



Department of
**Health, Social Services
and Public Safety**

www.dhsspsni.gov.uk

From The Chief Pharmaceutical Officer
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Date: 23 November 2011

For Action: Assistant Director Pharmacy and Medicines Management,
HSC Board & BSO
Heads of Pharmacy and Medicines Management of
HSC Trusts
Regulation Quality Improvement Authority

DRUG ALERT

DRUG RECALL TO HOSPITALS AND CLINICS

Dear Healthcare Professional

Janssen-Cilag Ltd

Velcade 3.5mg powder for solution for injection
Bortezomib EU/1/04/274/001

Batch number	Expiry date	Pack size	First distributed
9AZSY00	Dec 2011	1 x 3.5 mg	08.10.2009
9CZTF00	Feb 2012	1 x 3.5 mg	07.12.2009
AGZSH00	June 2013	1 x 3.5 mg	05.01.2011
AGZSH01	June 2013	1 x 3.5 mg	19.01.2011
AIZTY00	Aug 2013	1 x 3.5 mg	14.01.2011
AIZTY01	Aug 2013	1 x 3.5 mg	01.03.2011
BAZS100	Dec 2013	1 x 3.5 mg	18.04.2011
BAZS101	Dec 2013	1 x 3.5 mg	13.05.2011

Janssen-Cilag Ltd is recalling all remaining stock of the above batches due to concerns that acceptable levels of sterility assurance during manufacture cannot be guaranteed. Serious Good Manufacturing Practice (GMP) concerns were raised during an inspection of the contract manufacturing site for this product.

Please note that only the batches listed above are being recalled. More recent batches have been sourced from alternative manufacturing sites and there are currently no concerns for the sterility assurance of later batches.

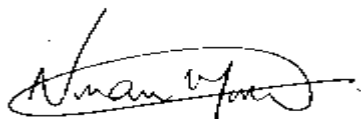
Any remaining stock of the batches listed above should be quarantined. Janssen-Cilag Ltd will be contacting direct customers with instructions for return and replacement/credit. For stock enquiries please telephone 0800 333 001.

Recipients are requested to report any suspected side effects associated with this product to the Yellow Card scheme. Reports can be made via <http://yellowcard.mhra.gov.uk/>.

For medical information enquiries, please contact the UK office of Janssen Cilag on 0800 0323013.

HSC Board/RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities and health care professionals.

Yours sincerely



DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:	Regional Medicines and Poisons Information Service
CMO	Regional Director of Supplies
CNO	RPQAS
CDO	Pharmaceutical Society of NI
CSSO	Senior Prison Pharmacist
SMO	Prison Service, Dundonald House
Director, Health Estates	Nursing Officer, Health Estates
Public Health Branch	Medical Officer, Castle Buildings
DHSSPS, Library	Regional Procurement Pharmacist
Extended nurse prescribers	NICPLD