14th February 2018

Direct Healthcare Professional Communication

VELCADE® (bortezomib) 3.5 mg vials
Potential defect of rotating and/or loose metal cap

Batch numbers: GJZT700, GJZT701, GJZT702, GJZT800, GJZT801, GJZTA00, GLZSN00 and GLZSN01

Dear Healthcare Professional,

Janssen, in agreement with the European Medicines Agency and the Medicines and Healthcare Product Regulatory Agency (MHRA), wishes to inform you of the following:

Summary

- **We have received reports of rotating and/or loose metal cap covering the stopper on 3.5 mg vials of Velcade following removal of the plastic flip-off lid.**
- **The defect concerns the following batch numbers: GJZT700, GJZT701, GJZT702, GJZT800, GJZT801, GJZTA00, GLZSN00 and GLZSN01.**
- **As a precautionary measure, vials with a loose cap should not be used.**

Further information

While no adverse events were reported in association with the loose caps, there is a potential risk to sterility. Health Care Professionals should also take the necessary steps to prevent possible drug exposure while handling these vials during reconstitution.

If you encounter any affected vial please contact Janssen Quality Assurance team to arrange a return or replacement on qajcuk@its.jnj.com or +44(0)1494567617.

If you have supplied units from these batches to any of your customers, please share with those customers a copy of this letter.

Call for reporting

Healthcare professionals are reminded to continue to report suspected adverse reactions associated with this product in accordance with the national spontaneous reporting system.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD" (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the MHRA Yellow Card free phone reporting line: 0800-731-6789
- or by electronic download through the Yellow Card section of the MHRA website

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset dates, treatment dates, product brand name and batch numbers.

Suspected adverse reactions should also be reported to Janssen-Cilag Limited on tel: 01494 567447, fax: 01494 567799 or by email at dsafety@its.jnj.com

Company contact points

If you have further questions or require additional information, please contact:
Janssen-Cilag Ltd. Medical Information Department:
Email: medinfo@its.jnj.com
Telephone: 0800 731 8450 or 01494 567 444

Yours faithfully,

Dr. Frank Wiegand
Medical Director
Janssen Cilag Ltd