

request-98346-592f3978@whatdotheyknow.com

Date 12 th March 2012

REVIEW OF FREEDOM OF INFORMATION ACT (FOIA) REQUEST FOI 12-046

1. INTRODUCTION

1.1 In an email dated 15/11/11 (sent via whatdotheyknow.com), Mrs xxxxxxxx requested a review of the Medicines and Healthcare products Regulatory Agency's (MHRA) response to the request relating to the Committee on the Safety of Devices (CSD), again sent via whatdotheyknow.com, on 30/10/11.

"I would like to know if the Committee on the Safety of Devices has been given information regarding a very serious incident on 24 June 2006 which specifically involved a specific Gantry Hoist, a specific Crossbar Spreader Bar and a specific sling provided by a local authority, which risk-assessed the combination?"

1.2 The MHRAs response was sent on 2 November 2011. Mrs xxxxxxxx also asked, in an email dated 4th March 2012 what is happening to her complaint in respect of this issue. I apologise for the delay in dealing with this review.

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 Mrs xxxxxxxx.

3. Background

3.1 The Agency's response to Mrs Cantwell's request was as follows:

"The Committee members would not have been made aware of this particular incident, which I note happened some time ago. Committee members do not investigate specific incidents. Investigation of reported incidents is carried out by MHRA device specialists and all information is collated through our adverse incident centre. As I am sure you are aware hoists are covered by very specific safety regulations. Could you please confirm that the incident below was reported to us? If you can provide more information then I may be able to help further."

3.2 This seems to me to be a clear and unequivocal response to the initial question asked, and should have concluded this FOI request. Had the MHRA acted correctly and logged this as an FOIA request initially, this could have been done.

3.3 Instead, in a follow up email dated 02/11/11, Mrs xxxxxxxx asked:

"I would like clarification whether it is or is not a requirement as of 24 June 2006 onwards for the local authority to inform the MHRA once they were informed of the incident."

To which the Agency replied on 10/11/11

"Under the Medical device Regulations there is a mandatory requirement on medical device manufacturers to report adverse incidents involving their devices which resulted or had the potential to result in serious injury or death to users."

Although we encourage and welcome reports from users [healthcare professionals, patients, members of the public etc.]there is no legal requirement for this and reports are made on a voluntary basis."

3.4 This reply elicited yet a further question from Mrs Cantwell on 11/11/11

"In which case could you please confirm that the two manufacturers in this particular incident did inform you and when did they do so?"

3.5 This question does not appear to have been answered, at least via the FOIA.

3.6 These emails effectively formed an ongoing discussion regarding Agency policy towards the safety of slings and hoists, e.g. requesting reviews and further investigations. Eventually, on 15 November, Mrs xxxxxxxx requested an internal review. This request was repeated on 21st November, 14th and 24th December, and 22nd January. These requests were all met by an automated answering service informing her that she would be answered when the recipient returned to work.

3.7 On 23rd December the situation was further confused when Mrs xxxxxxxx was notified that her request for an internal review had been referred and treated as a complaint. Understandably this served to confuse the matter and the requester. The complaints process should not have been employed to deal with the request for an internal review. Again, had the initial request been properly handled this would not have occurred.

4. CONSIDERATION OF THE ISSUES

Handling of the initial request:

4.1 Mrs xxxxxxxx's initial request was never logged or dealt with as a request under the FOIA. It was only brought within the scope of the Act when a further request for internal review was sent on 23rd January and came to the attention of the Agency's FOI officer. At this point the request was logged as an FOIA request in order that it could be internally reviewed as such.

4.2 The initial request dated 30th October should have been logged and processed as an FOIA request in the normal way, despite the question having apparently been answered. In the Agency's defence the initial request was probably dealt with as a routine business enquiry as it was answered quickly and in full. Although all requests for information fall within the remit of the FOIA, it would be impractical to treat every request received as being an FOIA request given that the Agency processes many thousands of requests for various types of information every year in the course of normal business.

4.3 However, given that the request was submitted via the whatdotheyknow.com website, and Mrs. xxxxxxxx indicated clearly on 15th November that she considered her request to be an FOIA request, something should have been done much sooner than 23rd January.

4.4 This would also have allowed the Agency to deal with the request in a more focused way and to separate out the elements of her correspondence that were applicable to the FOIA, and those which were not.

4.5 What unfolded from the date of the first request is a somewhat confusing and ongoing dialogue mixing requests for information, with complaints, and requests for actions completely outside the remit of the Act.

The Freedom of Information Act (FOIA)

4.6 The FOIA confers two basic rights to a requester:

- To be informed if the information is held
- To receive that information (subject to any relevant exemptions)

These rights apply to information held by a public authority.

4.7 The initial request was answered and, had it been processed correctly, the subsequent answer would have closed the request. Subsequent questions would then have been dealt with as new FOIA requests, rather than parts of an ongoing dialogue.

4.8 As this was not done at the time, I have looked at those elements of the correspondence which are properly FOIA requests to determine what further action is required.

Request dated 30/10/11

4.9 “I would like to know if the Committee on the Safety of Devices has been given information regarding a very serious incident on 24 June 2006 which specifically involved a specific Gantry Hoist, a specific Crossbar Spreader Bar and a specific sling provided by a local authority, which risk-assessed the combination?”

- This request has been answered

Request dated 02/11/11

4.10 "I would like clarification whether it is or is not a requirement as of 24 June 2006 onwards for the local authority to inform the MHRA once they were informed of the incident."

- This request has been answered

Request dated 02/11/11

4.11 "I had no idea that the MANUFACTURERS had to inform you of incidents rather than the prescribers of the sling, crossbar and hoist.

In which case could you please confirm that the two manufacturers in this particular incident did inform you and when did they do so?"

- I can find no indication that this request has been answered and I have asked the relevant section to provide it within 20 days.

4.12 Anything within the correspondence, other than a request for information held, is outside the remit of the FOIA. Therefore I have confined my review to what I believe are relevant requests under the Act.

4.13 However, I feel it important to point out that while the FOIA can allow access to information, and the complaints process can oblige us to review whether we have correctly followed procedures, neither of them is really a mechanism for bringing about change as such. Consequently, other matters arising from the correspondence, such as a perceived need for the creation of national policies, investigations into local authority practices, reviews about incident reporting etc, are not within the remit of the FOIA or the complaints process to address, and are issues that should be pursued by other means.

5. SUMMARY

- The Agency was at fault in not having initially dealt with the request as an FOIA request, and in not taking relevant action on the numerous requests for an internal review which followed.
- The unanswered request of 02/02/11 will be processed (as part of the initial request) and the answer provided to Mrs xxxxxxxx within 20 working days.

For these errors, I would like to apologise to Mrs xxxxxxxx.

5.1 A message will also be sent to all staff to alert them to the fact that requests for information submitted via the whatdotheyknow.com website should always be dealt with under the FOIA.

5.2 However, any failure, or perceived failure, to address matters other than providing requested information, are outside the scope of this review and should not be pursued via the FOIA

5.3 If Mrs xxxxxxxx remains dissatisfied she may ask the Information Commissioner (ICO) to make a decision on whether or not we have interpreted the FOIA correctly in handling her request. The ICO address is listed below:

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

Sue Jones
MHRA Corporate Policy
12th March 2012