

Request-97027-5100d729@whatdotheyknow.com

Date 29<sup>th</sup> February 2012

## **REVIEW OF FREEDOM OF INFORMATION ACT (FOIA) REQUEST FOI 11-484**

### **1. INTRODUCTION**

1.1 In an email dated 6<sup>th</sup> February 2012, Mr Steve Hinks requested a review of the Medicines and Healthcare Regulatory Agency's (MHRA) response to his request for information regarding an article on the MHRA webpage concerning chronic fatigue syndrome (CFS) and the Human Papillomavirus (HPV) vaccine. The original FOI request was in an email dated 13 December 2011 and supplemented by further questions in an email dated 11 January 2012.

### **2. PURPOSE OF INTERNAL REVIEW**

2.1 The purpose of this internal review is to determine whether the MHRA dealt properly with the applicant's requests under the Freedom of Information Act (FOIA) in its response.

The terms of reference of this review are:

- To read all correspondence between the applicant and the Agency, and any other relevant correspondence;
- To form an opinion on the handling of the correspondence by the Agency;
- To advise whether the actions taken by the Agency in reaching their decisions is justified under the FOIA;
- To make recommendations for further action by the Agency if appropriate; and
- To prepare a report of the review for the Agency and Mr Hinks.

### **3. Background**

3.1 In his initial email of 13 December, Mr Hinks explained that the article referred to his daughter's case and that it had stated *"that this case is being closely monitored and that specialists had been consulted and they had reported that there is no link between CFS and the HPV vaccine."* In this original email, Mr Hinks also requested the names of the specialists mentioned in the article, their qualifications, experience and knowledge of the specific case mentioned in the article. Mr Hinks also referred to Yellow cards submitted by the NHS in this case as well as one submitted by himself (as the father of the girl mentioned in the article). He mentioned that no-one from the MHRA had contacted the girl's family.

3.2 In its response, dated 11 January 2012, the MHRA stated that it had no record of publishing such a statement on its website in the time line mentioned in Mr Hinks's email. The MHRA went on to address the matter of the yellow cards and confirmed that it had received details of Mr Hinks's daughter's case from three different sources and that those reports had been linked together under a master number (ADR 21341121) along with all associated information relating to the case. The response sought to assure Mr Hinks that the reports were followed up with the healthcare professional for further information.

3.3 On 11<sup>th</sup> January, Mr Hinks sent a further email with more information relating to the published article and which identified the person reporting the information as being a K Darke:

*"On 5 December 2011 K Darke reported on NHS Choices the following comment:*

*There have been recent reports in the press regarding a 13 year old girl who has been in a 'waking' coma since having her third HPV vaccination. The girl was reported to have chronic fatigue syndrome (CFS).*

*The Medicines and Healthcare products Regulatory Agency (MHRA) has kept this issue under close review and its advice, endorsed by independent experts, is that the vaccine is not a cause of CFS.*

*See the MHRA website for a full report on the safety of HPV vaccine..."*

3.4 The MHRA wrote to Mr Hinks on 19<sup>th</sup> January explaining that it appeared that the article referred to had been placed on the NHS Choices website which is run by the Department of Health and not the MHRA. They also confirmed in this letter that there was no-one by the name of K Darke employed by the MHRA. (We have since confirmed that K Darke is in fact an employee of the Department of Health – this information was not available when the reply was sent on 19<sup>th</sup> January.) They went on to confirm that the report referred to in the article was a two-year safety review conducted in July 2010 by the independent advisory body,

the Commission on Human Medicines (CHM). This letter also gave the details of the members of the CHM, the independent experts referred to in the article.

3.5 Mr Hinks responded to this letter on 6 February asking for the response to be reviewed. The main thrust of the basis for asking for this review is that the MHRA have denied having any reports or articles on their webpages relating to the HPV vaccine during the period in question. Mr Hinks is “seriously concerned that dishonesty and cheating is going on within the DH and MHRA...”. His email then goes on to make certain comments relating to Professor Salisbury in relation to the HPV vaccine and the Cavarix EMC Medicine Guide.

#### 4. CONSIDERATION OF THE ISSUES

4.1 I have considered all of the detail of the correspondence between MHRA and Mr Hinks and also background investigations with the MHRA’s publishing team with regard to articles that may have appeared on the MHRA’s website relating to HPV vaccines.

4.2 The evidence I have seen, following a search of the website, shows that the last time the MHRA had any articles relating to CFS and the HPV vaccine was in October 2010 – this referred to the publication of the 2-year review of the use of the HPV vaccine and can be found at <http://www.mhra.gov.uk/home/groups/pl-p/documents/publication/con096842.pdf>. I can find no evidence to support the allegation that an article as described by Mr Hinks has ever appeared on the MHRA’s website, and particularly not in the timescale suggested by his first letter. I also do not believe that the MHRA would have cause to, nor choose to cover up such a publication had it appeared.

4.3 The only question in Mr Hinks’s original correspondence that appears not to have been addressed specifically relates to whether the experts referred to in the article had knowledge of this particular case. I accessed the article using the link provided in Mr Hinks’s 6<sup>th</sup> February email on the Department of Health’s (DH) webpage relating to immunisation. MHRA have confirmed that they did contribute to some of the wording in the DH’s Vaccine Update in November 2011, where this article appeared. They have also confirmed that, in the reference: “*The Medicines and Healthcare products Regulatory Agency (MHRA) has kept **this issue** under close review and its advice, endorsed by independent experts, is that the vaccine is not a cause of CFS*”, the term “this issue” relates to the global issue of whether there are links between HPV vaccine and CFS and not the specific issue of the 13

year old girl referred to in the article. The independent experts would not, therefore have specifically considered this individual case.

4.4 The comments at the end of the fourth paragraph of Mr Hinks's letter of 6<sup>th</sup> February makes new comments that are not related to the original FOI request and so are outside the remit of this review.

## **5. SUMMARY**

5.1 In conclusion, I believe that the Agency has given Mr Hinks accurate information regarding what has and has not been published on its website in relation to CFS and the HPV vaccine. Other comments made in the e-mail of 6<sup>th</sup> February 2012 are new and outside the remit of this review.

5.2 If Mr Hinks remains dissatisfied, he may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in this matter. The ICO address is listed below:

The Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF

**Sue Jones**  
**MHRA Corporate Policy**  
**29<sup>th</sup> February 2012**