

29 November 2013

Subject: COUNTERFEIT PRODUCT LABELLED AS PEGASYS® (pegylated interferon alfa-2a) Prefilled syringe 180 mcg/0.5 ml

Dear Healthcare Professional,

Executive Summary

Roche has been informed that a confirmed counterfeit product, labelled as Pegasys® 180 mcg/0.5 ml (pegylated interferon alfa-2a), has currently been identified in two European markets (Germany and Romania). It is not known exactly where else the counterfeit product could have been distributed, but this could circulate to other countries.

The purpose of this letter is to notify healthcare providers of this counterfeit and to seek your assistance in identifying and reporting counterfeit product to protect patient safety. The counterfeit products use some of the same batch numbers as genuine Roche Pegasys® batches. To date, the genuine batches have been distributed to several EU countries, and a number of International markets.

Chemical analysis confirmed that the counterfeit product does NOT contain pegylated interferon alfa-2a (the active ingredient of Pegasys®). It is not effective or safe. The counterfeit syringe should not be used.

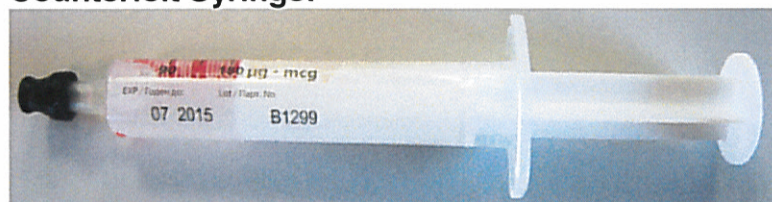
Visual Inspection

The counterfeit product is easily differentiated from genuine Pegasys® based on the features outlined below. The counterfeit product:

- is contained in a plastic syringe device (instead of glass)
- has a black tip cap (instead of grey)
- has a white plunger (instead of red)
- is missing a colour code and barcode on the carton

The picture below shows syringe batch number B1299, BUT similar counterfeits have been found with different batch numbers, which match genuine Roche batch numbers.

Counterfeit Syringe:



Roche Products Limited

6 Falcon Way, Shire Park
Welwyn Garden City
Herts AL7 1TW

Medical Information

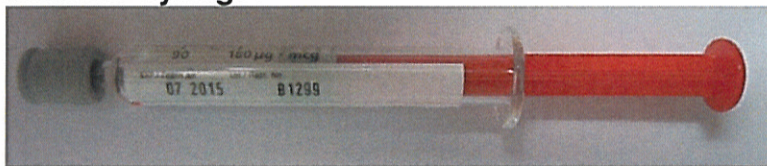
Tel.: +44(0)800 328 1629

Email: medinfo.uk@roche.com

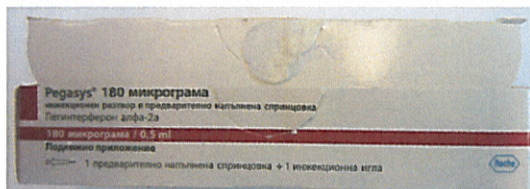
RXUKPEGA00391
November 2013

Registered in England
No. 100674

Genuine Syringe:



Counterfeit Carton:



Genuine Carton:



Chemical Analysis

Chemical analysis of a number of the counterfeit products identified to date was performed and found that the sample does not contain pegylated interferon alfa-2a (the active ingredient of Pegasys®). The syringe contained glucose solution (73 mg/ml), water and cellulose fibers. The liquid in the syringe and the syringe, including the needle, should be assumed to be non-sterile.

Required Actions

If you have any product in your possession that you suspect may be counterfeit, or whose authenticity you cannot confirm, or if you suspect a patient may have received counterfeit drug, you should immediately contact the Medicines Authority. In addition, you should contact Roche Medical Information by phone on +44 (0)800 328 1629 or via e-mail Medinfo.uk@roche.com for further information or any questions. Please retain the suspected counterfeit product for further investigations.

If you are aware of a patient experiencing any adverse effects that you think may be related to Pegasys® or to the use of counterfeit drug, please ask the patient to seek medical attention and report the event to Roche Products Limited. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44(0) 1707 367554. The counterfeit product does not contain pegylated interferon alfa-2a (the active ingredient of Pegasys®) and will not provide benefit to patients. In addition, use of the counterfeit may result in local skin/subcutaneous infections or reactions or septicemia. Administration of the glucose solution subcutaneously at this concentration is predicted to have minimal to no effect.

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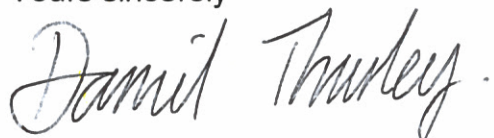
Actions from Roche

Patient safety is Roche's primary concern. As the implications for public health and safety are high, we take the issue of counterfeiting extremely seriously. We are cooperating with the appropriate Health Authorities and law enforcement agencies to aid their investigations, to determine the source of the counterfeit drug, and prevent its further distribution. However, the company has no official power to intervene directly and will not assume liability for damage claims related to counterfeit products. We have implemented technical anti-counterfeiting measures relating to the design, packaging and labeling of our products, along with working with authorities on a system to track and trace products from distribution to dispensary.

We strongly recommend purchasing Pegasys[®] exclusively through trusted sources in the regulated legal supply chain for use in approved indications. Roche limits the number of wholesalers whenever possible. Depending on local regulations, Roche sells directly to hospitals, pharmacies or governmental organisations.

Adverse drug reactions related to counterfeit product should also be reported to the Medicines Authority; ADR report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and sent to postlicensing.medicinesauthority@gov.mt or sent to ADR reporting 203, level 3, Rue d'Argens Gzira/GZR 1368.

Yours sincerely



Dr Daniel Thurley MA MB BChir MRCP FFPM
Medical Director - UK

For additional information please see the following:

WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT)

Via internet reporting: <http://www.who.int/impact/en/>

Pegasys[®] Summary of Product Characteristics (SmPC) is available at www.medicines.org.uk

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