Zalviso

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
T/0017	Transfer of Marketing Authorisation	06/08/2021	29/09/2021	SmPC, Labelling and PL	
R/0016	Renewal of the marketing authorisation;	23/07/2020	24/09/2020	SmPC and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of

[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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					Zalviso in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
IB/0015/G	This was an application for a group of variations. 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 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	27/01/2020	n/a		
WS/1719	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	16/01/2020	24/09/2020	SmPC and PL	
PSUSA/2798/ 201811	Periodic Safety Update EU Single assessment - sufentanil	25/07/2019	01/10/2019	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/2798/201811.
IB/0011	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	23/07/2019	01/10/2019	SmPC and PL	
IA/0010	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the	27/11/2018	n/a		

	finished product, including quality control sites (excluding manufacturer for batch release)				
IA/0009/G	This was an application for a group of variations. 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 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	27/11/2018	n/a		
N/0008	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	22/05/2017	01/10/2019	Labelling	
IB/0007	B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	10/05/2017	n/a		
IA/0003/G	This was an application for a group of variations. B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	11/01/2017	n/a		

IB/0006	B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test	04/01/2017	n/a		
IB/0005	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	04/01/2017	n/a		
IB/0004	B.II.d.2.d - Change in test procedure for the finished product - Other changes to a test procedure (including replacement or addition)	04/01/2017	n/a		
PSUSA/2798/ 201511	Periodic Safety Update EU Single assessment - sufentanil	02/09/2016	n/a		PRAC Recommendation - maintenance
IA/0002	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	27/04/2016	06/04/2017	SmPC	