	n/a		
IB/0004	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	12/09/2013	22/08/2014	SmPC, Annex II, Labelling and PL	
N/0003	Update of the local representatives contact details in the package leaflet and inclusion of an additional local representative of the Marketing Authorisation Holder for the new Croatian Member State. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	02/07/2013	22/08/2014	PL	Update of the local representatives contact details in the package leaflet and inclusion of an additional local representative of the Marketing Authorisation Holder for the new Croatian Member State.
IA/0002	A.4 - Administrative change - Change in the name and/or address of a manufacturer or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS	22/10/2012	n/a		

N/0001	Updated local representative contact details for Ireland, Malta and Spain. The MAH also made editorial changes in the Bulgarian, Spanish and French package leaflets and for the labelling in Denmark. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/03/2012	22/08/2014	Labelling and PL	