EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Bortezomib Hospira

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	16/05/2025		SmPC and PL	To update sections 4.6 and 5.3 of the SmPC with

[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/0000263654	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 sections 4.6 and 5.3 of the SmPC with information on pregnancy and preclinical information following approved changes for the reference product. The package leaflet is updated accordingly. In addition, the MAH took the opportunity to bring the PI in line with the latest QRD template version 10.4. Furthermore, the MAH took the opportunity to update the list of local representatives for IE and removed the UK (Northern Ireland), and the SmPC in CZ, DE, SI and SE have been updated with minor updates to align with the reference product and the QRD template.				information on pregnancy and preclinical information following approved changes for the reference product. The package leaflet is updated accordingly.