Ucedane

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
IB/0014	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	19/01/2024		SmPC, Annex II 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/0013	A.7 - Administrative change - Deletion of manufacturing sites	05/07/2022	09/10/2023	SmPC, Annex II and PL	
R/0011	Renewal of the marketing authorisation.	27/01/2022	28/03/2022	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 Ucedane in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity.
N/0012	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/12/2021	28/03/2022	PL	
IB/0009	C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH	16/06/2021	28/03/2022	SmPC and PL	To extend the indications of medicinal product for hyperammonaemia due to isovaleric acidaemia, hyperammonaemia due to methylmalonic acidaemia, and hyperammonaemia due to propionic acidaemia following assessment of the same change for the reference product.
IA/0010	B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products	11/06/2021	n/a		
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	28/09/2020	28/03/2022	PL	
IAIN/0006	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	30/06/2020	n/a		

N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	30/08/2019	04/02/2020	PL	
IG/1105/G	This was an application for a group of variations. 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 responsible for importation and/or batch release - Not including batch control/testing	06/06/2019	04/02/2020	Annex II and PL	
II/0002/G	This was an application for a group of variations. B.II.a.1.a - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in imprints, bossing or other markings B.II.a.1.b - Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking - Changes in scoring/break lines intended to divide into equal doses B.II.a.2.b - Change in the shape or dimensions of the pharmaceutical form - Gastro-resistant, modified or prolonged release pharmaceutical forms and scored tablets intended to be divided into equal doses B.II.b.5.a - Change to in-process tests or limits applied during the manufacture of the finished	31/01/2019	04/02/2020	SmPC and PL	As a result of this group of variation and implementation of score lines for dosing increments of 50 mg, the SmPC have been updated as follows: 3. PHARMACEUTICAL FORM Dispersible tablet. The tablets are white, oval and biconvex with one score line and engraving LL. The tablets are rod-shaped, white and biconvex with three score lines on both sides and engraving "L/L/L/L" on one side. The tablet can be divided into four equal doses. 4.2 Posology and method of administration The breaking of the tablets in halves allows most of the required posology adjustments. Occasionally, the use of

	product - Tightening of in-process limits B.II.b.5.e - Change to in-process tests or limits applied during the manufacture of the finished product - Widening of the approved IPC limits, which may have a significant effect on overall quality of the finished product B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range C.I.2.a - Change in the SPC, Labelling or PL of a generic/hybrid/biosimilar products following assessment of the same change for the reference product - Implementation of change(s) for which NO new additional data is required to be submitted by the MAH				quarter tablets may also be useful to adjust the posology prescribed by the physician. It is not possible to administer Ucedane to patients who require dose adjustments of 50 mg. In such cases, other carglumic acid products which allow for these dose adjustments should be used. The PL have been updated accordingly.
T/0003	Transfer of Marketing Authorisation	12/10/2018	07/12/2018	SmPC, Labelling and PL	
IB/0001	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	19/07/2017	30/07/2018	SmPC, Labelling and PL	