

Dr Ben Goldacre

By email only to [\[redacted\]](#)

**FOI 09 473**

1 February 2010

Dear Dr Goldacre

I am writing further to my letter of 30 December 2009 about your Freedom of Information Act (FOIA) request of 30 November 2009 about statins.

You 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.

Under section 1(3) of the FOIA a public authority need not comply with a request unless any further information reasonably required to locate the information is supplied. If a request is too broad or general in nature (for example, seeking information on a topic over many years), public authorities have a duty to provide advice and assistance to the applicant in order to focus the request. A public authority need not comply with a request where the cost of dealing with it would exceed the appropriate limit, £600 for central government.

In relation to questions 1 and 2, to search for and provide all the documents and correspondence we hold dating back to 2008 would exceed the amount of information we can provide under the FOIA. I have included at Annex 1 a

chronology of events based on the limited information that the MHRA holds as this may help you focus your request. When a requestor asks for documents held over a large period I ask them to narrow their request down to a 3 month period so that I can conduct a more focussed search.

In answer to question 3, following correspondence with their respective Reference Member States (RMS) (see below), consultation was held with the Marketing Authorisation Holders (MAHs) listed overleaf.

<b>MAH</b>	<b>Product</b>	<b>RMS</b>
AstraZeneca	Crestor (rosuvastatin)	The Netherlands (NL)
Bristol Myers Squibb	Lipostat (pravastatin)	UK
Merck, Sharp & Dohme	Zocor (simvastatin)	UK
Novartis	Lescol/Lescol XL (fluvastatin)	France
Pfizer	Lipitor (Atorvastatin)	Germany
Merck, Sharp & Dohme	Lovastatin	Spain

A number of MAHs sought clarification from their respective RMS. The MHRA does not hold copies of all correspondence between each MAH and their RMS. Following clarification from the MHRA, the last MAH to reach agreement on the proposed wording was AstraZeneca in respect of Crestor. As the Netherlands is the RMS for Crestor a significant amount of dialogue on this issue was between the Dutch Medicines Evaluation Board (MEB) and AstraZeneca. MHRA does not hold all correspondence or dialogue between AstraZeneca and the MEB or between any other MAHs and their respective RMS so this is not included at Annex A. You may also wish to contact the MEB and EMEA to see what information they hold. AstraZeneca are aware that this information has been released into the public domain but do not know who has requested this information.

### **Background**

By way of background on the products that your request refers to, there are 6 brand leading statins, all licensed through the Mutual Recognition (MR) procedure, although only 5 are marketed in the UK. This means the MAH applies

for a licence in one Member State, which then applies throughout the EU. The Member State the MAH applies to is known as the RMS. The RMS leads on the regulation of that medicine including updates to product information. I should add that in law, the product information is copyright of the MAH and the legal duty is on them to update it. If they do not agree to update information because they do not believe that it is warranted based on the safety data that they have accumulated, they have the opportunity to set out reasons why or request further data from regulators to support the regulator's proposal. Ultimately though, regulators can compel MAHs to update information but this is only done if voluntary agreement cannot be reached. Voluntary agreement was reached in this case.

Following the publication of the UK's statin review in February 2008, the conclusions of the review were considered by the European Pharmacovigilance Working Party (PhVWP) of the Committee for Medicinal Products for Human Use (CHMP) and were then released as a UK Public Assessment Report (PAR) in November 2009.

Since the new information applied to the entire class of medicines, it was important to ensure a co-ordinated, Europe-wide approach to the changes. Anything less than an across the board approach could have had patient safety implications resulting from inappropriate switching between statins. The Member States responsible for the 6 brand leading statins were asked to liaise with the relevant companies about the introduction of the new product information.

Implementation of the changes across the statin class was dependent on all MAHs agreeing to the wording for the proposed new product information. However, not all MAHs immediately agreed with the need for implementation as based on their safety data, they did not believe common wording across the class was appropriate. They considered that the product information for each product should be based solely on safety data for that product, and not others of the same class and some sought further clarification on this from their RMS.

As the UK had already made health professionals aware at a very early stage in the consultation that the statin review was ongoing through the DSU article, we considered that health professionals would communicate this to patients as appropriate.

If I do not hear from you within 20 days I will assume you do not wish to proceed with your request. If you wish to discuss any aspect of your request please contact me.

Yours sincerely

*Stephen Fawbert*

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## Annex A

### Chronology since February 2008 based on information held by the MHRA

DATE	
4 February 2008	MHRA Drug Safety update published
June 2008	UK implementation plan agreed by PhVWP
July 2008	Letters sent to innovator MA Holders by relevant RMS about inclusion of core wording across the class
9 July 2008	NL receive response from AZ stating that based on their safety data core wording was not warranted at this time. AZ requested data via the RMS from the PhVWP to justify the inclusion of core wording.
19 February 2009	NL receive further response from AZ stating that based on their safety data and the limited information provided, core wording was not warranted at this time.
6 May 2009	AZ response to NL preliminary assessment report of PSUR 11 stating why core wording was not warranted at this time and clarification to justify the inclusion of core wording sought.
8 October 2009	MHRA Telecon with AZ
16 October 2009	MHRA/MEB Meeting with AZ
20 October 2009	UK update to PhVWP
26 October 2009	Letters sent to UK MA Holders
3 November 2009	MHRA Drug Safety update published
3 November 2009	Statins UKPAR published