Date: 23 May 2018

Vectibix® (panitumumab) 400mg/20 mL: reports of defective vials

Dear Healthcare Professional,

Amgen in agreement with the European Medicines Agency and the Malta Medicines Authority would like to inform you of the following:

Summary

- Amgen has received a number of complaints that the rubber stopper and metal crimp cap of vials of Vectibix® had come off when the flip-off cap was removed.
- Vial container closure integrity (CCI) testing showed that if the vial cap issue is present, the vial container closure integrity is maintained.
- A safety assessment to determine risks to patients did not identify any safety concern.
- Doctors, clinicians and hospital pharmacists should check vials of Vectibix® with the batch numbers below to see if the metal seals are loose or if the rubber stopper and cap are attached at an angle (see Image 1 below).
- Do not use Vectibix if the vial is defective or if the rubber stopper comes off when the flip-off cap is removed (see Image 2 below).
- Vials must be removed from the box to be visually inspected.
- Return any defective vials to Amgen. Instructions are provided further below.

Background on the Safety Concern

In the European Union Vectibix® is indicated for the treatment of adult patients with wild-type RAS metastatic colorectal cancer (mCRC). Vectibix® must be administered as an intravenous infusion via an infusion pump, using a low protein binding 0.2 or 0.22 micrometre in-line filter, through a peripheral line or indwelling catheter.

Healthcare professionals in the EU should inspect vials of Vectibix® with the following batch numbers :

1082836A, 1082836B, 1082838B, 1082839A, 1083219, 1083472, 1082833A, 1083687A, 1083950A, 1084104A, 1084296, 1084610A, 1084610B, 1085738A, 1085738B, 1084671, 1084739, 1085378,

1085742A, 1085742B, 1087026A, 1087026C, 1087026D, 1087027A and 1087026B

It is estimated that 5.5% of vials from these batches could be defective. In mid-March 2018, Amgen started distributing new unaffected batches of Vectibix®.

Image 1: Vial with rubber stopper and cap attached at an angle

Image 2: Vial with a rubber stopper, which came off while the flip-off cap was removed

Instructions for Returning Vials to Amgen

For return/refund instructions please contact Amgen at the following e-mail address: complaint@amgen.com

Call for Reporting

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the Medicines Authority by post or e-mail: ADR reporting/ Sir Temi Zammit Building, Malta Life Sciences Park, San Gwann or on www.medicinesauthority.gov.mt/adrportal

Company Contact

Should you have any questions or require additional information regarding the use of Vectibix, please contact Medical Information on Cherubino Ltd, Delf Building, Sliema Road, Gzira, GZR 1637. Telephone number 21 343270 and email: pharmacovigilance@cherubino.com.mt for access to further information

Yours sincerely,

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Regulatory Affairs & Pharmacovigilance