Brukinsa

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
IA/0007/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder	15/12/2022	n/a		

[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).

	or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.II.e.4.a - Change in shape or dimensions of the container or closure (immediate packaging) - Non-sterile medicinal products 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.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.II.b.5.c - Change to in-process tests or limits applied during the manufacture of the finished product - Deletion of a non-significant in-process test B.II.e.2.c - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter)				
IB/0006	B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data	18/11/2022	n/a		
II/0003	Extension of indication to include treatment of adult patients with chronic lymphocytic leukaemia (CLL)	13/10/2022	15/11/2022	SmPC and PL	Please refer to Scientific Discussion 'Brukinsa-EMEA/H/C/004978/II/0003

	for Brukinsa; as a consequence, sections 4.1, 4.2, 4.4, 4.8, 5.1 and 5.2 of the SmPC are updated. The Package Leaflet is updated in accordance. Version 1.3 of the RMP has also been submitted. The variation leads to amendments to the Summary of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
II/0002	Extension of indication to include treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one-prior anti-CD20-based therapy, based on data from 88 patients with R/R MZL from 2 ongoing pivotal studies; Study BGB-3111-214: A Phase 2, open-label, single-arm study designed to evaluate the safety and efficacy of zanubrutinib in patients with R/R MZL, and Study BGB-3111-AU-003: A first-in-human, Phase 1/2, dose-escalation and selection, PK/pharmacodynamic, safety, and efficacy study in adult patients with R/R or treatment-naive B-cell malignancies. As a consequence, sections 4.1, 4.2, 4.5, 4.8 and 5.1 of the SmPC are updated, and the Package Leaflet is updated in accordance. Version 1.1 of the RMP has also been submitted. In addition, the one additional year of market protection requested by the MAH has been granted. The variation leads to amendments to the Summary	15/09/2022	28/10/2022	SmPC and PL	Please refer to Scientific Discussion 'Brukinsa-H-C-004978-II-0002'

	of Product Characteristics and Package Leaflet and to the Risk Management Plan (RMP). C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IAIN/0004	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	29/04/2022	28/10/2022	Annex II and PL	
IAIN/0001/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites 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	21/12/2021	28/10/2022	Annex II and PL	