Farydak

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
IAIN/0028	A.1 - Administrative change - Change in the name and/or address of the MAH	12/10/2023		SmPC, Labelling and PL	
T/0027	Transfer of Marketing Authorisation	01/03/2023	24/04/2023	SmPC, Labelling and	

[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).

				PL	
PSUSA/10409 /202208	Periodic Safety Update EU Single assessment - panobinostat	16/03/2023	n/a		PRAC Recommendation - maintenance
IA/0025	A.6 - Administrative change - Change in ATC Code/ATC Vet Code	31/03/2022	08/07/2022	SmPC	
PSUSA/10409 /202108	Periodic Safety Update EU Single assessment - panobinostat	10/03/2022	n/a		PRAC Recommendation - maintenance
IAIN/0023	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 responsible for importation and/or batch release - Not including batch control/testing	21/06/2021	08/07/2022	Annex II and PL	
IA/0022	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)	31/05/2021	n/a		
PSUSA/10409 /202008	Periodic Safety Update EU Single assessment - panobinostat	11/03/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10409 /201908	Periodic Safety Update EU Single assessment - panobinostat	26/03/2020	02/06/2020	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10409/201908.
R/0020	Renewal of the marketing authorisation.	27/02/2020	28/04/2020	SmPC, Labelling and PL	

T/0018	Transfer of Marketing Authorisation	15/10/2019	04/11/2019	SmPC, Labelling and PL	
IA/0017/G	This was an application for a group of variations. 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) A.7 - Administrative change - Deletion of manufacturing sites	19/08/2019	n/a		
IG/1099	A.7 - Administrative change - Deletion of manufacturing sites	24/05/2019	n/a		
IB/0015	B.I.b.1.z - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Other variation	03/05/2019	n/a		
PSUSA/10409 /201808	Periodic Safety Update EU Single assessment - panobinostat	14/03/2019	n/a		PRAC Recommendation - maintenance
II/0013	Update of the RMP to version 5.0 in order to remove the commitment to conduct a non-interventional PASS study (LBH589D2408) of panobinostat use in relapsed or relapsed/refractory multiple myeloma patients who have received at least two prior regimens including bortezomib and an immunomodulatory agent in a real-world setting according to the current EU prescribing information and document adherence to dosing regimen	14/02/2019	n/a		

	(including the dosing card, blister pack) by describing clinical characteristics, frequency and severity of the medication error events; listed as a category 3 study in the RMP. C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation				
IA/0012	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	18/06/2018	06/06/2019	SmPC, Annex II, Labelling and PL	
T/0011	Transfer of Marketing Authorisation	20/03/2018	12/04/2018	SmPC, Labelling and PL	
PSUSA/10409 /201708	Periodic Safety Update EU Single assessment - panobinostat	08/03/2018	n/a		PRAC Recommendation - maintenance
IB/0009	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	26/10/2017	n/a		
PSUSA/10409 /201702	Periodic Safety Update EU Single assessment - panobinostat	28/09/2017	n/a		PRAC Recommendation - maintenance
PSUSA/10409 /201608	Periodic Safety Update EU Single assessment - panobinostat	23/03/2017	23/06/2017	SmPC	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10409/201608.
IB/0007/G	This was an application for a group of variations.	23/01/2017	n/a		

	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.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.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation				

	B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation				
IB/0005/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.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.d.1.z - Stability of AS - Change in the re-test period/storage period or storage conditions - Other variation B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure 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.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or	23/09/2016	16/02/2017	SmPC and PL	

	deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.2 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - New certificate for a starting material/reagent/intermediate/or excipient from a new or an already approved manufacturer B.III.1.b.3 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Updated certificate from an already approved manufacturer B.III.1.b.4 - Submission of a new/updated or deletion of Ph. Eur. TSE Certificate of Suitability - Deletion of certificates (in case multiple certificates exist per material) B.I.b.2.z - Change in test procedure for AS or starting material/reagent/intermediate - Other variation B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation				
PSUSA/10409 /201602	Periodic Safety Update EU Single assessment - panobinostat	02/09/2016	n/a		PRAC Recommendation - maintenance
II/0002/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	21/04/2016	n/a		

	intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method B.I.b.1.g - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Widening of the approved specs for starting mat./intermediates, which may have a significant effect on the quality of the AS and/or the FP B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate				
II/0003	Update of section 4.6 of the SmPC in order to amend the safety information with a recommendation for pregnancy testing prior to treatment with Farydak, as a cautionary measure, in the Product Information. The Package Leaflet and the RMP (finally agreed version: 2.4) are updated in accordance.	25/02/2016	16/02/2017	SmPC, Labelling and PL	

	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
II/0001	Update of section 5.1 of the SmPC in order to update the safety information with regard to the key secondary endpoint of overall survival in the study D2308 to fulfil an Annex II condition (ANX 001). The Annex II of the product information is updated accordingly to remove the condition. As a consequence the RMP ver.2.2 is provided. In addition, the Marketing authorisation holder (MAH) took the opportunity to correct an oversight in the Annex IIIA and add the Days and Weeks in section 5 under 'Other' in alignment with the approved blister foil mock-ups. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/02/2016	16/02/2017	SmPC, Annex II and Labelling	Section 5.1 of the SmPC has been updated to include the results from the final analysis of the Overall survival (OS) from the pivotal study CLBH589D2308. OS was the key secondary endpoint. OS was not statistically significantly different between the two treatment groups. The median OS was 40.3 months in the panobinostat + bortezomib + dexamethasone arm and 35.8 months in the placebo + bortezomib + dexamethasone arm (Hazard ratio: 0.94 (95% CI: 0.78, 1.14)).