Malta, 9 April 2008

Circular No. P05/2008

Dear Healthcare Professional,

Re: EMEA recommendation of a new contraindication for Velcade (bortezomib)

As part of its continuous monitoring of medicines, the European Medicines Agency (EMEA) has recommended that Velcade (bortezomib) should not be used in patients with certain severe pulmonary or heart problems (acute diffuse infiltrative pulmonary and pericardial disease). The EMEA's Committee for Medicinal Products for Human Use (CHMP) has, nevertheless, concluded that the benefits of Velcade are greater than its risks except when used in the mentioned patient categories.

The Committee has also recommended the strengthening of existing warnings on pulmonary disorders by advising doctors to perform chest X-rays prior to starting patients on treatment with Velcade. It has additionally recommended that new information on cardiac and pulmonary side effects observed during the post-marketing phase be included in the product information.

The Medicines Authority has participated in these discussions held at the EMEA and is in agreement with the **press release** and **Q&A document** issued by the EMEA, attached here for your perusal.

Medicines Authority
198, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 email: info.mru@gov.mt