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## **Drug Alert**

### **CLASS II RECALL**

**ACTION WITHIN 48 HOURS**

Date: 25 November 2011

Our Ref: MDR 6\_11/11

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### **VELCADE (bortezomib) 1.0mg powder for solution for injection effecting all batches in stock in Malta**

Janssen Cilag International NV is recalling under the supervision of the Malta Medicines Authority, VELCADE (bortezomib) 1.0mg powder for solution for injection batches currently in Malta, all of which have been manufactured at one of their contract manufacturing sites Ben Venue Laboratories (BVL), Ohio (USA). The recall will be undertaken up to pharmacy level. It follows an inspection of the BVL manufacturing facilities where deficiencies in sterility assurance at BVL were identified.

Velcade 1mg powder for solution for injection is only manufactured at BVL and therefore, all 1mg vials will be recalled and will be temporarily unavailable. Velcade 3.5mg powder for solution for injection is available from alternative manufacturing sites which are not affected by this recall and the MAH has committed to make this available locally by next Monday.

Simon Serge  
**Medicines Inspector**