

Dr Ben Goldacre

By email only to [request-24031-2382c647@whatdotheyknow.com](mailto:request-24031-2382c647@whatdotheyknow.com)

**FOI 09 473**

30 December 2009

Dear Dr Goldacre

Thank you for your Freedom of Information Act (FOIA) request of 30 November about statins. Your request has been passed to me as I coordinate FOIA requests for Vigilance and Risk Management of Medicines Division.

You have asked about delays in updating statin product information referred to in the February 2008 Drug Safety Update (DSU) and specifically for:

1. all documents and correspondence relating to this delay;
2. the discussions between the MHRA, the EMEA, and the company about the addition of this new side effects information to the side effects listed on the label, and
3. the name of the company concerned.

The MHRA has identified information we hold that falls within your request. Much of this information relates to information that was written by third parties and we are still in the process of discussing release of this information with them. I will not therefore be able to meet the 20 day deadline of 31 December but will respond to you by the end of January 2010.

Please contact me if you wish to discuss your request.

Yours sincerely

*Stephen Fawbert*

**Mr Stephen Fawbert**  
**Freedom of Information Coordinator**  
**Vigilance and Risk Management of Medicines Division**  
**Tel: 020 7084 2788**