Bortezomib SUN

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, please also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued [2] / amended on	Product Information affected [3]	Summary
Variation type IB /	C.I.2 Change(s) in the Summary of Product	06/05/2025		SmPC and PL	To update section 4.6 and 5.3 of the SmPC and

[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).

EMA/VR/0000263638	Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted C.I.2.a - To update section 4.6 and 5.3 of the SmPC and section 2 of the PL in order to update information on pregnancy and preclinical clinical information following the assessment of the same change for the reference product Velcade in procedure EMEA/H/C/000539/II/0102. Additionally, the MAH took the opportunity to implement editorial corrections to align the annexes to the related counterpart of the originator, to correct for typographical errors, and to bring the PI in line with the latest QRD template version 10.3. Furthermore, the MAH updated the contact information of the local representatives for DE and PL.				section 2 of the PL in order to update information on pregnancy and preclinical clinical information following the assessment of the same change for the reference product Velcade in procedure EMEA/H/C/000539/II/0102.