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Press Office

Press release

European Medicines Agency update on stolen vials of Herceptin

EU national authorities and EMA cooperating in response to criminal activities

This is an update from the European Medicines Agency on the latest information relating to the stolen vials of Herceptin (trastuzumab) in Italy. The vials, some of which were tampered with, were later re-introduced illegally into the supply chain in some countries.

The Italian law enforcement authorities are currently investing the theft. However, the situation goes beyond EU and national current practices for handling quality or product defects; these are extraordinary circumstances driven by criminal activities that require special measures and strong collaboration from authorities across the EU.

National competent authorities are working rapidly to identify all concerned batches and put in place appropriate measures to protect the health of EU citizens. In parallel to the investigations, all vials suspected of being affected are being recalled from the EU market. In addition, Member State authorities are considering temporary measures including quarantine of suspected products or restriction of parallel distribution of the concerned products.

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 national authorities. So far no evidence has been identified of any tampered vials of Alimta or Remicade being distributed.

Only a small number of vials of the three medicines are thought to be affected and so far there are no reports that any harm has come to patients in relation to the falsified medicines. It is not expected that the precautionary actions will result in shortage of medicines for patients.

Healthcare professionals are reminded to pay extra attention when handling or administering any of the concerned medicines. Any suspicion of tampering or question of authenticity should be reported immediately to the local health authorities.

In relation to Herceptin, a letter has been sent to EU healthcare professionals with advice on identifying falsified Herceptin vials, this including:

- Batch numbers and expiry dates on most vials do not match those on the outer package;

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- There is liquid present in some vials of Herceptin powder for solution (Herceptin is a white to yellow powder);
- Evidence of tampering with the rubber stoppers, crimping caps or lids;
- Falsified vials are labelled as 'Italian Herceptin® 150 mg' (may have been re-labelled and re-packaged in the local language).

New information has become available in relation to concerned batches.

For Herceptin, in addition to batch numbers H4311B07, H4329B01, H4284B04, H4319B02, H4324B03, H4196B01, H4271B01, H4301B09 and H4303B01, previously communicated, the following batch numbers are now also confirmed to be concerned: H4143B01, H4293B01, H4180B01 and N1010B02.

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.

This is based on information available at present and will be updated as the situation evolves.

Falsified medicines must not be used because they cannot be considered safe or effective.

Patients who have any concerns should speak to their doctors who are best placed to confirm the authenticity of their medicine and assess their condition.

The EMA is monitoring the situation closely and will provide updates as appropriate.

More about the medicines

Herceptin is an anticancer medicine which is used to treat patients with breast cancer as well as metastatic gastric (stomach) cancer. It is mainly used in hospitals. 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. It is given under the supervision of a doctor who is qualified in the use of chemotherapy. Alimta is a powder that is made up into a solution for infusion (drip into a vein). It contains the active substance pemetrexed.

Remicade is an anti-inflammatory medicine, used to treat 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 and is administered under the supervision and monitoring of a specialised doctor.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. This is an update to the press release European Medicines Agency alerts EU healthcare professionals after vials of falsified Herceptin identified, issued 16 April 2014.
3. Herceptin was approved in the European Union on 28 August 2000. For more information please see the EPAR published on the EMA website. The marketing authorisation holder for Herceptin is Roche Registration Ltd.

4. Alimta was approved in the European Union on 20 September 2004. For more information please see the EPAR published on the EMA website. The marketing authorisation holder for Alimta is Eli Lilly Nederland BV.
5. Remicade was approved in the European Union on 13 August 1999. For more information please see the EPAR published on the EMA website. The marketing authorisation holder for Alimta is Janssen Biologics BV.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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