

To Whom It May Concern

Basel, February 2012

Confirmed counterfeit of Avastin vials 400 mg/ 16 ml, B6011B02, B6010 and B86017

Dear Madam,
Dear Sir,

Roche was informed by a Swiss wholesaler about suspected counterfeits of Avastin vials 400 mg/ 16 ml.

The batch numbers on the folding boxes do not match the batch numbers on the vials.

The wholesaler also informed Swissmedic.

MHRA in UK is investigating this case as some of the product was supplied to a UK wholesaler. In parallel FDAs Office of Criminal Investigation in the US is doing an investigation of the same case as product was distributed to the US and some of the vials were supplied to the market.

We have received some samples for investigation and it is confirmed that the affected batch was not packaged in this make-up and one of the batch numbers was not even produced by Roche.

Investigation of the packaging material and vials revealed the following:

- The batch number on the folding box is B6011B02, MFD 03/2011, EXP 03/2013. The genuine batch was packaged only in Turkish packaging configuration and the variable data do not match.
- The secondary packaging material is in EFA configuration but showed several differences compared to Roche packaging material.
- The batch number on the vials are either B6010, MFD 03/2010, EXP 03/2012 or B86017, MFD 03/2011, EXP 03/2013. B6010 is a genuine Roche batch number and variable data match. The batch was supplied to Algeria, Lebanon, Iran, Egypt, Kuwait, Saudi Arabia, Jordan, United Arab Emirates, Dubai, Oman, Yemen, Canada, Russia, Belarus, Moldova, Ecuador, Costa Rica, Morocco, Tunisia, Israel, Kosovo, Singapore, Philippines, Malaysia, Palestine, Ukraine, Albania, Armenia, Turkmenistan and Macedonia in 2010 and beginning of 2011.