Adasuve

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
II/0033	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	01/09/2022	31/10/2022	SmPC, Annex II, Labelling and PL	
PSUSA/10113 /202108	Periodic Safety Update EU Single assessment - loxapine (pre-dispensed inhalation powder)	07/04/2022	n/a		PRAC Recommendation - maintenance

[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).

II/0032	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	06/05/2021	n/a		
II/0030	Submission of the category 3 final report from Drug Utilization study AMDC-204-403 EU (A Multinational Retrospective Medical Record Review to Evaluate Utilization Patterns of Adasuve-Staccato loxapine for inhalation in agitated persons in routine clinical care). In addition, the MAH also submitted the second report with results of the healthcare professional survey on the effectiveness of the additional risk minimisation measures in Annex 7 of the RMP submitted with this variation. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	14/06/2019	n/a		
N/0031	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/05/2019	31/10/2022	PL	
PSUSA/10113 /201808	Periodic Safety Update EU Single assessment - loxapine (pre-dispensed inhalation powder)	14/03/2019	n/a		PRAC Recommendation - maintenance
IB/0029	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	20/02/2019	n/a		
IB/0027	B.I.a.2.e - Changes in the manufacturing process of	22/11/2018	n/a		

	the AS - Minor change to the restricted part of an ASMF				
N/0026	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	07/11/2018	31/10/2022	PL	
PSUSA/10113 /201708	Periodic Safety Update EU Single assessment - loxapine (pre-dispensed inhalation powder)	08/03/2018	n/a		PRAC Recommendation - maintenance
R/0024	Renewal of the marketing authorisation.	09/11/2017	15/01/2018	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 Adasuve in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IA/0023	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	24/05/2017	n/a		
PSUSA/10113 /201608	Periodic Safety Update EU Single assessment - loxapine (pre-dispensed inhalation powder)	09/03/2017	n/a		PRAC Recommendation - maintenance
IB/0022	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	21/02/2017	n/a		
N/0021	Update of the package leaflet with revised contact details of the local representatives for Denmark, Finland, Iceland, Norway, Sweden and Cyprus. In addition, the MAH took the opportunity to make	28/11/2016	15/01/2018	PL	

	minor linguistic amendments in the Danish labelling and in the Czech, Danish, Icelandic, Norwegian and Swedish package leaflets. Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)				
PSUSA/10113 /201508	Periodic Safety Update EU Single assessment - loxapine (pre-dispensed inhalation powder)	17/03/2016	n/a		PRAC Recommendation - maintenance
N/0018	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/10/2015	15/01/2018	PL	
PSUSA/10113 /201502	Periodic Safety Update EU Single assessment - loxapine (pre-dispensed inhalation powder)	10/09/2015	n/a		PRAC Recommendation - maintenance
T/0017	Transfer of Marketing Authorisation	13/08/2015	25/08/2015	SmPC, Labelling and PL	
IB/0016/G	This was an application for a group of variations. 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) B.II.f.1.e - Stability of FP - Change to an approved stability protocol	06/07/2015	25/08/2015	SmPC	
IAIN/0014	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	02/06/2015	n/a		

IA/0015	B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process	28/05/2015	n/a		
PSUSA/10113 /201408	Periodic Safety Update EU Single assessment - loxapine (pre-dispensed inhalation powder)	12/03/2015	n/a		PRAC Recommendation - maintenance
IAIN/0012	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	08/12/2014	n/a		
II/0010/G	This was an application for a group of variations. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	23/10/2014	25/08/2015	SmPC, Labelling and PL	
II/0009	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/09/2014	25/08/2015	SmPC	
PSUV/0007	Periodic Safety Update	11/09/2014	n/a		PRAC Recommendation - maintenance

IAIN/0008	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	05/06/2014	n/a		
IB/0006	To extend the shelf life of the finished product from 24 to 36 months. The applicant took the opportunity to revise the shelf life specifications of the finished product in order to bring them in line with the stability protocol. 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)	08/04/2014	03/06/2014	SmPC	
PSUV/0005	Periodic Safety Update	06/03/2014	n/a		PRAC Recommendation - maintenance
IAIN/0004	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	16/12/2013	n/a		
IAIN/0003	C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the back-up procedure of the QPPV	28/05/2013	n/a		
IB/0002/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside	03/05/2013	03/06/2014	SmPC, Labelling and PL	

	the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes				
IAIN/0001/G	This was an application for a group of variations. C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the pharmacovigilance system	17/04/2013	n/a		