Odomzo

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
IA/0037	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	07/04/2021		SmPC and PL	
II/0035	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	25/02/2021	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).

PSUSA/10408 /202006	Periodic Safety Update EU Single assessment - sonidegib	14/01/2021	n/a		PRAC Recommendation - maintenance
IA/0034	A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release)	30/10/2020	n/a		
N/0032	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/09/2020		PL	
IB/0031	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	17/07/2020	n/a		
PSUSA/10408 /201912	Periodic Safety Update EU Single assessment - sonidegib	09/07/2020	n/a		PRAC Recommendation - maintenance
R/0028	Renewal of the marketing authorisation.	26/03/2020	20/05/2020	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 Odomzo in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
II/0024	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	12/03/2020	n/a		
PSUSA/10408 /201906	Periodic Safety Update EU Single assessment - sonidegib	16/01/2020	n/a		PRAC Recommendation - maintenance

IA/0027/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	11/10/2019	n/a		
N/0025	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	08/08/2019	04/10/2019	PL	
PSUSA/10408 /201812	Periodic Safety Update EU Single assessment - sonidegib	11/07/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10408 /201806	Periodic Safety Update EU Single assessment - sonidegib	17/01/2019	n/a		PRAC Recommendation - maintenance
IB/0021	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)	02/10/2018	04/10/2019	SmPC and PL	
IB/0020	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	08/08/2018	n/a		
PSUSA/10408 /201712	Periodic Safety Update EU Single assessment - sonidegib	12/07/2018	n/a		PRAC Recommendation - maintenance
II/0016	C.I.11.b - Introduction of, or change(s) to, the obligations and conditions of a marketing	25/01/2018	08/05/2018	Annex II	

	authorisation, including the RMP - Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment is required				
PSUSA/10408 /201706	Periodic Safety Update EU Single assessment - sonidegib	11/01/2018	n/a		PRAC Recommendation - maintenance
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)	15/12/2017	08/05/2018	SmPC, Labelling and PL	
IAIN/0018/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Replacement or addition of a manufacturer	14/12/2017	n/a		

	responsible for importation and/or batch release - Not including batch control/testing				
II/0011	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	06/07/2017	08/05/2018	SmPC and PL	
PSUSA/10408 /201612	Periodic Safety Update EU Single assessment - sonidegib	06/07/2017	n/a		PRAC Recommendation - maintenance
IB/0014/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 B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place 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	04/07/2017	n/a		
IB/0013	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	06/06/2017	n/a		
II/0010	C.I.4 - Change(s) in the SPC, Labelling or PL due to	01/06/2017	08/05/2018	SmPC and PL	

	new quality, preclinical, clinical or pharmacovigilance data				
T/0012	Transfer of Marketing Authorisation	31/03/2017	31/05/2017	SmPC, Labelling and PL	
II/0008/G	This was an application for a group of variations. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority 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	26/01/2017	31/05/2017	SmPC	
II/0007	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	26/01/2017	n/a		
PSUSA/10408 /201606	Periodic Safety Update EU Single assessment - sonidegib	12/01/2017	n/a		PRAC Recommendation - maintenance
II/0005	To resolve two post-authorisation measures (Post Authorisation Efficacy Studies) listed in the Annex II.D of the Marketing Authorisation, resulting in an update of the sections 4.8 and 5.1 of the SmPC, the Annex II and RMP.	10/11/2016	31/05/2017	SmPC and Annex II	

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
PSUSA/10408 /201512	Periodic Safety Update EU Single assessment - sonidegib	07/07/2016	n/a		PRAC Recommendation - maintenance
II/0004/G	This was an application for a group of variations. Submission of the final Clinical Study Reports (CSRs) for studies X2114 and X2203, whereby the MAH committed to collect cardiac events, second primary malignancies and fractures. These two exploratory studies conclude that the safety profile for sonidegib remains unchanged. None of them led to an update of the product information. In addition, the MAH proposed updates to the EU Risk Management Plan (RMP, v3.2) to reflect completion of these studies (X2114 and X2203) and changes to the due dates for provision of the final study reports for the category 3 studies LDE225C2301 and LDE225X2104. The requested group of variations proposed amendments to the Risk Management Plan. 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	26/05/2016	n/a		

	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
IB/0002	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/03/2016	n/a		
II/0001/G	This was an application for a group of variations. Update of sections 4.2 and 5.2 of the SmPC to add information on posology and pharmacology of sonidegib in hepatic impaired patients based on results from study CLDE225A2113 (MEA 006) and update of section 4.5 of the SmPC to add information on Drug-Drug interaction with proton pump inhibitors (esomeprazole) based on results from study CLDE225A2118 (MEA 007). The Risk Management Plan of the product has been updated accordingly and the final version approved is 3.1. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	28/01/2016	24/02/2016	SmPC	No dose adjustment is necessary in patients with mild (Child Pugh class A) or moderate (Child Pugh class B) hepatic impairment. Results from a clinical study demonstrated a change in sonidegib exposure (32% and 38% decrease in AUC and Cmax) after co-administration of a single dose of Odomzo 200 mg with esomeprazole (a proton pump inhibitor) at 40 mg daily for 6 days in healthy subjects. This interaction is not expected to be clinically significant.