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## Worldwide Biopharmaceutical Businesses

Thursday, 22nd March 2012

### **Somavert (pegvisomant) Manufacturing Update**

Dear Doctor,

With this letter, Pfizer is informing Somavert prescribers that an improved drug substance manufacturing process was approved by the EMA in April 2011. As part of the approval, EMA acknowledged that this change to the manufacturing process “improves the quality profile of the B2036 protein (pegvisomant)”.

From 23<sup>rd</sup> March 2012, Lot number Z00530 packs of SOMAVERT 10 mg powder and solvent for solution for injection commercialized in Ireland will be manufactured and made available according to the new manufacturing process. Batches of other Somavert strengths (15 mg and 20 mg) will be released to the market place after these dates (for the next few months, available Somavert 15 mg and 20 mg presentations will therefore have been manufactured using the older process).

This new production process was developed to:

- streamline the purification and pegylation processes with an improved quality profile of the resulting drug substance;
- reduce levels of host cell-related impurities in the protein extract; and
- introduce a new amino acid source of vegetable origin to eliminate materials of animal origin in an early stage of the manufacturing process.

While there is no reason to expect any specific safety concerns, prescribers are reminded to enhance patient surveillance as patients begin using the product made by the new manufacturing process and report safety concerns following established procedures, as detailed below.

Healthcare professionals should report any serious adverse events to Pfizer at 1800 633363. Alternatively, this information may be reported to the IMB by calling (01) 6764971, using on-line reporting forms at: [www.imb.ie](http://www.imb.ie) or by emailing [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie).

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Pfizer Limited  
Walton Oaks, Dorking Road, Walton on the Hill,  
Tadworth, Surrey KT20 7NS, UK  
Telephone: +44 (0)1304 616161



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If you have any questions about this letter or for more information about Somavert, please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or telephone: 180063363. You may also request a member of the medical team to contact you for a more in-depth discussion.

Yours faithfully,

A handwritten signature in black ink, appearing to read "Declan O'Callaghan".

Declan O'Callaghan  
Director of Medical Affairs, Pfizer