Empliciti

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/0012	Extension of Indication to include treatment in combination with pomalidomide and dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on the last therapy. As a consequence, sections 4.1, 4.2, 4.4, 4.6, 4.8, 4.9, 5.1, 5.2 and 6.6 of the SmPC are updated. The Package Leaflet is updated	25/07/2019	23/08/2019	SmPC and PL	Please refer to the Scientific Discussion – Empliciti-H-C-3967-II-0012

[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).

	in accordance. In addition, the Marketing authorisation holder (MAH) took the opportunity to update the list of local representatives in the Package Leaflet. The RMP (version 2.1) is updated to reflect the new indication. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
IB/0017/G	This was an application for a group of variations. 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 B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	29/07/2019	n/a		
PSUSA/10500 /201811	Periodic Safety Update EU Single assessment - elotuzumab	14/06/2019	n/a		PRAC Recommendation - maintenance
IB/0016	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	25/04/2019	n/a		
II/0013	B.II.b.2.c.3 - Change to importer, batch release arrangements and quality control testing of the FP - Including batch control/testing for a biol/immunol product and any of the test methods is a biol/immunol/immunochemical method	28/02/2019	02/04/2019	Annex II and PL	

IG/1059	A.1 - Administrative change - Change in the name and/or address of the MAH	15/02/2019	02/04/2019	SmPC, Labelling and PL	
PSUSA/10500 /201805	Periodic Safety Update EU Single assessment - elotuzumab	17/01/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10500 /201711	Periodic Safety Update EU Single assessment - elotuzumab	14/06/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10500 /201705	Periodic Safety Update EU Single assessment - elotuzumab	11/01/2018	n/a		PRAC Recommendation - maintenance
IB/0009/G	This was an application for a group of variations. 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.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	08/01/2018	n/a		
II/0006	C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	13/07/2017	04/10/2017	SmPC	
PSUSA/10500 /201611	Periodic Safety Update EU Single assessment - elotuzumab	09/06/2017	n/a		PRAC Recommendation - maintenance

IA/0007/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites A.7 - Administrative change - Deletion of manufacturing sites	23/05/2017	n/a		
IA/0005	B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	09/03/2017	n/a		
PSUSA/10500 /201605	Periodic Safety Update EU Single assessment - elotuzumab	12/01/2017	n/a		PRAC Recommendation - maintenance
II/0003	B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol	24/11/2016	n/a		
II/0001/G	This was an application for a group of variations. 1) IA -A.6 - to add the ATC Code following granting by WHO in the SmPC and bring the labelling in line with the latest QRD template (V10.0). 2) II- B.I.a.1.e – to add BMS-Devens as an alternate active substance manufacturer. 3) IB- B.I.a.1.f –to add BioReliance, Rockville, MD as alternative in-process testing site for preharvest samples for Mycoplasma, in vitro adventitious virus and MVM (Minute Virus of Mice) testing.	10/11/2016	04/10/2017	SmPC, Annex II and Labelling	

	4) II- B.I.a.3.c – to increase (5-fold) the batch size of elotuzumab drug substance from 5,000 L to 25,000 L at BMS-Devens site. 5) IB -B.I.a.4.b – to implement of a new in-process control for Triton X-100 at both, BMS-Syracuse and BMS-Devens sites. 6) II-B.I.a.4.d – to widen the viral filtration load limits from ≤ 347 L/m2 to ≤ 516 L/m2. A.6 - Administrative change - Change in ATC Code/ATC Vet Code B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product 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.I.a.3.c - Change in batch size (including batch size ranges) of AS or intermediate - The change requires assessment of the comparability of a biological/immunological AS B.I.a.4.b - Change to in-process tests or limits applied during the manufacture of the AS - Addition of a new in-process test and limits B.I.a.4.d - Change to in-process tests or limits applied during the manufacture of the AS - Widening of the approved in-process test limits, which may have a significant effect on the overall quality of the AS				
