Alkindi

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/0019	Update of section 4.2 of the SmPC in order to update posology recommendations in case of incomplete dosing, following the request by PRAC in the AR for procedure PSUSA/00010674/202208; the Package Leaflet is updated accordingly. C.I.3.z - Change(s) in the SPC, Labelling or PL intended to implement the outcome of a procedure concerning PSUR or PASS or the outcome of the assessment done under A 45/46 - Other variation	14/12/2023	25/01/2024	SmPC and PL	

[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).

IA/0022	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	24/01/2024	n/a		
IB/0020	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	06/11/2023	n/a		
IA/0018/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	12/05/2023	n/a		
IB/0017	B.II.b.5.z - Change to in-process tests or limits applied during the manufacture of the finished product - Other variation	04/04/2023	n/a		
PSUSA/10674 /202208	Periodic Safety Update EU Single assessment - hydrocortisone (centrally authorised products for adrenal insufficiency, paediatric use only)	16/03/2023	n/a		PRAC Recommendation - maintenance
R/0014	Renewal of the marketing authorisation.	15/09/2022	09/11/2022	SmPC, Labelling and PL	

PSUSA/10674 /202108	Periodic Safety Update EU Single assessment - hydrocortisone (centrally authorised products for adrenal insufficiency, paediatric use only)	10/03/2022	n/a		PRAC Recommendation - maintenance
IAIN/0013/G	This was an application for a group of variations. B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary 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 responsible for importation and/or batch release - Not including batch control/testing B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	07/02/2022	09/11/2022	Annex II and PL	
IAIN/0011	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	03/05/2021	19/05/2021	SmPC and PL	
PSUSA/10674 /202008	Periodic Safety Update EU Single assessment - hydrocortisone (centrally authorised products for adrenal insufficiency, paediatric use only)	11/03/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10674 /202002	Periodic Safety Update EU Single assessment - hydrocortisone (centrally authorised products for adrenal insufficiency, paediatric use only)	03/09/2020	n/a		PRAC Recommendation - maintenance
PSUSA/10674 /201908	Periodic Safety Update EU Single assessment - hydrocortisone (centrally authorised products for	12/03/2020	n/a		PRAC Recommendation - maintenance

	adrenal insufficiency, paediatric use only)				
IB/0007	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	16/10/2019	09/03/2020	SmPC, Annex II and PL	
PSUSA/10674 /201902	Periodic Safety Update EU Single assessment - hydrocortisone (centrally authorised products for adrenal insufficiency, paediatric use only)	05/09/2019	n/a		PRAC Recommendation - maintenance
IAIN/0005/G	This was an application for a group of variations. A.1 - Administrative change - Change in the name and/or address of the MAH A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	11/03/2019	09/03/2020	SmPC, Annex II, Labelling and PL	
PSUSA/10674 /201808	Periodic Safety Update EU Single assessment - hydrocortisone (centrally authorised products for adrenal insufficiency, paediatric use only)	14/02/2019	n/a		PRAC Recommendation - maintenance
T/0003	Transfer of Marketing Authorisation	06/08/2018	06/09/2018	SmPC, Labelling and PL	
IB/0002/G	This was an application for a group of variations. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	29/06/2018	06/09/2018	SmPC	

	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)				
IAIN/0001/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) B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary 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 responsible for importation and/or batch release - Not including batch control/testing	03/05/2018	06/09/2018	Annex II and PL	