



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency alerts EU healthcare professionals after vials of falsified Herceptin identified

The European Medicines Agency (EMA) has been informed that vials of the cancer medicine Herceptin (trastuzumab), thought to have been stolen in Italy, including from hospitals, have been tampered with and re-introduced under false credentials into the supply chain in some countries. This is currently being investigated by Member State authorities and updates will be provided as more information becomes available. Italian law enforcement authorities are currently investigating the theft and are looking at whether other medicines may also be affected.

No affected product has so far been identified at hospital level and there are no reports that any harm has come to patients in relation to the falsified medicine and authorities are working to avoid this.

Healthcare professionals across the European Union (EU) are being alerted to the falsified Herceptin vials and are being provided with information on signs seen so far that may indicate a vial is not genuine. These include:

- the batch numbers and expiry dates on most vials do not match those on the outer package;
- 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;
- the falsified vials are labelled as Italian Herceptin[®] 150 mg.

This is based on the information available at present. If healthcare professionals notice anything else that looks suspicious in relation to Herceptin vials they should alert their national competent authority.

Falsified medicines must not be used. Appropriate measures to protect public health are being taken by Member States.

¹ For the latest information on the medicines concerned and the regulatory actions taken in the context of this investigation, please refer to the medicines regulatory authorities in Italy and Germany: [Italian medicines agency \(AIFA\)](#), [Paul Ehrlich Institute \(PEI\)](#) and [Federal Institute for Drugs and Medicinal Devices \(BfArM\)](#).



The numbers of the Herceptin batches known to be affected are H4311B07, H4329B01, H4284B04, H4319B02, H4324B03, H4196B01, H4271B01, H4301B09 and H4303B01.

Although only a small number of vials is thought to be affected, the marketing authorisation holder for Herceptin, as a precautionary measure, is recalling vials suspected of having being falsified.

In addition, parallel distributors across the EU are being alerted with the above information.

The EMA is coordinating the response by the appropriate health authorities in the Member States. Although all information is not yet available, it is not expected that this will result in shortage of medicines for cancer patients.

Patients who have any concerns should speak to their doctors who are best positioned 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 medicine

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.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Herceptin was approved in the European Union on 28 August 2000 and it is marketed throughout the EU. For more information on Herceptin, please see EPAR published on the EMA website:
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_Summary_for_the_public/human/000278/WC500049819.pdf
3. The marketing authorisation holder for Herceptin is Roche Registration Ltd.
4. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

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