Efmody

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/0013	Update of sections 4.2, 4.4, 4.5, and 4.8 of the SmPC based on the pooled safety analysis of DIUR-006; this is a phase 3 extension study of efficacy, safety and tolerability of hydrocortisone in the treatment of congenital adrenal hyperplasia. The Package Leaflet is updated accordingly. In addition,	27/03/2025		SmPC and PL	The SmPC has been amended to better explain the potential effects of the drug on the electrolytes balance, as well as its impact on the results of investigations. For more information, please refer to the Summary of Product Characteristics.

[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).

	the MAH took the opportunity to introduce editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0011/G	This was an application for a group of variations. C.I.7.b - Deletion of - a strength A.7 - Administrative change - Deletion of manufacturing sites	05/12/2024		SmPC, Annex II, Labelling and PL	
IAIN/0012	A.1 - Administrative change - Change in the name and/or address of the MAH	14/11/2024		SmPC, Labelling and PL	
WS/2740/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place B.II.b.2.a - Change to importer, batch release arrangements and quality control testing of the FP - Replacement/addition of a site where batch control/testing takes place	03/10/2024	n/a		
IAIN/0009/G	This was an application for a group of variations.	06/08/2024		Annex II and	

	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.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site			PL	
IA/0008	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	09/05/2024	n/a		
IA/0007	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		
IA/0006	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	27/09/2023	n/a		
PSUSA/9176/ 202211	Periodic Safety Update EU Single assessment - hydrocortisone (for centrally authorised products for adrenal insufficiency, congenital adrenal hyperplasia,	22/06/2023	23/08/2023	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for

	modified-release formulations)				PSUSA/9176/202211.
IB/0004/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 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	21/06/2022	29/06/2023	SmPC, Labelling and PL	
IA/0002	B.II.b.5.b - Change to in-process tests or limits applied during the manufacture of the finished product - Addition of a new test(s) and limits	10/05/2022	n/a		
IAIN/0001/G	This was an application for a group of variations. 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 B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site	08/06/2021	08/07/2022	SmPC, Annex II and PL	