Stolen vials of Herceptin® (trastuzumab) Alimta® (pemetrexed) and Remicade® (infliximab) illegally re-introduced in some EU markets but not in Malta

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Information on the concern

Products, originally labeled as Italian Herceptin 150 mg vials, have been stolen, probably in Italy and then later re-introduced illegally into the supply chain in some countries including the UK, Finland, Germany, Austria and Sweden. Both Roche Products Ltd and the Medicines Authority are following the issue closely and to date, none of the reported affected batches are on our local market.

In the affected products, the original Italian label and outer package may have been replaced by labels and packaging in the local language of the destination country. The suspect vials and original outer packaging feature genuine Roche batch numbers but in some cases, the batch numbers on the vials and outer packaging may not match. In addition, some vials may contain liquid rather than powder, or closures may show physical signs of tampering.

Roche Products Ltd has issued a Direct Healthcare Professional Communication (DHPC) providing more details on the issue of Herceptin. The DHPC can be accessed at www.medicinesauthority@gov.mt/dhpc

Health care professionals are requested to contact the Medicines Authority if they have any query or suspect any problem with any of the affected medicinal products.

For Herceptin the following batch numbers are known to be concerned:

H4105B01, H4136B02, H4196B01, H4143B01, H4150B01, H4152B04, H4171B01, H4168B02, H4169B01, H4179B02, H4180B01, H4184B01, H4185B02, H4194B01, H4195B01, H4261B01, H4263B02, H4271B01, H4279B01, H4284B04, H4293B01, H4303B01, H4301B09, H4311B07, H4319B02, H4324B03, H4329B01, N1001B01, N1002B02, N1002B03, N1010B02.

In addition to initial findings concerning Herceptin, vials of two other medicines, Alimta (pemetrexed) and Remicade (infliximab), are now also confirmed as being part of the theft. Samples of batches distributed are being tested by the European authorities. So far no evidence has been identified of any tampered vials of Alimta or Remicade being distributed.

Medicines Authority
203 Level 3, Rue D'Argens, Gzira, GZR 1368 – Malta.
Tel. (+356) 23439000 Fax. (+356) 23439161 www.medicinesauthority.gov.mt

For Alimta, the following batch numbers are known to be concerned: C134092E, C021161E and C160908C.

For Remicade, the following batch numbers are known to be concerned: 3RMA66304, 3RMA67102, 3RMA68106 and 3RMA67602

In Malta

For Healthcare Professionals and Patients

- Herceptin is an anticancer medicine which is used to treat patients with breast cancer as well as metastatic gastric cancer. Herceptin contains the active substance trastuzumab and is available as a 150mg powder to be made up into a solution for intravenous infusion or as a solution for subcutaneous injection. Only the intravenous formulation appears to be affected.
- Alimta is used to treat lung cancer and is a powder that is made up into a solution for infusion. It contains the active substance pemetrexed.
- Remicade is an immunosuppresive agent used in the treatment of inflammation in rheumatoid arthritis, Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis and psoriasis. It contains the active substance infliximab. Remicade is a powder that is made up into a solution for infusion.

For more information please visit **www.ema.europa.eu**

Reporting Adverse Drug Reactions

Suspected Counterfeit products or Adverse Drug Reactions (side effects) associated with these products may be reported using the Medicines Authority form which can be downloaded from **http://www.medicinesauthority.gov.mt/adrportal** and sent by email/mail to **postlicensing.medicinesauthority@gov.mt** or to the marketing authorisation holder or their local representatives.

Prof John J Borg PhD (Bristol)
Post-licensing Director

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

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