**23rd January 2012**

**Circular No. P01/2012**

Dear Healthcare Professional,

**Re: European Medicines Agency gives recommendations to prevent administration errors with Velcade (bortezomib)**

The Medicines Authority would like to make you aware of the European Medicines Agency (EMA) recommendations on how to avoid administration errors with the anticancer medicinal product Velcade (bortezomib) which is authorised and marketed in Malta. This issue is being raised after the occurrence of three fatal cases of administration errors that occurred with Velcade in the European Union, where the medicine was accidentally given intrathecally instead of intravenously (into a vein). The EMA's Committee for Medicinal Products for Human Use (CHMP) is reminding healthcare professionals that Velcade should only be given by injection into a vein and is recommending precautionary measures to prevent further administration errors from occurring.

Velcade is used for the treatment of patients with multiple myeloma, through proteasome inhibition. It is available as a powder for solution for injection and is currently only authorised to be given via the intravenous route. Since its authorisation in 2004, three patients have died because Velcade was accidentally injected intrathecally instead of intravenously. All three cases involved patients who were also receiving intrathecal chemotherapy at the same time as Velcade.

To prevent further administration errors from occurring, the Marketing Authorisation Holder (MAH) and the CHMP agreed on a DHPC (Direct Healthcare Professional Communication) to be sent out to healthcare professionals[1] reminding them that Velcade should only be given intravenously.

[1]Haematologists, Oncologists. Hospital Pharmacists at MDH and Boffa Hospital, Haematology Nurses, Oncology Nurses, and the Lumiere Society (a multiple myeloma patient association).



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This DHPC was approved by the Medicines Authority and sent by the MAH representatives in Malta on the 16th of January 2012. In line with the information in the DHPC, healthcare professionals are advised to consider the following specific precautionary measures.

- When possible, different connectors should be used for medicines to be administered via intrathecal or intravenous route.
- When possible, intrathecal chemotherapy should be administered at a different time than any other parenteral chemotherapy (chemotherapy given by injection or drip into a vein).
- Syringes should be clearly labelled with the name of the medicine and route of administration to be used.
- Procedures should be in place for double checking the labelling of syringes before administration.
- Intravenous and intrathecal injections should be handled only by suitably trained healthcare professionals.
- Healthcare professionals involved in administration or management of cancer chemotherapy should be trained and informed of the dangers of intrathecal administration of Velcade and of the recommended measures to prevent this from occurring.

The current European public assessment report for Velcade can be found on the EMA's website: http://www.ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports

Healthcare professionals are encouraged to maintain vigilance on Velcade. Suspected Adverse Drug Reactions may be reported using the Medicines Authority yellow card scheme or online at http://www.medicinesauthority.gov.mt/pub/adr.doc or to the marketing authorisation holder or their local representatives.

***Healthcare professionals are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.***



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