To Whom It May Concern

Basel, 13 November 2013

TWIMC Letter: Confirmed Counterfeit of Pegasys PFS 180 mcg/0.5 ml, Batches B1299B03, B3008B03, and Suspected Batch B1297B11 in Germany and Romania

Roche References: TW211864, TW215563, TW215880, TW215894, TW216179, TW216190

Dear Madam,
Dear Sir,

On September 17, 2013 we were notified by the German parallel importing company Haemato Pharm AG of a suspected counterfeit of Pegasys PFS 180 mcg/0.5 ml, batch B1299B03, with Romanian and Bulgarian make-up (reported to Roche Pharma AG in Grenzach, Germany). On October 14, 2013 a TWIMC letter was sent to all global affiliates where Pegasys is registered.

Subsequently, Roche has been notified of more suspected counterfeit syringes found in Romania and Germany.

Summary of Results per Batch Number:
Batch B1299B03:
Results from initial case (TW211864):
The results from the comparison of the counterfeit sample with the genuine Roche retain sample:

- The printing quality of the variable data is different.
- The tip cap on the counterfeit sample is black instead of grey for the genuine product.
- The color of the plunger for the counterfeit sample is white instead of red for the genuine product.
- The counterfeit syringe is made of plastic rather than glass for the genuine product.

An analysis of the complaint sample (Pegasys PFS 180 mcg/0.5 ml, batch B1299B03) confirmed the product as counterfeit. Chemical analysis showed that the sample does not contain pegylated interferon alfa-2a (the active ingredient of Pegasys). The syringe contained glucose solution (73 mg/ml). The content of the syringe was turbid and can be assumed to be not sterile.

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On November 11, both Germany and Romania reported additional cases of suspected counterfeit syringes for batch B1299B03. Romania reported that there have been 4 patients who have received suspected counterfeit product from batch B1299B03 in the period between July and September 2013. 3 syringes are being retrieved for analysis (TW216190). In Germany, a local wholesaler reported finding 4 suspected syringes (TW216179). These cases will be investigated and the results reported when available.

The syringe batch B1299 was distributed to the following countries: Romania, Bulgaria, Spain, Sweden, Latvia, Lithuania, the Czech Republic, Australia, Pakistan, France, and Italy.

Batch B3008B03:
On November 1, 2013 our affiliate in Romania received a report of a suspected counterfeit for batch B3008B03.

The results from the comparison of the counterfeit sample with the genuine Roche retain sample are (TW215563):

- The printing quality of the variable data is different.
- The tip cap on the counterfeit sample is black instead of grey for the genuine product.
- The color of the plunger for the counterfeit sample is white instead of red for the genuine product.
- The counterfeit syringe is made of plastic rather than glass for the genuine product.
- Chemical analysis was performed and found that the sample does not contain pegylated interferon alfa-2a (the active ingredient of Pegasys). The syringe contained glucose solution. The content of the syringe can be assumed to be not sterile.

An analysis of the complaint sample (Pegasys PFS 180 mcg/0.5 ml, batch B3008B03) confirmed the product as counterfeit.

The syringe batch B3008 was distributed to the following countries: Romania, Bulgaria, Portugal, Greece, and Poland.

Batch B1297B11:
On November 5, 2013 our affiliate in Romania received a report of 3 suspected counterfeit syringes for batch B1297B11 (TW215880). Roche is currently working to retrieve the complaint samples for analysis.

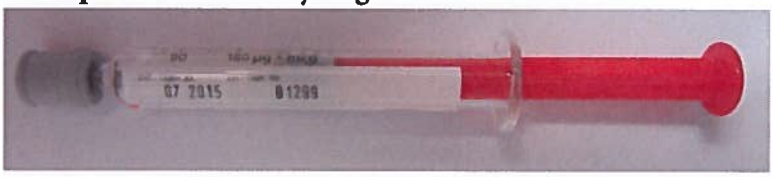
On November 6, Roche Grenzach was notified of a suspected counterfeit, associated with an adverse event for batch B1297B11. The complainant reported painful swelling at the injection site. Roche is currently working to retrieve the complaint sample for analysis (TW215894).

The syringe batch B1297 was distributed to the following countries: Romania, Portugal, Italy, Norway, Serbia, and Vietnam.

Photos of Counterfeit Syringe and Carton:

Example of Counterfeit Syringe from Batch B1299:

Example of Genuine Syringe from Batch B1299:



Example of Counterfeit Carton from Batch B1299B03:

Example of Genuine Carton from Batch B1299B03:

Communication:

On September 25, the regional Health Authority (HA) in Brandenburg, Germany (surveillance authority of Haemato Pharm AG) issued a Rapid Alert Class 1 to the German HA BfArM as well as all regional HAs in Germany, proposing that all parallel distributors in EU should be informed. A recall was not considered at this time by the German HA. The German Legal Authority Bundeskriminalamt is working on the case.

On September 27, A TWIMC letter was sent to Roche Bulgaria and Romania, who informed their local Health Authorities. On September 26 EMA was informed, and on September 27 Swissmedic respectively. EMA has been updated regarding the current cases.

On October 15, a Dear Healthcare Professional (DHCP) letter, reviewed by EMA, was sent to the 28 EU countries, Pakistan and Australia. National Health Authorities determined whether the letter should be disseminated in their market.

We are working closely with Health Authorities and law enforcement to determine the source of the counterfeit material.

Sincerely,

F. Hoffmann-La Roche Ltd

Hugues Isel
Global Quality Manager

Dr. Andreas Gugger
Global Quality Manager