Lumeblue

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
R/0007	Renewal of the marketing authorisation.	27/03/2025	22/05/2025	SmPC, Annex II and PL	Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Lumeblue in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. The Product information was updated to ensure compliance

[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).

					to current standards (e.g. QRD templates).
T/0006	Transfer of Marketing Authorisation	22/10/2024	14/11/2024	SmPC, Labelling and PL	
PSUSA/2029/202305	Periodic Safety Update EU Single assessment - methylthioninium chloride	11/01/2024	n/a		PRAC Recommendation - maintenance
II/0004	Update of section 4.2 of the SmPC in order to introduce a new posology regimen based on scientific literature and PK/PD results from studies CB-17-01/17 and CB-17-01/15; CB-17-01/17 is an open-label, randomized, cross-over, safety and bioavailability descriptive study in healthy volunteers receiving a full and a split dose regimen of bowel cleansing preparation for colonoscopy; CB-17-01/15 is a single dose, randomised, parallel groups, open label, efficacy study in patients receiving a split dose regimen of bowel cleansing preparation for colonoscopy. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	25/05/2023	11/09/2023	SmPC	SmPC new text: The total dose of the medicinal product must be taken orally during or after the intake of low-volume (e.g. 2 L) or high-volume (e.g. 4 L) polyethylene glycol (PEG) based bowel cleansing preparation and should be completed the evening prior to the colonoscopy to ensure there is enough time for the tablets to reach the colon and locally release the methylthioninium chloride prior to the colonoscopy. The patient should take the medicinal product with the low-volume (e.g. 2L) or high-volume (e.g. 4 L) PEG based bowel cleansing regimen chosen by the healthcare provider according to the same dosing schedule. For more information, please refer to the Summary of Product Characteristics.
IB/0003/G	This was an application for a group of variations. B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change	24/11/2021	n/a		

	in the manufacturing process B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process				
T/0002	Transfer of Marketing Authorisation	08/04/2021	21/05/2021	SmPC, Labelling and PL	
IAIN/0001/G	This was an application for a group of variations. A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release A.2.a - Administrative change - Change in the (invented) name of the medicinal product for CAPs	15/12/2020	19/05/2021	SmPC, Annex II, Labelling and PL	